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Implementation of a Laboratory Network in Georgia

February 2005

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Order No WP 009

Mission

Partners for Health Reformplus is USAID's flagship project for health policy and health system strengthening in developing and transitional countries. The five-year project (2000-2005) builds on the predecessor Partnerships for Health Reform Project, continuing PHR's focus on health policy, financing, and organization, with new emphasis on community participation, infectious disease surveillance, and information systems that support the management and delivery of appropriate health services. PHRplus will focus on the following results:

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

February 2005

Recommended Citation

Pierson, Antoine, February 2005. *Implementation of a Laboratory Network in Georgia.* Bethesda, MD: The Partners for Health Reform*plus* Project, Abt Associates Inc.

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

Submitted to: USAID/Tbilisi

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Abstract

A functioning public health laboratory service is a critical component of the infectious disease surveillance and the primary health care systems in Georgia, which have been undergoing a major reform since 2002.

This report is the first attempt to develop a realistic model for the network of bacteriological and serological laboratories in Georgia and provide recommendations on such key issues as the ideal number of such labs in the country, their categorization by level, minimum standards in terms of staffing, equipment, bio-safety and quality control, referral system, and functional links to other health care institutions. The document also provides an estimate of how much it would cost the government to run this model and suggestions for the financial sustainability plan.

It is expected that this report will speed up reaching the consensus between the country's principal stakeholders on the future direction for the development of laboratory service and provide guidance to a group of international donors that are assisting Georgia in this process.

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Acronyms

AFSSAPS	*Agence Française de Sécurité Sanitaire et des Produits de Santé* (French Agency for Health Safety and Healths products)
AST	Antibiotic Susceptibility Testing
ATCC	American Type Culture Collection
CCHF	Congo Crimea Hemorrhagic Fever
CIF	Curatio International Foundation
CSR	Communicable Disease Surveillance and Response
CTL	Costing Tool for Laboratories
EQC	External Quality Control
EU	European Union
FDA	Food & Drug Administration
GTZ	*Gesellschaft fur Technische Zusammenarbeit*
IDS	Integrated Disease Surveillance
IQC	Internal Quality Control
LAT	Laboratory Assessment Tool
MoLHSA	Ministry of Labor, Health and Social Affairs
NCDC	National Center for Disease Control
NRL	National Reference Laboratories
PCU	Project Coordination Unit
PHR*plus*	Partners for Health Reform*plus* Project
QA	Quality Assurance
TADR/DTRA	Threat Agent Detection & Response
TBE	Tick Borne Encephalitis
US	United States
USAID	United States Agency for International Development
VPD	Vaccine Preventable Disease
WHO	World Health Organization

Acknowledgments

The author would like to thank Levan Baramidze at the Ministry of Labor, Health and Social Affairs; and Paata Imnadze, at the National Center for Disease Control in Tbilisi for their technical and information support during his consultancy visit; Tamara Sirbiladze at the USAID office in Tbilisi; Anton Luchitsky and Hirshini Patel of PHR*plus* for facilitating this mission; Mamuka Djibuti, Ivdity Chikovani, George Gotsadze, and Keti Goguadze of Curatio International Foundation for their support and contributions to this work and the final product; PHR*plus'* Lynne Franco for the technical review of the report, and Linda Moll and Maria Claudia De Valdenebro for the support in editing and production; and numerous public health professionals from the Ministry of Health, NCDC, TB program, Infectious Diseases Research Center, WHO, World Bank, European Union, and US-funded dangerous pathogens program in Georgia who generously gave their time to, and shared insights into, the subjects relevant to this mission.

The production of this paper was funded by USAID under the prime contract No. HRN-C-00-00-00019-00 and subcontract No. 02-011-HPSS-7544.

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1. Introduction

Georgia is currently implementing a number of reforms aimed at improving primary health care and integrated disease surveillance (IDS) and response, a component of which is laboratory strengthening. Eight major partners have projects with one or several components linked to laboratory strengthening:

- Threat Agent Detection and Response (TADR)/DTRA/highly dangerous pathogens
- World Bank primary health care development project
- European Union (EU) project on primary health care (PHC) in Kakheti region
- Tuberculosis program
- Disease surveillance/U.S. Agency for International Development (USAID)/Partners for Health Reform*plus* (PHR*plus*), Curatio International Foundation (CIF)
- Malaria network
- HIV/AIDS program
- World Health Organization (WHO)/Communicable Disease Surveillance and Response (CSR) strengthening program

Details about these programs can be found in Annex A.

This paper describes the findings and recommendations of the PHR*plus* project.

1.1 Objectives

PHR*plus* was asked by USAID/Georgia and the Ministry of Labor, Health and Social Affairs (MoLHSA) specifically to help develop a realistic model for the network of bacteriological and serological laboratories in Georgia. In doing so, it would provide recommendations on the following:

- The ideal number of such labs in the country
- Their categorization by level
- Minimum standards in terms of staffing, equipment, biosafety, and quality control
- A referral system and functional links to other health care institutions

It was also to provide an estimate of how much it would cost the government of Georgia to run this model and implications in terms of fixed and variable costs, as well as suggestions for the financial sustainability plan.

In meetings between MoLHSA and CIF staff, it was decided to extend the scope of the work to cover all laboratories activities in the country. This was due to:

- Differential diagnosis of VPDs, which need to enlarge the initial spectrum of diseases targeted
- The future World Bank project activities
- The Highly Dangerous Pathogens project and the new laboratories it is strengthening
- The future implementation of International Health Regulations (IHRs), with the National Center for Disease Control (NCDC) as the focal point
- Common needs of several programs (communicable and noncommunicable diseases) for sample transportation
- Common needs for laboratory staff training
- Common need for a national laboratory quality assurance (QA) manual

This paper is the product of the third consultation in this effort. The two earlier missions resulted in the following:

- In 2002, assessment of laboratories in Georgia with a focus on vaccine preventable diseases (VPDs)
- In 2003, a laboratory QA manual for VPD diagnosis

1.2 Background

1.2.1 Findings of Rapid Assessment of Laboratories

During the July 2002 mission to Georgia, laboratories in several parts of Georgia were assessed:

- Tbilisi (NCDC, Infectious Disease Hospital laboratories, Cito private laboratory)
- Batumi (public health laboratories, Infectious Disease Hospital)
- Kutaisi
- Rustavi (sanitary laboratory, Infectious Disease Hospital)

A paper questionnaire was developed in collaboration with WHO/CSR/Lyon and used for the purpose of these evaluations.

Since the time of the assessment, CSR/Lyon developed a computerized laboratory assessment tool (called LAT), which allows the user to automatically generate indicators when filling in the tool during assessment. Indicators are grouped into 10 modules representing 10 key laboratory activities.

In order to have a precise idea on how a Georgian intermediate laboratory would do in such an assessment, it was decided to use LAT when assessing the Gori Bacteriology Hospital. (Gori, one of the visited sites, is in central Georgia.) Five laboratories (see Annex C for photographs) were visited there:

- Hospital bacteriology laboratory (detailed assessment using WHO LAT)
- Hospital clinical laboratory
- Children's hospital clinical laboratory
- Tuberculosis (TB) center laboratory

- Sanitary inspection laboratory (former "*sanepi*" laboratory)

Gori assessment findings were applied to the LAT on 15/12/05. Results of the computerized assessment are summarized Table 1 and detailed in Annex B.

Table 1: Summary of Gori Bacteriology Laboratory Assessment

General indicator	37%
Average number of daily specimens	1
1-building facilities and utility service	61%
2-biosafety, hygiene and security	8%
3-specimen collection and recording	45%
4-equipment	48%
5-reagents and supply	47%
6-analysis and test performed	71%
7-laboratory staff & working time	53%
8-total quality	14%
9-reporting, analysis and communication	19%
10- outbreak participation	0%

(<50%: red, 50-85%: yellow, >85%: green)

Certain key findings apply to all laboratories visited:

- Laboratory workload is very light (average 1-2 sample/day in bacteriology), which does not allow laboratory staff to maintain their proficiency over time
- Laboratory staff is too numerous for the workload
- Laboratories are too numerous in the area
- Laboratories are not well equipped in terms of both quantity (only one microscope available in Gori bacteriology laboratory) and quality (monocular solar microscope instead of electrical binocular one, as example), and equipment is not well maintained
- Cold chain is not monitored
- Very limited level of quality assurance: no procedures, no internal quality control (IQC) (e.g., no reference strains), no external quality control (EQC)
- Very low level of biosafety
- Very little commitment from central level: no supervision, no recommendation, no continuous training, no promotion of QA, no provision of quality material, etc.
- No central reagent registration unit ➔ each lab has the possibility to buy non-controlled reagents (such as expired antibiotic discs sold in Tbilisi; see photo in Annex C)
- Clinicians' distrust of laboratory results

- Clinicians with little knowledge of how to analyze and interpret laboratory results
- No communication between the laboratories visited in the same town

1.2.2 Lack of a Laboratory Network

Related to several assessment findings, laboratories in Georgia currently operate as single units, i.e., they are not linked into a laboratory network. This contributes to a number of laboratory shortcomings:

- Lack of coordination,
- Lack of standardization
- Low-quality analysis, low reproducibility
- Regular overlaps and duplication with other structures
- Dispersion of efforts and resources
- No centralization for:
  - Reagents and supplies
  - Quality assurance implementation
  - Waste management
- Limitation of the resources in general

These shortcomings waste resources and ultimately jeopardize the quality of health care.

1.3 Current Preparedness for a Laboratory Network in Georgia

1.3.1 MoLHSA Laboratory Authority

There currently is no structure in the MoLHSA specifically in charge of laboratories and laboratory science. This inhibits the development of a laboratory network. Nevertheless, an association of laboratory specialists has been created. This association is quite active and regularly collaborates with the licensing unit in order to ensure laboratory visits/inspections and various other expert missions. One of the leaders of this association is Dr Tina Bukia, professor of biochemistry at the State Medical Academy. She has visited four laboratories in two different periods (last time was summer 2004).

1.3.2 Laboratory License Criteria

Several licenses can be distributed to the laboratories, depending on the range of analyses they perform:

- Bacteriology
- Virology
- Immunology
- Clinical diagnosis (hematology)

- Biochemistry
- Serology
- Cytology (cellular level)
- Histopathology (tissue level)
- Toxicology
- Cytogenetical analysis

For each of these components, several criteria are currently being integrated into the licensing process:

- Building and space
- Staff
- Equipment
- Diseases
- Tests
- Tests volume

Dr Bukia found the criteria to be at a high level, but there are only criteria for each activity. There is no specific checklist designed to help an assessor and no specific requirements in the following very important fields:

- Biosafety (NCDC is working in this field and will issue standards soon)
- External quality control: participation in an EQC program is neither required nor compulsory (this refers to the act of participation and not to successful participation)
- Procedures/quality assurance: no basic QA policy and procedures are required, no analytical procedures are required prior to licensing

In addition, once awarded, the license duration is permanent, i.e., a licensed laboratory does not have to renew its license. Laboratories licensed under less-restrictive earlier criteria do not have to submit to a new visit; they can continue with their old license forever. Such a situation will not motivate laboratories to respect or maintain standards once licensed, and should be changed.

The licensing process requires an onsite visit, during which adherence of the lab to the existing standards is checked. However, as these visits are done without a standardized checklist, the quality of a visit depends on the expert appointed to do the visit. This approach precludes an independent scoring system for each lab; nor can improvement of laboratory quality be monitored over time.

1.3.3 Inspection of Laboratories

Prior to any inspection, government (court) authorization is required, and an official permit has to be shown to the inspected laboratory. Inspections are not viewed as a means to improve the overall quality of laboratory activity, but much more as a punitive, “police” action, leading only to fines and restrictions. Nor are inspections done on a regular basis, preventing improvement from becoming a regular activity. Again, the lack of a standardized ways of applying the criteria (i.e., checklist) is a problem for inspectors, and also for the targeted laboratory (no guidance before inspection).

No EQC activity is performed in addition to inspections. Thus, control is "static" (only conditions are checked), whereas EQC is "dynamic" (laboratory performance is checked).

1.3.4 Links with Health Insurance

Currently, there are no specific links between laboratories, license departments, and health insurance, and there are no official price lists for laboratory analyses applicable in all public structures of the country. Each laboratory sets its own prices. This means that prices can vary greatly.

Some federal (public) programs (TB, cancer, etc.) are free of charge to the patient; laboratories are reimbursed by the related vertical programs. Reimbursements to laboratories performing these tests are very low, even below the reagents' cost associated with the analysis. In contrast, prices at private laboratories for similar analyses are usually 10–100 times higher than the reimbursements by the vertical programs.

This system has additional limits: when a patient is suspected of developing TB, he goes to the TB center, which performs lung radiography and bacilloscopy. The patient must pay for both (radiography is around 15 laris) and is reimbursed only if one of these tests is positive. This practice limits the effectiveness of these programs; to encourage people to seek a diagnosis, laboratory investigation for such diseases should be free of charge.[1]

Laboratory links with health insurance and federal public health programs should be strengthened.

1.3.5 Analysis Nomenclature

A list of analyses that should be performed at each laboratory level has been developed. Table D-1 (in Annex D) summarizes the contents of a book issued by the Georgian license unit and the NGO "Genesis" in 2004. This table shows, for each of three levels, which analysis should be performed and which techniques linked to these analyses should be available (sampling, staining, observing, etc.). Any time you advance a level, all the analyses of the lower level should also being performed (not shown in the table in order to avoid useless repetition). The summary of the current standards is a very good beginning.

- Strengths of the list:
  - Its existence: few countries have such lists
  - It tries to address several level of laboratories, grouped around four levels
  - It groups analyses by discipline and technical aspects that are required for some laboratory levels

- Weaknesses of the list:
  - Not all analyses are covered

[1] It should be noted that some analyses are free of charge at the NCDC and the Tbilisi Infectious Disease Center laboratory, for example, investigation of meningitis.

- There is little precision about the analytical method that should be used and little difference between screening and confirmation
- Important analyses not available in the country are not planned (where to send, how to send, what to expect back)
- Too many types of laboratories should be performing the same type of analysis. The number of laboratory types should be reduced in order to simplify
- There is no cost or cost range linked to each analysis.
- It is still not officially validated by the Georgian MoLHSA

Note about analysis prices:

Prices are determined by the market in Georgia, but a standard price can be established for all the public facilities. This price could also be an indication for patients and private laboratories.

It is recommended that the price be expressed using a coefficient (C), for example, glucose measurement would cost 5C, HIV serology 20C, etc. If 1C = 20 tetri (fictitious number), this mean glucose analysis would cost 1 lari and HIV serology 4 laris.

This coefficient can be revised on an annual basis, without having to republish the entire list of prices. In addition, this coefficient can be a good and simple way to monitor the activity of a laboratory, when summing up all analyses expressed by a coefficient.

1.3.6 Biosafety Standards

Today, there are no clear biosafety standards in Georgia. NCDC is developing a list of standards, but it is not close to being released. Once the standards are established, the question will remain of who will check their application in each laboratory.

1.3.7 Sampling Requirements

Currently, no specific certification is required for persons who take samples for lab tests. Such certification would facilitate the national standardization of specimen sampling, standardization of sample identification, and standardization of sample container and eventual transport media associated with samples. Nor are there clear instructions for sample takers regarding remedial action they should take if a problem arises.

1.3.8 Signature Requirements

No laboratory can be opened in the country without a medical doctor on the staff. The doctor usually signs off on the analysis result form. In small facilities with only a single doctor, signature responsibility transfers to the lab technician when the doctor is absent (for meetings, vacation, illnesses, etc.). Procedures related to this transfer of signature should be clarified, as should the other responsibilities linked to this transfer of authority:

- Respect of the procedures
- Preventive maintenance of equipment

- Security issues
- Results validation
- Results transmission

1.3.9 Reagents and Supply Registration

No specific agency for registration of reagents exists. This allows the commercialization of low quality reagents with:

- Low sensitivity
- Low quality control before release
- Expired reagents

In addition to the lack of reagent registration standards, no central supply unit is available for laboratory items. Custom duties for laboratory supplies have not been established. (Many countries charge low duties for drugs, laboratory, and radiology supplies).

1.3.10 Equipment Procurement

The equipment unit has been completely restructured in the past years and a large staff turnover has taken place. New norms are currently being redefined, but those responsible for the unit lack guidance in establishing these norms.

In addition to redefining norms for each type of equipment, the staff have to work on maintenance issues critical for ensuring equipment lifespan (availability of persons who specialize in the operation and maintenance of the equipment, access to [importation of] spare parts, preventive maintenance procedures, basic training of end users, etc.)

A list of manufacturers, approved on the basis of their quality system process, should be issued. Only these manufacturers should be considered for public tenders. In addition to ensuring procurement of good-quality equipment, this will simplify maintenance issues by decreasing the range of models of the same equipment (different microscopes, centrifuges, photometers, etc.) that are used.

1.3.11 External Quality Control

Georgia currently has no specific organization in charge of EQC/EQA programs. Some surveys are carried out by the national “laboratory bureau.” Two organizations that have some experience in organizing schemes are:

- Genetic Ecological Centre, which organized several surveys in biochemistry
- NCDC, which has just launched a program in bacteriology (in collaboration with WHO/CSR/Lyon unit)

1.4 Current Organizational Issues

1.4.1 Existing Types of Public (non-private) Laboratories

The definition of "public" laboratory is imprecise; these laboratories in Georgia may best be identified as those laboratories that are not purely "private." A distinction is made between public "bacteriology" laboratories (direct microscopy, culture, and AST) and "clinical" ones (hematology, biochemistry, and sometimes blood grouping). Different levels of public laboratories in the country are:

- **Primary health care laboratories**
  - Polyclinics: not all have a laboratory component
  - Ambulatories: very few have a laboratory component

Where PHC laboratories exist, most are "clinical," with basic biochemistry and hematology tests.

- **District laboratories**
  - Public health laboratories (originally "sanepi" laboratories), with two types:
  - Inside public health centers, including parasitology/malaria diagnosis laboratories
  - Sanitary laboratory, performing mostly food and water analysis (bacteriology and physicochemical components), but also some stool analysis
    - Blood bank laboratories: almost all 66 districts have blood banking services, and they are usually also in charge of serology
  - Sexually transmitted disease (STD) laboratories, linked to STD consultation center, exist in most of the districts (not in districts close to large urban areas)

Laboratories linked to women's consultation centers

- **Hospital laboratories**
  - District hospital (bacteriology/clinical)
  - Children's hospital (bacteriology/clinical), sometimes divided between in- and outpatients
  - City hospital (bacteriology/clinical), in the big towns
- **Regional laboratories**
  - Laboratories heading one of the 12 regions of the country
  - Not really developed except in Batumi, where NCDC has a branch lab
  - Sometimes a larger district laboratory considered as regional as in Kutaisi
  - Kutaisi, Poti, and Batumi have regional hospitals, also equipped with laboratories
- **Reference laboratories**
  - NCDC
    - Diphtheria
    - Polio

- Malaria
- Tuberculosis laboratory
- AIDS laboratory
- Oncology/hematology (oncology center)
- Other?

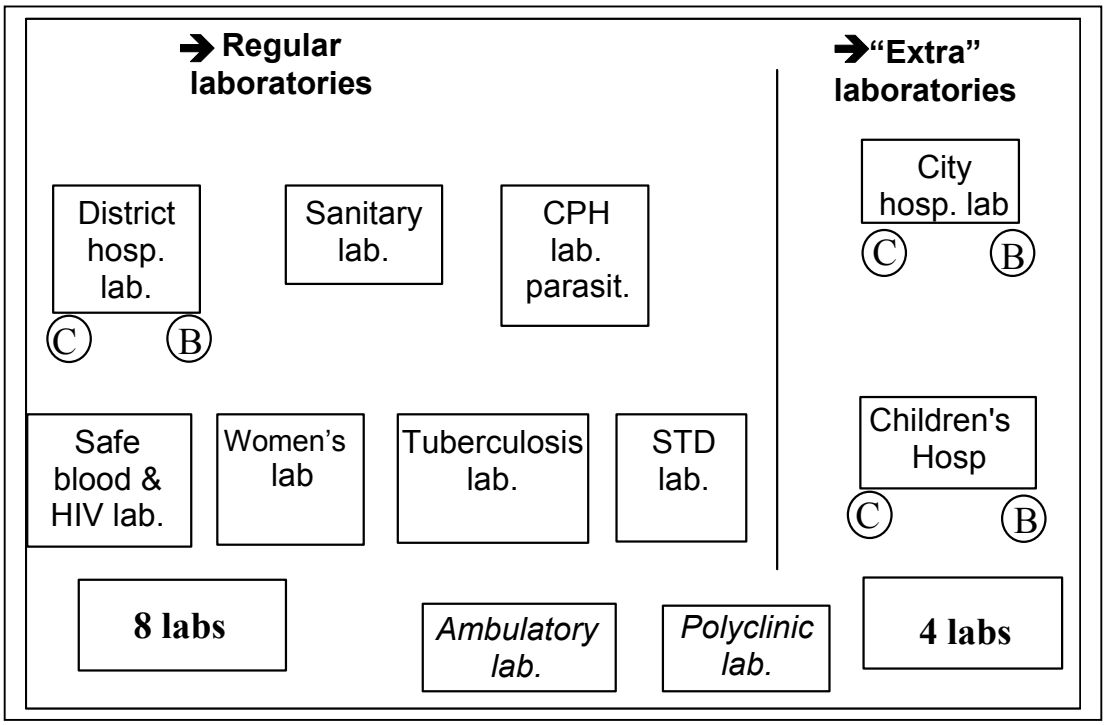
- **Other laboratories:**
  - Railroad health care system
  - Army (Ministry of Defense)
  - Ministry of Internal Affairs, Ministry of Defense

Note about reference laboratories:

Usually a laboratory is a reference for a limited number of diseases/disease families. However, it appears that there are not reference laboratories for all types of disease. In addition, the reference status is not always clearly formalized (through decree or official publication).

1.4.2 Organization of the Laboratories at District Level

Figure 1. Laboratories at the District Level



Note: "B" and "C" refer to "Bacteriology" and "Clinical" laboratories

Judging from the Gori laboratory assessment and the list in the preceding section, there are surplus laboratories. This leads to insufficient laboratory support in term of:

- Staff
- Equipment
- Reagents and supply
- Training
- Building conditions

In addition, the current system is not cost-effective. The many smaller laboratories – as opposed to a large network – prevents laboratories from buying large, expensive equipment (chemistry auto-analyzer, automated cell counting, haemostasis analyzer, ELISA systems, blood culture analyzer, and automated antibiotic susceptibility testing, etc.)

2. Defining a Laboratory Network

The previous section discussed the shortcomings of a health system when it lacks a laboratory network. This chapter defines a laboratory network, and how to go about designing and implementing such a network.

2.1 Improving Laboratory Confirmation: International Health Regulations

The purpose of the International Health Regulations is to ensure maximum security against the international spread of diseases with minimum interference in world traffic. IHR origins date back to the mid-19th century when repeated cholera epidemics overran Europe (1830–47).

In 1951, WHO member states adopted the International Sanitary Regulations, which were renamed the International Health Regulations in 1969. IHR regulations were modified in 1973 and 1981. The regulations were originally intended to help monitor and control six serious infectious diseases: cholera, plague, yellow fever, smallpox, relapsing fever, and typhus. Today, only cholera, plague, and yellow fever are notifiable diseases.

The world is changing and very few urgent public health risks stay solely within national boundaries. Coupled with increases in global traffic and trade, new microbes have appeared and old diseases have re-emerged. The World Health Assembly has responded to these changes:

- In the early 1990s the return of old epidemics such as cholera in South America and the emergence of new infectious agents such as Ebola hemorrhagic fever resulted in a resolution calling for the revision at the 1995 World Health Assembly.
- The recent outbreak of SARS (Severe Acute Respiratory Syndrome), the growing threats linked to avian influenza, and the many human and economic consequences linked to these outbreak accelerated the process.
- In 2001, the World Health Assembly adopted a resolution on global health security: epidemic alert and response in which WHO was to support its member states in **identifying, verifying** and responding to public health emergencies of international concern.
- In January 2004, the WHO Executive Board decided to convene the Intergovernmental Working Group on the Revision of the IHR in November 2004.

What will change in the new IHR?

New IHR regulations linked to surveillance/laboratory network are bolded:

1. Updating existing measures of the current IHR
    - Guide on Ship Sanitation
    - Guide on Hygiene and Sanitation in Aviation
    - Guide to **Early Warning** Systems in **Disease Surveillance.**

2. Proposed key changes and benefits to Member States
    - Real time event management system (including **disease diagnosis**)
    - National core surveillance capacities: IHR requirements of **detecting, reporting** and responding to public health emergencies of international concern.
    - Notification for public health emergencies of international concern

In conclusion:

All member states need to improve their surveillance system, including the laboratory confirmation component, which is crucial for early identification and characterization of any causative agent, making further rapid notification possible. A deadline of May 2010 has been proposed for implementation of the new regulations: all member states should be able to rely on a functional and quality controlled surveillance network at this stage.

> Implementation of IHR (compulsory) can be the ideal moment to reform, review, and reorganize the global laboratory system in Georgia, including IHR-specific diseases (mostly epidemic-prone diseases) but also all other diseases or programs needing laboratory confirmation or information.

2.2 Why Implement a Laboratory Network?

Implementing a laboratory network will allow Georgia to resolve the problems discussed earlier and improve laboratories' **quality/cost/efficiency** ratio:

- Quality:
    - Centralized supply of quality controlled reagents
    - National quality assurance program
    - Staff receive refresher on critical issues
    - National data management system
- Cost:
    - Reorganization of the laboratories → optimization of all working conditions, workload and analytical processes → economy
    - Centralized supply of reagents → economy of scale
    - Preventive maintenance policy → increased equipment lifespan
- Efficiency:
    - Sample transportation instead of patient transportation (if any)
    - Improved data management
    - Improved links between laboratories and disease surveillance systems
    - Improvement of the prescription/interpretation of medical analysis

2.3 What is a Laboratory Network?

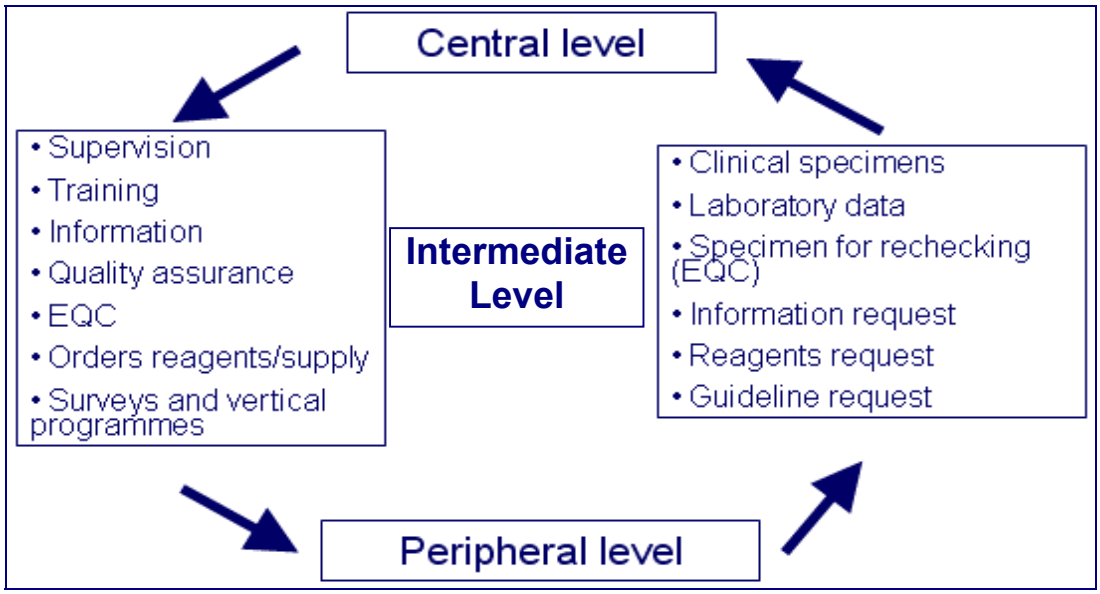
Usually, three levels of laboratories are recommended in a country:

1. 'Central' level: reference laboratories
2. 'Intermediate' level: regional laboratories
3. 'Peripheral' level: district laboratories

A fourth level can also be defined at PHC level, when some laboratory activities are performed (usually limited to very basic screening tests, in addition to specimen shipment associated).

Different types of exchange among the levels can be observed, as shown in Figure 2.

Figure 2: Exchanges between Levels of a Laboratory Network



2.3.1 Mission of the National Laboratory Network:

Providing quality and timely services, at the right place, responding to the needs of:

- The patient
- The community
- The health care system staff:
  - Clinicians
  - Epidemiologists
  - Sanitary engineers
- Decision makers and politicians

2.4 Key Institutions to Involve in Implementing a Laboratory Network

Several institutions are should be involved:

- Ministry of Health
  - License, norms and standards unit
  - Reference laboratories (NCDC, TB reference lab, other reference labs)
  - Equipment unit
  - Quality control inspection unit
- Other ministries:
  - Ministry of Agriculture
  - Ministry of Defense
  - Ministry of Foreign Affairs

They may be assisted by the partners listed in the introduction to this report.

3. Steps in Developing a Laboratory Network

There are 10 basic steps to developing a laboratory network:

1. Normative step (laws, decrees, standards) ➔ global frame of the lab work
2. Organization of the labs (number/levels…)
3. Package of analysis by level
4. Methodology for each analysis (level-dependent)
5. Equipment needed to perform the analysis following the methodology chosen
6. Staff needed to perform the analysis using the methodology
7. Quality assurance (procedures, maintenance, training of the staff, etc.)
8. Relations between laboratories (specimen flow/data flow)
9. Costing of all activities
10. Practical implementation of the network, how to organize activities

The following sections describe each step.

3.1 Legal Framework for a Laboratory Network

This section addresses the overall framework that should be implemented prior to the laboratory network. It will also address some key issues that should be solved to ensure the sustainability of the future network. The following sections describe these normative steps.

3.1.1 Agreement on Definitions:

Precisely defining terms relevant to laboratory work is prerequisite to a laboratory network. The definitions should exist in written form – in the present case, in the Georgian language – and be available in all laboratories. This will allow all laboratory specialists to understand each term in the same way, and thus carry out their work in a like manner. For example, there currently is confusion about terms such as 'licensing,' 'certification,' and 'accreditation':

- A **license** is authorization from a licensing unit that allows a laboratory to be opened, as long as it respects/follows national norms
- Once open, the laboratory must seek **certification** in specific areas of activity (viral serology, mycobacteriology, haemostasis, etc.) or for all types of activities. International laboratory specific standards have to be respected (for example, ISO 17025)

- If the laboratory is part of a bigger structure (for example, a hospital), this structure can seek **accreditation**. A global norm (from the ISO 900X type of norms) will be followed and the entire institution will be accredited. These norms are not laboratory-specific, but cover any type of service-providing activities.

Table 2 contains an initial (non-limiting) list of terms requiring clear definition:

Table 2: Laboratory-related Terms Requiring Clear Definition

• Accreditation	• Licensing
• Analysis	• Procedure
• Analysis report	• Qualification
• Analytical system	• Quality
• Assessment/evaluation	• Quality assurance
• Certification	• Reference values
• Confidentiality	• Request form
• External quality control	• Sample/specimen
• Internal quality control	• Sampling
• Laboratory	• Transferability/reproducibility
• Laboratory staff (all categories)	• Validation

3.1.2 MoLHSA Laboratory Authority

Also needed is a unit at the level of the MoLHSA that coordinates laboratories and laboratory science. It may be called a "laboratory office" or "laboratory coordination team," or "laboratory bureau." Depending on the country, this unit may exist:

- As a laboratory-only unit
- Joined with drugs/pharmacy
- Joined with radiology

Terms of reference of such a laboratory coordination unit must be precisely defined as do the unit's relations with the licensing unit, the NCDC, other reference laboratories, and all the other entities linked to laboratories and laboratory science (including education).

3.1.3 Laboratory License Criteria

There must be clear and sufficient licensing criteria and standardized tools to measure whether labs meet the criteria. These criteria should include:

- Building and space
- Staff
- Equipment
- Diseases
- Tests
- Tests volume
- Biosafety (NCDC is working in this field and will issue standards soon)
- Participation in EQC

- Existence of QA procedures

A license should be granted only after physical inspection of the laboratory and should require periodic renewal; three years is a reasonable period for license validity.

3.1.4 Inspection of Laboratories

Inspections should be viewed as a means to improve the overall quality of laboratory activity. They should be done on a regular basis, so that improvements can be noted. Inspectors should have standardized criteria (checklist) and also can be used by laboratories as guidance prior to inspection. Inspections should include EQC, which allows for a very "dynamic" assessment of real laboratory performance.

3.1.5 Links with Health Insurance

Linking health insurance reimbursement to laboratory licensing and ensuring that coverage with federal programs is coordinated in terms of incentives to patients and real costs of laboratory analysis.

3.1.6 Analysis Nomenclature

The current range of laboratory types should be simplified and standardized, with responsibility for specific analyses assigned to specific laboratory levels. More details about analysis by level can be found in section 3.2 and Annex D.

3.1.7 Biosafety Standards

The laboratory network needs to have biosafety standards in place, and an operative mechanism to verify that standards are being followed. These standards should include:

- Vaccination policy for laboratory staff (already existing)
- Sterilization standards
- Disinfection and disinfectant standards
- Laboratory safe work standards
- Dangerous goods transportation (national) standards
- Waste disposal standards

3.1.8 Sampling Requirements

Good sampling (and a good sampling strategy) is the basis of a good analysis. When sampling is correctly performed, 30 percent of the analysis is done. In contrast, not even the best laboratory is able to get a good result with a bad sample. The development of a basic certificate for those taking samples would allow this standardization. It should also include a clear scope of responsibility.

3.1.9 Signature Requirements

All analysis results forms need a signature. When the medical doctor is not available to sign, procedures for clear transfer of authority are needed. These include:

- Respect of the procedures
- Equipment preventive maintenance
- Security issues
- Results validation
- Results transmission
- Reagents and supply registration

3.1.10 Reagent Standardization

Analysis standardization in a laboratory network also requires reagent standardization. A central supply unit facilitates:

- General decrease of all supply costs
- Control of the quality and registration of kits
- Easy standardization among laboratories
- Decrease of shortages at the peripheral level
- Equipment characteristic determination

Norms for each type of equipment must be in place, considering the maintenance issues (availability of specialist in the country, spare parts importation, preventive maintenance schemes, basic training of end-user, etc.). Having an approved list of manufacturers eligible for public tenders, based on their quality system process, will improve the quality of equipment and simplify maintenance issues in decreasing the number of different models of the same equipment (different microscopes, centrifuges, photometers, etc.).

3.1.11 Organization of EQC

Objectives of EQC schemes:

Laboratory-oriented objectives:

- Identifies possible deficiencies in laboratory practice and guides participants in corrective actions
- Identifies the reliability characteristics of particular methods, materials, and equipment under routine conditions and suggests corrective actions
- Assesses and monitors the impact of training; helps preparation of future training

Public health-oriented objectives:

- Provides the basis for the comparability of results during epidemiological surveillance and disease control

- Collects information on laboratory measurements (intra- and inter-laboratory) to alert professionals and/or government bodies about problems related to traceability and harmonization of results, and establishes limits of acceptability of results as appropriate for a given purpose;
- Collects information for the purpose of licensing or accrediting of laboratories;
- A specific unit for EQC should be created. Usually, EQC organizers are linked to reference laboratories, but these laboratories should already be participating in one or several EQC programs before becoming the organizer. It shoud be clearly stated policy that all laboratories must participate in the national EQC program. Initially, only participation is compulsory – these programs should not be punitive. Before the EQC program becomes stricter, support can be provided allowing for real improvement.

EQC programs should be established for different types of laboratory activities, similar to the licensure model. For example, a laboratory owning five licenses (biochemistry, immunology, etc.) will have to participate in five EQC programs.

Ideally three, but minimally two surveys per year per program must be organized. Once again, participation should be compulsory.

Generally, EQC programs are free to public laboratories, but not to private ones.

Important note: A network needs regular activities and should be of clear benefit to its members. Therefore, in addition to their impact on quality, EQC programs can be a good way to begin a laboratory network. Such programs initiate communication, are performed on a regular basis and are followed by corrective actions.

3.1.12 National Quality Assurance Program

Surrounding the EQC program, a national QA program has to be promoted. It should be in charge of:

- Developing a national QA manual
- Providing reference material
- Assessing laboratories
- Organizing external quality control
- Promoting internal quality control
- Training on coordination and evaluation[2]

[2] In collaboration with the medical university and appropriate ministry offices.

3.2 Organization of Laboratories: Level, Number

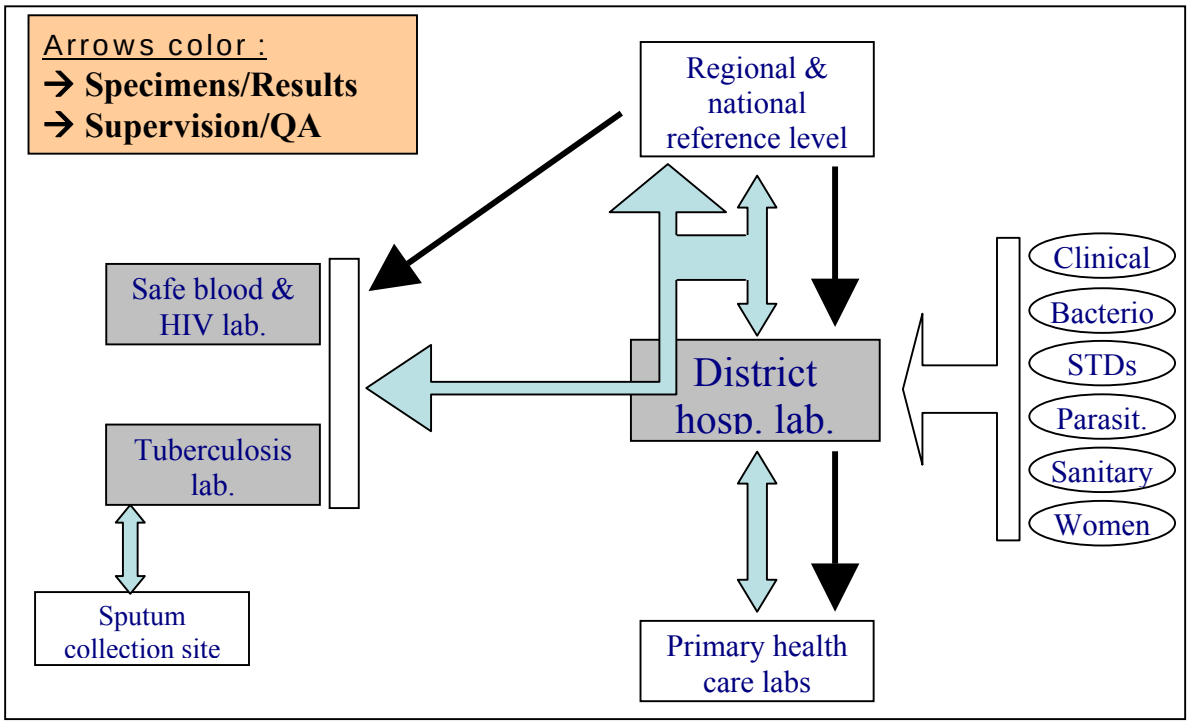
3.2.1 Proposed Reorientation of District-level Laboratories

The ultimate goal is to have ***one strong polyvalent laboratory*** in each district. As shown to the right in Figure 2, this laboratory would be structured in different units:

- Clinical analysis (biochemistry, hematology, haemostasis)
- Human bacteriology analysis
- Sexually transmitted diseases analysis (except HIV and hepatitis issues)
- Parasitology analysis (including stool parasites and malaria)
- Food and water analysis (microbiology as well as physicochemical analysis)
- Analysis linked to maternal–child care

A night shift service has to be implemented inside the "clinical" unit of the laboratory, in order to get at least one laboratory per district able to function on a 24-hour basis, seven days a week (24/7).

Figure 3: Proposed Modification of the Number of Labs at the District Level



In addition to the large central laboratory, two other laboratories should exist at the district level:

- Safe blood/HIV laboratory: in charge of *all* serologies for the district (linked to blood banking issues as well as for other purpose such as measles). This separation of serological issues will allow better equipment for the blood bank unit
- Tuberculosis laboratory: depending on the district, either a sputum collection site or a real

TB diagnosis laboratory should be available. Due to the specificity and the biohazardous character of TB diagnosis centers, due to the existing links and programs with different partners (as shown in Annex A) and the existing network, it seems relevant to keep this separation.

3.2.2 Relations between Laboratories

Appropriate relations between laboratories were illustrated in Figure 1. Again, three levels will be considered:

- District:
  - Central district laboratory
  - Safe blood/HIV laboratory
  - Tuberculosis laboratory (if available)[3]
  - Other small laboratories from PHC/clinics located at the periphery of the district
- Regional[4]
  - Central regional laboratory (larger district lab)
  - Safe blood/HIV laboratory (if available)
- National
  - Sample dispatching unit
  - Reference laboratories

As shown in Figure 3, the future central district laboratory will be the heart of the district level organization:

At the district level:

- Reception of the samples from:
  - Other hospitals → analysis (eventually referred to higher level if exceeds possibilities)
  - PHC dispensaries/clinics → analysis (eventually referred to higher level if exceeds possibilities)
  - Safe blood and HIV laboratory → referred to higher level for safe blood/HIV (regional or national)
  - Tuberculosis laboratory → referred to higher level for tuberculosis (national only)
- Reception of results and data from regional/national level → transmission of the results:
  - Inside the hospital
  - To other hospitals
  - To safe blood/HIV laboratory

[3] Sputum collection centers are not considered, as a part of the regular TB network
[4] A regional level for TB diagnosis has not been planned in Georgia; diagnostic activities currently are split between district and reference levels, and the sputum collection level is the peripheral level

- To TB laboratory
- To PHC/clinics

Even for TB and safe blood/HIV laboratories, the communication regarding samples between the district and regional/national levels will be done through the large district laboratory in order to simplify transportation relays.

At regional level:

Note: This model implies that regional laboratories are functional and are able to perform a larger analysis package than at the district level. The regional polyvalent laboratory also plays the role of district lab (no duplication inside the same town)

The regional polyvalent laboratory:

- Receives samples from lower level laboratories (district laboratories and public health laboratories from their area) → analysis (eventually referred to higher level if exceeds possibilities)
- Receives results/data from national level → transmission to regional laboratories and district level
- Receives results from national TB and safe blood/HIV national laboratories → transmission to regional safe blood/HIV laboratory (if any) and to district level TB and safe blood/HIV laboratories
- Re-send empty boxes, ice bags, and ice packs to the correct district laboratory

At national level:

Note: This model implies that a clear reference level has been established.

A dispatching unit should be created in Tbilisi, in charge of receiving all samples from the periphery. This unit could be ideally located inside one of the reference centers (NCDC, infectious disease hospital, TB reference laboratory, etc.). This unit performs the following activities:

- Receives all the samples from periphery
- Receives all the results from reference laboratories
- Receives documents and data from different authorities (laboratory bureau, surveillance unit, reference laboratories, etc.)
- Coordinates cold chain and transportation supplies for all network
- Sends samples to correct reference laboratory (depending on the specificities)
- Sends results/data to correct regional laboratory
- Re-sends empty boxes, ice bags, and ice packs to the correct regional laboratory
- Maintains a global database for disease referring and disease confirmation → excellent tool for epidemiologists and disease surveillance

3.3 Package of Analysis Done at Each Level

The determination of the list of analyses to be performed at each of the laboratory levels is one of the activities that will condition the future network of the laboratory. Initial work has already taken place in Georgia, but it needs to be taken farther. Table D-2 in Annex D, which contains 19 parts, lists a large variety of analyses that could be available.[5] The table should be filled-in by a working group or by the newly created laboratory bureau.

Note: the Vaccine Preventable Diseases surveillance project (implemented by Curatio International Foundation) developed a QA manual (see Annex A) where the analysis linked to VPDs has been linked to laboratory levels.

3.4 Methodology for Each Analysis by Level

For each analysis by level (Table D-2 in Annex D), there is one simple question: "How should each analysis be performed? (Which methodology should be used?)"

Selecting the analysis method will require finding a balance between the cost and the quality of the result. One needs to keep in mind to look for *adequate* technology and not necessarily the most advanced technology. The methodology can be different depending on the laboratory level, in particular:

- Screening-oriented at district level
- First row confirmation at intermediate level
- Definitive confirmation/full characterization at reference level

Example with Hepatitis B diagnosis:

- Ag HbS screening test → rapid test, no specific equipment required (QA requirements are existing but are limited)
- Ag HbS confirmation → ELISA machine (with good QA level), reagents management (including cold chain)
- Other antigens or antibodies (biological follow-up of the disease) → ELISA machine (ideally two) with full QA policy, large reagents management, specialists for interpretation, involvement in the national EQA system, etc.

Example with blood sugar determination:

- Glucose estimation with dipsticks → rapid test, no specific equipment required. QA requirements exist but are limited.
- Glucose home determination with glucometer (auto-control for diabetic people) → improved rapid test, need for equipment. QA requirements are more extensive, yearly maintenance/checking visit remain an issue
- Glucose routine determination with colorimeter (hospital routine method). Usually glucose oxydase method is used (GOP/POD) with a colorimeter. Reagent management is simple. QA

[5] Due to their specificity, neither histopathology analysis nor analysis linked to reproduction and medically assisted procreation have been included in this table.

requirements are high, regular maintenance, IQC and EQC participation are required.

- Glucose specific determination with precise 37° spectrophotometer using Hexokinase method (no other "oses" than glucose will interfere), usually for slight hyperglycemia confirmation, glucose one-day follow-up (six samples/24 hours). This method requires very strict QA level, very well-maintained equipment, good reagent management (three times more expensive than glucose oxydase).

These brief examples show the importance of the methodology and its many consequences.

3.5 Equipment Needed at Each Level

Once analyses by level are defined (including methodology that should be used depending on the level), a list containing all types of laboratory equipment should be developed. This has to be done for each laboratory level. This list should enable laboratories to perform the set of analyses planned, using the methodology planned.

In Table E-1 (Annex E) provides an equipment list and it should be filled in. It is recommended to fill each of the four levels of laboratory (PHC, district, regional, central). Also in Table E-2 (Annex E) shows the same type of list developed for the specific purpose of VPDs in 2003 following a workshop gathering several key persons from the country (MoH, NCDC, WHO, etc.). but only including three levels of laboratories (without PHC level). This list covers only VPDs needs (no biochemistry or hematology activities are included), but provides an example.

3.6 Staff Needed at Each Level

Once analysis, methodology, and equipment have been defined, it is possible to estimate the number of staff needed for the networked laboratories, in order to run the system to ensure efficient operation of the IDS system.

A rapid survey should be performed in order to estimate:

- The existing workload in the various laboratories
- If the workload is light, the main reasons:
  - Quality of analysis performed?
  - Range of analysis proposed?
  - Quality of prescription and interpretation?
  - Geographical factors (access, weather, etc.)
  - Financial factors?
  - Other factors?
- How would this workload be affected if a large central district laboratory were created?

Once the workload is roughly estimated, it is possible to determine the number of staff needed. All staff categories have to be considered. If the laboratory has night shifts, they must be included in the estimate.

Once established, and if able to estimate the cost[6] of each staff category, it will be possible to know how much the staff component of the network costs.

Table 3: Number of Staff Needed, by Level of Laboratory

	PHC		District		Intermediate	
	RANGE		RANGE		RANGE	
Director						
Senior specialist						
Technician						
Janitor/cleaner/driver/guard						
Technician assistant						
Secretary, administrator						
Logistician/stock manager						
Electrician/equipment maintenance						
total						

3.7 Quality Assurance

As noted several times in this report, QA should be one of the factors contributing to this future network. The QA concept can be broadened to include all laboratory activities in a concept called "**Total Quality**".[7] Total quality includes:

- Laboratory assessment
- Equipment issues (registration, inventory, preventive maintenance, curative maintenance, etc.)
- Cold chain issue (control, monitoring, etc.)
- Staff management
- Premises management
- QA manual/standard operating procedures
- Internal quality control
- External quality control
- Norms, certification and accreditation

In addition, several other activities should be developed:

- Reagents and supply registration
- Preparation of training needs for staff

[6] Including taxes, benefits, bonuses, pension, training, EQA, housing, health insurance, etc.
[7] WHO/CSR/Lyon developed a one-week training module on "total quality," already available in French, and available in English in May 2005 (first English-language training session in June 2005 in Bordeaux, France)

A critical and urgent activity is the development of a national QA manual that should be used in all the Georgian laboratories. The VPD manual (see Annex A) could be completed to cover all laboratory activities:

- Creation of a QA committee
- Definition of the list of procedures needed
- Creation of several working groups to write these procedures
- Validation of these procedures
- Distribution list

Annex F contains a preliminary list of procedures, covering only the needs of communicable diseases. It can be used as a starting point from which to develop the list of procedures needed. For networking purpose, special attention should be given to all the procedures concerning liaison between laboratories (transportation, results. etc.)

3.8 Transportation and Communication between Laboratory Levels (Specimen and Information Flow)

Schematically, four levels of laboratories can be defined in Georgia:

- PHC
- District/rayon (66)
- Region (11 + Tbilisi)
- Reference (not yet identified)

All transportation and communication links between these laboratories have to be planned. For the present, PHR*plus* decided to use an average of eight PHC laboratories per district, 61 districts (five urban districts are not in the global system, as they will only have inter-urban relations), and 11 regions. (See section 3.2 for more details about relations between levels.) Figure 4 depicts the links between laboratory levels.

Primary health care level → Rayon level:

Once a week, samples will be transported by local buses from PHC to the rayon level. Results will be brought back the following week by the same transporter.

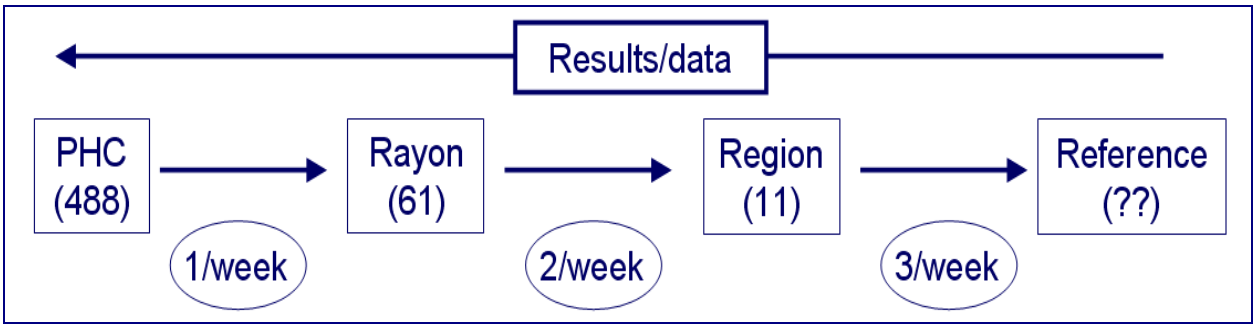
Rayon level → Regional level:

Twice a week, samples will be transported by local buses from the rayon to the regional level. Results will be brought back with the following transport.

Regional level → Reference level:

Three times a week, samples will be transported by local buses from the regional to the reference level (sample dispatching unit). Results will be brought back with the following transport.

Figure 4. Data Transport between Laboratory Levels



Needs for this sample/results system:

- Transportation boxes, strong triple package are recommended in order to follow the international legislation and enable re-use of boxes for four years (normal lifespan of these items)
- Cold chain supplies: cold boxes, cold pack
- Brief guideline for sampling/sample preparation/sample transportation
- Training of staff, every two years this number of staff should be trained in sampling:
  - Three people per regional labs (3X11 = 33 people)
  - Two people from rayonal/district lab (2X61 = 122 people)
  - One person from PHC (488X1 = 488 people)

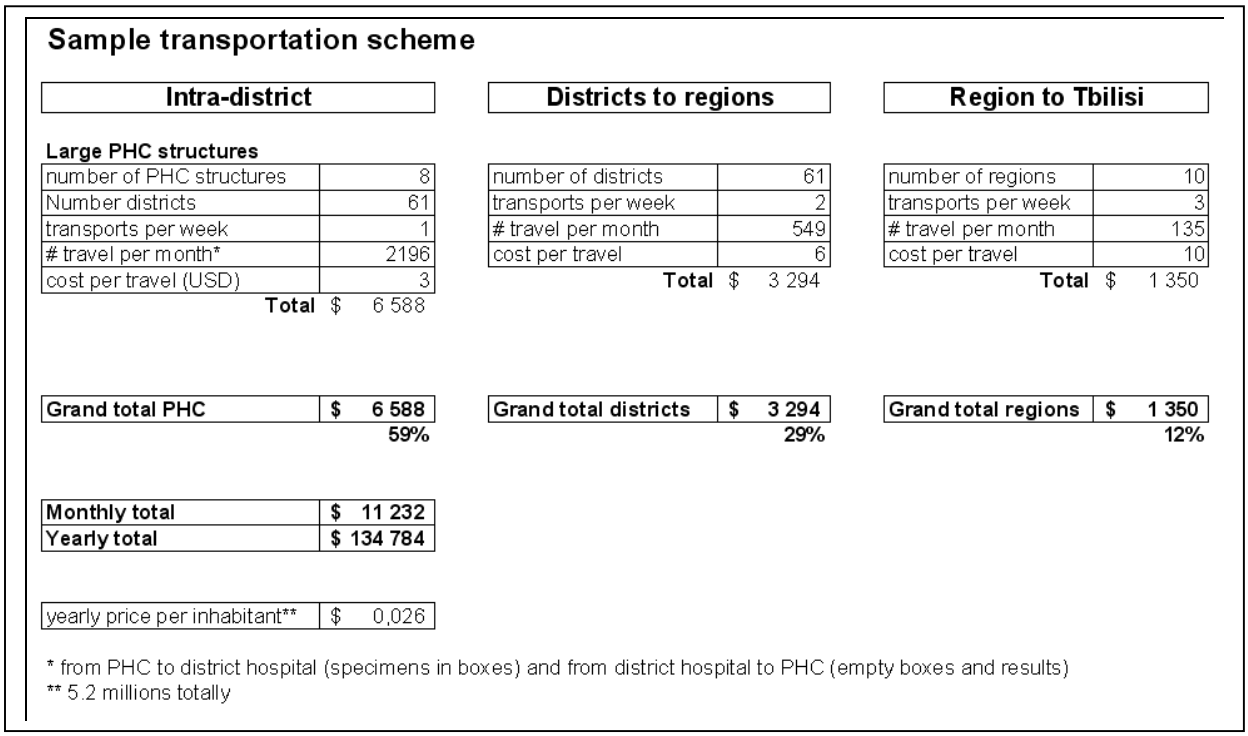
This training should be done as "training of trainers" in order for them to be able to re-train colleagues when back in their laboratories

At district level, results and specimens are centralized by the district laboratory before dispatching to the adequate recipient laboratory.

3.9 Costing of Future Activities

Note: All tables and graphs (included in this report as pictures) are also available in MS Excel® format.

Figure 5: Budget for Each Level of Sample Transportation



Sample transportation scheme

Intra-district		Districts to regions		Region to Tbilisi	
Large PHC structures					
number of PHC structures	8	number of districts	61	number of regions	10
Number districts	61	transports per week	2	transports per week	3
transports per week	1	# travel per month	549	# travel per month	135
# travel per month*	2196	cost per travel	6	cost per travel	10
cost per travel (USD)	3	**Total**	$ 3 294	**Total**	$ 1 350
Total	$ 6 588				
Grand total PHC	**$ 6 588**	**Grand total districts**	**$ 3 294**	**Grand total regions**	**$ 1 350**
	59%		**29%**		**12%**
Monthly total	**$ 11 232**				
Yearly total	**$ 134 784**				
yearly price per inhabitant**	$ 0,026				

* from PHC to district hospital (specimens in boxes) and from district hospital to PHC (empty boxes and results)
** 5.2 millions totally

Figure 5: provides details about transportation costs of such a system, sorted by area (PHC→Rayon, Rayon → Region, Region → Reference)

Details about training costs and sampling equipment costs can be found in Annex G.

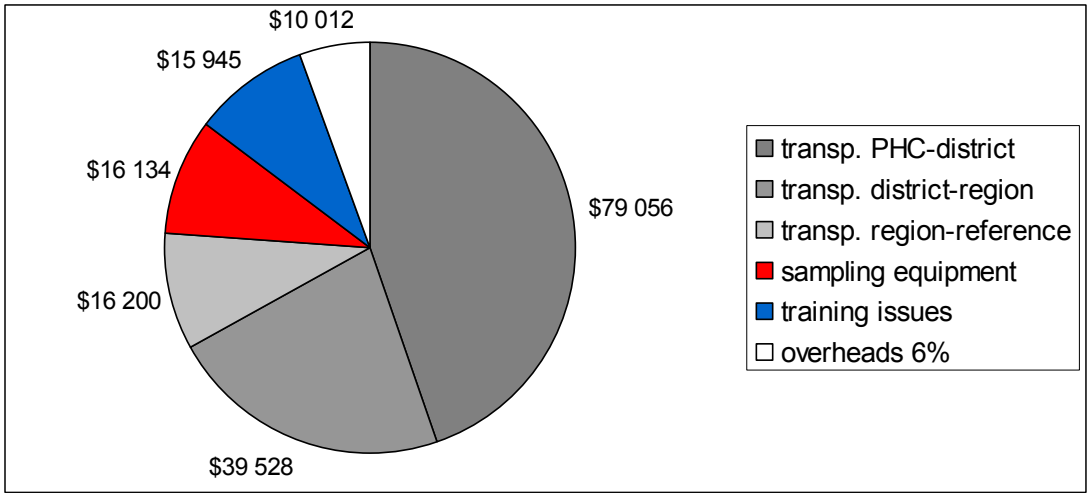
Table 4 and Figure 6 summarize all the costs for a basic but reliable system for sample transportation. As seen, the costlier part is the transportation from all PHCs to the district laboratory.

Table 4: Budget Categories for Transportation of Lab Samples

Transportation PHC-district	$ 79 056
Transportation district-region	$ 39 528
Transportation region-reference	$ 16 200
Sampling equipment	$ 16 134
Training issues	$ 15 945
Overheads 6%	$ 10 012
TOTAL yearly	$ 176 875

Cost/PHC	$ 162
Cost/district	$ 648
Cost/region	$ 1 473

Figure 6: Graphic Representation of the Budget for Transportation of Lab Samples



In Annex G, a tool newly developed by WHO/CSR/Lyon has been used in order to cost the entire national Georgian network.

4. Main Recommendations for Georgia

About the overall framework in which the network will be implemented:

1. Define terms clearly
2. Create a laboratory bureau at the Ministry of Health level

About license and inspection

3. Refine license criteria, and include a time component for validity of license
4. Develop a national checklist for laboratory inspection, to include biosafety, EQC, and quality assurance
5. Include a time-limited duration for the license once awarded

About norms and standards

6. Review the different types of laboratories and reduce to four clear levels
7. Review the list of analyses that should be performed at each level, including a price coefficient, and the recommended method to be used to perform the analysis
8. Develop a reasonable pricelist covering the main analyses that should be available in public labs
9. Provide guidance to the equipment unit in order to help them with finalizing the new equipment norms, maintenance issues, and manufacturer recommendations
10. Finalize the biosafety standards being drafted by NCDC and plan their progressive introduction into the license requirements
11. Promote the national standardization of specimen sampling by developing a 'sampling certificate' that each person taking samples should earn prior to working
12. Develop minimum standards allowing reagents registration in Georgia[8].

About several indirect units useful for the network implementation:

13. Promote a health economics survey about the relevancy of a national laboratory supply unit, eventually joined to other existing structures (drugs, medical supplies, radiology)
14. Create a specimen dispatching unit in Tbilisi inside one of the reference laboratories

About global policy for laboratories and quality assurance

15. Implement a global QA program including

[8] As this issue seems an emergency when looking at some kits sold in Tbilisi, it is recommended to adopt as soon as possible temporary standards based on an existing one (European Economic Commission, French, U.S. Food and Drug Administration, etc.) until Georgia's is developed.

- △ QA manual (NCDC staff trained in Lyon should be in working group)
- △ Provision of reference material
- △ Organization of external quality control
- △ Promotion of internal quality control
- △ Organization of training sessions

About the network

16. Write a proposal and contact funding agencies, soliciting their interest in network creation participation
17. Organize the network

Note: on the CD-ROM provided with this report, a set of documents useful for network implementation can be used (section “Other documents”). Annex H also contains the list.

Annex A. Other Programs and Partners Working on Laboratory Strengthening

TADR/DTRA/Highly Dangerous Pathogens

The Biological Weapons Threat Agent Detection and Response (TADR) Surveillance System is a program run by the US Ministry of Defense, aiming at:

- Establishing an integrated, secure and sustainable disease surveillance system in Central Asia (Uzbekistan and Kazakhstan are also part of this project)
- Ensure biosecurity and biosafety of biological facilities
- Support human, environmental, and veterinary disease monitoring
- Promote potential for integration into a regional disease surveillance system

This will be done through:

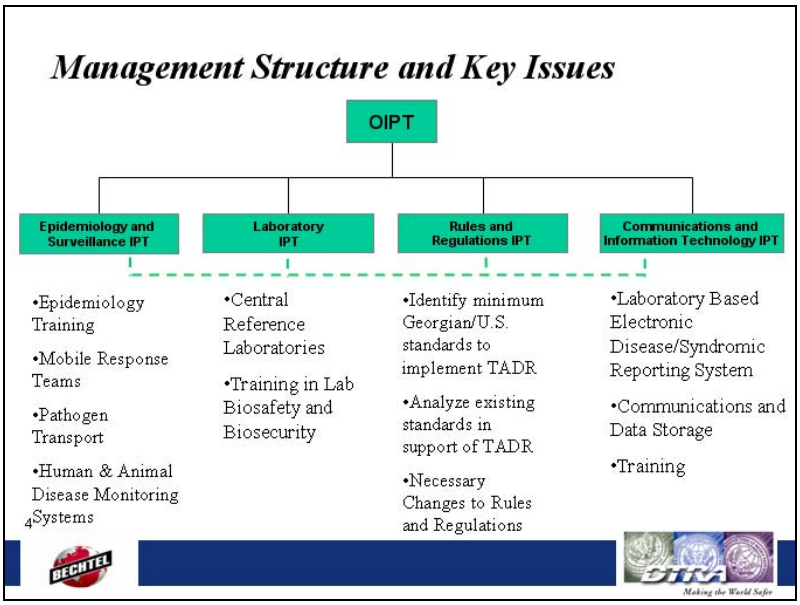
- Construction of several high security laboratories in the country
- Modern, standardized, reliable diagnostics methods, as PCR-based diagnostics, ELISA.
- Improved communications, transport, and integration e.g. computerization
- Data analysis and sharing

In addition to activities strengthening epidemiology and disease surveillance in general.

This project is focusing on a limited number of diseases:

- Endemic plague
- Brucella
- Anthrax
- CCHF
- TBE
- Unique viruses (Tomdy, Barmody, Sadavaria Valley Fever, Karshi)
- Camelpox
- HFRS

Figure A-1. Operational Flowchart of the DTRA Project



World Bank Project on Primary Health Care

The main project development objective is to improve coverage and utilization of quality primary health care (PHC) based on a model of family medicine/general practice, with an emphasis on reaching the poor and disadvantaged. In the long run, strengthening PHC services is expected to have a beneficial impact on the health status of the Georgian population through prevention, early detection, and the treatment of diseases responsible for a high burden of disease in the population (e.g., cardiovascular diseases, tuberculosis, and acute respiratory infections). Implementation of PHC is also expected to have a positive impact on the quality, cost-effectiveness and efficiency of health service delivery in Georgia. Three components of this project have been defined; a summary of these components is below. Issues related to the laboratory are **bolded** and detailed.

Component 1: PHC Service Delivery (Estimated Costs: US$ 15.23 million total)

- *Sub-component 1.1: Establishing PHC Clinics in Urban and Rural Areas* The purpose of this sub-component is to develop PHC services in up to 74 rural and high mountain areas. The project would support: (i) civil works for refurbishing the PHC clinics; (ii) basic office, diagnostic, therapeutic and **laboratory equipment for all PHC clinics**; (iii) vehicles in areas where the terrain is rough; and (iv) packet radio communication in selected locales.
- *Sub-component 1.2: PHC Referral Pilot:* The objective of this sub-component is to test how the referral mechanism will work for maternal and child health services from PHC clinics in rural and high mountain areas to the regional hospital level. This pilot will be carried out in the Imereti region, and will link PHC clinics to the Kutaisi MCH Center. The project will support: (i) partial rehabilitation of Kutaisi Maternity and Pediatric Hospital to establish the perinatal center; (ii) office, diagnostic, therapeutic and **laboratory equipment for the center**; (iii) **training workshops for PHC teams** in the latest international protocols for MCH; and (iv) local technical assistance for monitoring and evaluation of the pilot.
- *Sub-Component 1.3: Community-based Information, Education and Communication (IEC).*

Component 2 - Institutional Development (Estimated Costs: US$ 7.29 Million Total)

Sub-component 2.1 - Capacity-building for PHC Training: The purpose of this sub-component is to support training capacity in PHC. The proposed project will support: (i) civil works for rehabilitation of up to five regional family medicine training centers (RFMTC) and selected office space for the Family Medicine Faculty; (ii) basic office, diagnostics, therapeutic and **laboratory equipment for the RFMTC** and office equipment for the Postgraduate Faculty; (iii) stipends for doctors and nurses undergoing the training of trainers (TOT) and for trainees undergoing retraining in family medicine/general practice; (iv) international and local technical assistance for developing a family medicine residency program curriculum and a business plan for the Family Medicine Faculty; and (v) workshops and study tours for staff of the Family Medicine Faculty to help build capacity in the management of family medicine residency programs, continuing education for family doctors and accreditation and licensing of family doctors. During Phase I, two RFMTCs will be developed in Kutaisi and Batumi for Western Georgia

Sub-component 2.2 - Capacity-building in the Management of PHC Services: The objective of this sub-component is to build the capacity of the Public Health Department within the MoLHSA for policy-making, planning and regulation of PHC services.

Sub-component 2.3: Strengthening Health Management Information Systems for PHC: The objective of this sub-component is to strengthen the design and implementation of a health management information system (HMIS) for primary health care.

Sub-component 2. 4: Support for PHC Health Care Financing Reforms: The objective of this sub-component is to build health care financing policy-making capacity in Georgia.

Component 3 - Project Management Support (Estim. costs US$ 1.24 million total)

European Union Project on PHC in Kakheti Region

The European Commission will support the primary health care reform undertaken by the Georgian government with a total grant of € 7.5 million for a period of three years (2003-2006). The project provides technical assistance at national and regional level in the areas of capacity building and reform of the health care finance system (allocation of € 2.5 million). It also foresees investments in Kakheti region in terms of **provision of equipment and refurbishment** of existing PHC infrastructure and related water and energy supplies, training of doctors, nurses and practice managers, and addressing information, education and communication needs of health professionals and the population (€5 million).

Before refurbishing, constructing and equipping PHC facilities and Family Medicine services in Kakheti region, the government decided that an inventory and needs assessment of the existing health infrastructure and resources should be conducted. The European Union supported this decision and a data collection exercise (September-November 2003); data processing and mapping with GIS (Geographical Information System) was conducted in joint efforts with Geographics Company supported by DFID. Subsequently, a criteria-based approach has been applied by a team of European experts to prioritize the allocation of funds for refurbishment, construction, equipment and staffing to assist the MoH in developing a more effective and optimal system for allocation of health care resources toward PHC in Kakheti region.

In the field of laboratory, several PHC/polyclinics will be re-equipped and re-supplied with reagents and consumables. The analysis package will be limited to a basic list (level IV in the laboratory

classification). The possibilities of also refurbishing a regional Kakheti laboratory are being considered by those responsible for implementation.

Important note: Those responsible for disease surveillance in the MoH should rapidly consider the issues of the analysis package by level (and equipment related to it) as this EU granted project will need such documents very soon and this could be the ideal situation to field test these packages on a large scale

Tuberculosis Program

Several partners are involved in TB surveillance/diagnosis.

When only considering the diagnosis aspect, USAID and Merlin are involved in re-equipping several diagnosis centres (In Tbilisi for USAID, in the Gori area for Merlin).

The work performed is appropriate, and a basic, but reliable, laboratory has been rapidly visited in Gori hospital. See photographs in Annex C.

Another program, funded by GTZ, was also focusing on diagnosis:

After a couple of TB laboratory assessments, it was evident that the number of TB diagnosis laboratories in Georgia was bigger than the needs. For example, some labs were having an average number of 0,5 per day.

It has been decided to close some of the laboratories and to strengthen the remaining ones. Closed laboratories have been transformed into "sputum collection sites" able to collect, register and ship specimens to the next TB laboratory. Today, around 35 collection sites and 35 TB laboratories are available.

Figure A-1. Map Showing Organization of Specimen Collection for TB

The map in Figure A-1 shows how the system is organized. The transportation is done on a weekly basis, using local buses. Special boxes are used to transport the specimens. Results are brought back with

another bus (2 directions). The yearly cost to run the transportation issues only is around 800-1000 USD per month:

35 transports X 4.5 weeks X 2 = 315 transportations.

The system has a final price around US$ 3. This amount is very reasonable.

Strengths of the system:

- The organization
- The rationalization of TB diagnosis in the country (balance between labs and collection sites)
- The use of local transportation systems → reliable and sustainable
- The low cost of the system → sustainable

Weaknesses of the system:

- Funded by an external agency → what about the transportation costs after the project?
- Very good system at district level, but no communication between the peripheral TB lab and the central reference one → very few sputum referred for TB culture (only done at reference level)
- Transportation is not following international security standards (triple package, labeling, security, confidentiality management…)

This system is a good example of specimen transportation/laboratory networking. Without the lack of communication with the central level, it would have been an ideal system. As for safe blood and HIV laboratories (see below), those responsible for TB would also be very interested in participating in a common network for sample and specimen transportation.

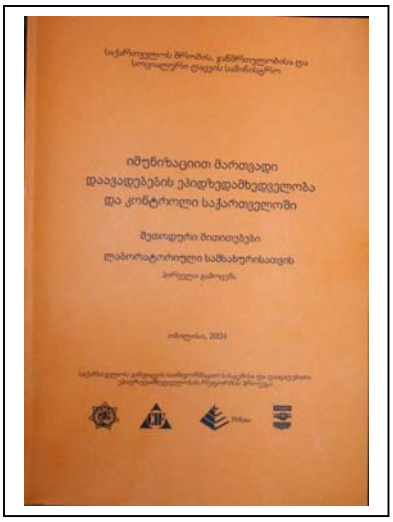
Disease Surveillance/USAID/PHR*plus* and CIF

A large project on health information and disease surveillance has been implemented by the Georgian NGO Curatio International Foundation (2002-2005). Work focuses on several components of health information and VPD surveillance:

- Strengthening immunization MIS
- Strengthening VPD surveillance
- Improving management capacities

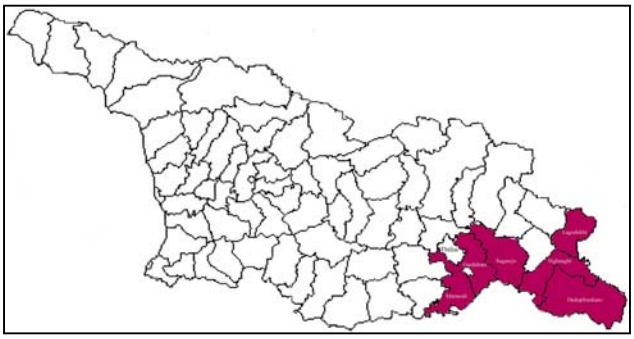
The importance of laboratory confirmation was highlighted when beginning VPD surveillance. A global assessment of several laboratories was carried out in July 2002 (see *ix*), and a laboratory *quality assurance manual for VPD diagnosis* was issued in 2004. Laboratory QA manuals issued in Georgia are not numerous and such tools really impact the way analyses are performed (see photograph of the manual).

Figure A-2. VPD Quality Assurance Manual



Laboratories networking together usually share the same quality assurance manual, covering all tasks and procedures used in a laboratory. The VPD quality manual could ideally be the basis of a more comprehensive manual able to cover all communicable disease diagnoses, and perhaps more.

Malaria Network



The map shows the districts with reported cases of malaria in 2000.

Georgia is the only European country that submitted a proposal to *The Global Fund* that received a positive answer from them. This proposal will really allow them to improve the management of Malaria in the country.

Prior to this project, each district is supposed to have a parasitology laboratory (half of the former soviet "sanepi" system that is in charge of diagnosis. With differences from one lab to another, they are mostly not reaching satisfactory levels.

The future project (1,125 Mill. USD including 0,8 Mill. USD from Global Fund) will allow the persons in charge of malaria to strengthen the existing national programme for effective Malaria prevention and control. Six different strategies will be used together:

1. Strengthening institutional capacities of the National Malaria Control Programme (NMCP) and the general health care services;
2. Improvement of national capacities for and **access to early diagnosis** and adequate treatment of Malaria;
3. Promotion of cost effective and sustainable vector control;

4. Strengthening of the country surveillance mechanism;
5. Improvement of community awareness and participation in malaria control and prevention, and
6. Enhancing intersectional collaboration.

In the field of laboratories, different activities will be carried out:

- Provision of 80 microscopes
- Provision of adequate stain and consumables
- Refreshing of the microscopists

Through this programme, a future malaria-specific laboratory network will be promoted soon.

HIV/AIDS

Thirty-five transfusion laboratories are present in the country. They insure blood safety in performing HIV and Hepatitis serologies. Few of them have an ELISA machine available for serology. Most of them are using rapid tests.

A very good serology/virology laboratory is located in the infectious disease hospital in Tbilisi, and is able to confirm any abnormal result. Around 10 sera are referred to them monthly for HIV confirmation. Two other larger laboratories will be available in Batumi and in Zugdidi.

When peripheral laboratories are referring samples, they usually freeze the serum and pack it with ice-packs into a cool bag. The bag is then carried to Tbilisi by one of the laboratory technicians, either by road or by car. The system works well for this small amount of samples but is not cost-effective (cost of the technician transportation and fees) and doesn't allow regular surveys to be performed.

Dr. Tengiz Tsertsvadze, National AIDS coordinator, expressed his interest for a global multi-disease network for laboratory specimen transportation that may allow each vertical programme to facilitate the confirmation of some important diseases.

WHO/CSR Strengthening Program

A two-year training and mentoring program for 8 Eastern and Central European countries[9] began in early 2003. The aim of this program is to strengthen disease surveillance in:

- Actively involving laboratories in the surveillance system
- Providing refreshers in good laboratory practices
- Providing strong training in biosafety and quality assurance
- Begin the creation of a national laboratory network
- Help to write a national plan of action for laboratory activities

[9] Belarus, Bulgaria, Georgia, Moldova, Romania, Russia, Turkey, Ukraine

Two high-level people from NCDC attended this program and are actively involved in these activities[10]

In addition to this mentoring program, several tools and training sessions have been developed by WHO/CSR/Lyon:

- A laboratory assessment tool
- An Internet resource portal for public health laboratories
- A costing tool for the laboratory network (still being developed, see its field-test in Georgia in Annex G)
- Quality assurance programs (regional & national)

Training modules for laboratories (biosafety, quality assurance, samples management during outbreaks)

[10] Details can be found at www.who.int/csr/labepidemiology

Annex B: Assessment of Gori Hospital Bacteriological Laboratory

Table B-1: Details of the Gori Computerized Assessment

General indicator: 37%

1-building facilities and utility service	61%
Building conditions	50%
Fluids conditions (Water supply conditions)	48%
% of benched room utilized	100%
Number of benched rooms (level dpt)	50%
Communication	20%
Communicable diseases coverage	100%
2-biosafety, hygiene and security	8%
Use of safety equipments	30%
Availability of safety procedures	0%
Level of safety trainings	0%
Safety conditions	25%
Disinfection/sterilization of equipments	0%
Availability of waste disposals	0%
Availability of biosafety documentation	0%
3-specimen collection and recording	45%
Quality of samples received	80%
Sampling procedures	0%
Quality of sampling request form	0%
Critical thinking when handling samples	0%
Quality of the logbook	67%
Macroscopic examination	50%
Specimen storage	100%
Quality of the specimen tracking	60%
4-equipment	48%
% of mini funct. Equipment available	55%
% of opti funct. Equipment available	28%
% of basic mini funct equipment available	71%
% of basic opti funct equipment available	39%
5-reagents and supply	47%
Reagents preparation from powder	50%
Quality of reagent management	0%
Availability of funds for reagents	50%
Use of expired reagents	0%
Availability of basic staining reagents*	50%
Availability of special staining reagents*	NA
Availability enteric transp./culture media*	67%
Availability menin. transp./culture media*	100%
Availability other transport/culture media*	100%
Availability AST reagents/culture media*	25%
Availability of specific antisera*	25%
Availability of serology reagents*	NA
6-analysis and test performed	71%
Availability of screening tests	100%
Global indicator on availability of reagents	96%
AST availability	50%
Availability of identification	60%
Availability of high level identification	NA
Availability of very specific tests	50%
7-laboratory staff & working time	53%
Presence of a senior staff	100%
% of senior staff	100%
Presence of cleaning staff	100%
Availability of staff training	0%
Availability of formal training	0%
Analysis decision	100%
Working hours and days of work	25%
Critical thinking outside working hours	0%
8-total quality	14%
Availability of technical procedures	67%
Availability of IQC	0%
Availability of EQC	0%
Availability of temperature charts	33%
Performing of preventive maintenance	0%
Performing of equipment adjustments	0%
Availability of documentation/spare parts	0%

9-reporting, analysis & communication	19%	10- outbreak participation	0%
Availability of disease reporting	20%	Involvement during outbreaks	0%
Availability of activity recording	50%	Specific outbreak supply	0%
Availability of electronic activity recording	NA	Outbreak participation	0%
Availability of sample referring	0%	Specific outbreak guidelines	0%
Laboratory supervision	0%	Specific outbreak procedures	0%
Availability of lab/lab collaboration	25%	Critical thinking with outbreak specimens	0%

- NA means that these analysis are not applicable, i.e., not needed in the lab, 0% mean that no reagents are available but should be present

Annex C: Photographs of Laboratories Assessed in Gori

Hospital bacteriology laboratory



Microscopy facility (monocular solar microscope); expired reagents (1993) bought in Tbilisi the month prior to consultancy; wooden stock for heating (-5° the day of assessment) stored in bacteriology room.

Hospital clinical laboratory



Biochemistry bench; sampling room; electrical wires (centrifuge)

Children hospital clinical laboratory

		Hematology bench Old spectrophotometer (but still functioning)

Tuberculosis centre laboratory

		Tuberculosis diagnosis cabinet Stain and chemicals

Sanitary inspection (former "sanepi") laboratory

		Benches Physico-chemical analysis room

Annex D: Analysis by Level

This first table is a summary of a book just issued by both the license unit and the NGO "Genesis" at the end of 2004. This table shows, depending on the level of the laboratory (3 levels defined) which analysis should be performed and which techniques linked to these analyses should be available (sampling, staining, observing, etc.). Any time you advance a level, all the analyses of the lower level should also be performed (in order to avoid useless repetition)

Note: the book was only available in Georgian, and a rapid translation was kindly performed on the occasion by Dr. T. Zardiashvili. There may be some imperfections or terminology may not be very accurate.

Table D-1. Provisory List of Analysis by Level Developed by the License Unit and NGO "Genesis"

LEVEL	TYPE OF MEDICAL UNIT	ANALYSIS	METHODS
		Clinical laboratories	
I	* ambulatory	blood general analysis	obtaining blood from finger
		Hemoglobin	blood processing and microscopy in liquid condition
	* ambulatory, day hospital	N of erythrocytes	blood smear fixation/staining, hemato/cyto-diagnostics
		N of leucocytes	urine processing and microscopy
	* primary health care	N of platelet	stool processing and microscopy
		rate of erythrocytes sedimentation	phlegm smear fixation/staining, hemato- and cyto- diagnostics
	* district hospital	blood coagulation and bleeding time	
		microscopy smears for malaria identification	
		urine general	
		determination of proteins in urine	
		determination of glucose in urine	
		determination of bile pigments in urine	
		stool general analysis	
		stool research for latent bleeding	
		phlegm mucous general lab. investigation	
		Biochemical analysis	
		determination of glucose in urine	obtain blood (venous and capillary)
		prothrombin index determination	isolation of plasma

LEVEL	TYPE OF MEDICAL UNIT	ANALYSIS	METHODS
		Clinical laboratories	
II	* district (municipal hospital)	reticulocytes determination in blood	sampling and investigation of duodenal contents
		cytological determination of fetal hemoglobin	sampling and rese investigation arch of gastric juice
	* public health care centre	blood group and rhesus	genital samples lab diagnostics
		ketone and nitrites in blood	CSF lab research
	* medical-social hospital	rate of haemturia	
		nepichenko rule (shaped elements in urine)	
		Zimnitski assay	
		Ben-Jones albumen determination in	
		stool research for helminthes & helminthes eggs	
		stool research for protozoa identification	
		CSF bacteriology	
		lab research of duodenal contents	
		determination of gastric acidity	
		cytobacteriology of skin and mucous membranes	
		cytobacteriology of eye swab	
		cytobacteriology of vaginal swab	
		cytobacteriology of urethral swab	
		swab bacteriology to detect gonococcus	
		Biochemical analysis	
		total protein in blood	
		creatinin in blood	
		urea in blood	
		Thymol trial	
		glucose determination in blood	
		B lipoproteins determination in blood	
		total cholesterol in blood	
		total bilirubin	
		direct bilirubin	
		Iron	
		rheumatic factor	
		C-reactive protein in blood	
		direct bilirubin	
		diphenylamine trial	
		antistreptolyzine determination in blood	
		Haemostasis	

LEVEL	TYPE OF MEDICAL UNIT	ANALYSIS	METHODS
		Clinical laboratories	
		Coagulogram	
		blood coagulation time by Ivy	
		time of serum recalcification	
		fibrinogen concentration determination	
		thrombin time	
		fibrinolysis activity determination	

LEVEL	TYPE OF MEDICAL UNIT	ANALYSIS	METHODS
		Clinical laboratories	
III	* regional (republic) hospital	hematocrit determination in blood	lab investigation of serosity
		osmotic resistance of erythrocytes	
	* specialized hospital	determination of mean diameter of erythrocytes	
		cytological determination of fetal hemoglobin	
	* clinical hospital	puncture sample cytological research	
		catheter (from cavity organs) cyto-bacteriology	
	* dispensary	sperm cytobacteriology	
		vagina purity rate	
	* polyprofile dispensary	direct fluorescence for chlamydia, virus etc detection,	
		prostate secretion lab investigation	
	* polyclinic	various pathologic material research for BK	
	* maternity welfare centre/clinic	Biochemical analysis	
		Triglycerides	
		HDL cholesterol	
		LDL cholesterol	
		aspartate aminotransferase ASAT	
		alanine aminotransferase ALAT	
		gamma-glutamyl transferase GGT	

Table D-2. Detailed List of Analysis by Level to be Filled in.

This second table is a list of all analysis, grouped by discipline. It should be filled in before initiating the laboratory network.

Sampling

Analysis name	PHC	DIS	REG	REF	ABR
blood (capillary)					
blood (veinous)					
CSF					
Ear					
Ganglion					
induced expectorations					
Medullar					
Mycology					
Nose					
overflow (dropsy, pleural, articulation…)					
Skin					
Sputum					
STDs samples					
Stool					
Throat					
Uretral					
Vaginal					
Wound					

Cytology-hematology

Analysis name	PHC	DIS	REG	REF	ABR
Adenogramme					
auto-hemolysis test					
blood hemogramme (complete)					
blood protoporphyrin determination					
cyto-chemical analysis					
determination CD4 CD8 CD3					
ESR determination					
Hematocrit					
hemoglobin electrophoresis					
hemoglobin F measurement					
hemoglobin measurement (total)					
hemoglobin solubility (itano)					
hemopathy diagnosis					
hemopathy follow-up					
Medullogramme					
research of Heinz particles					
research of sickle cells					
reticulocyt count					
Splenogramme					
thrombocyte count					

Hemostasis

Analysis name	PHC	DIS	REG	REF	ABR
antithrombin III determination					
beta thromboglobulin					
bleeding time					
cephalin activated time					
circulating anticoagulant research					
differential II, VII, IX, X					
euglobulin lyse test					
F IX determination					
F VIII determination					
F XI					
F XII					
F XIII					

FDP determination					
fibrinogene determination					
fibrinopeptid A					
LMW heparin measurement					
protein C determination					
protein S determination					
prothrombin time					
standard heparin measurement					
thrombin time					
thrombocytic factor 4					
thromboxan B2					
Willebrand factor determination					

Immuno-hematology

Analysis name	PHC	DIS	REG	REF	ABR
ABO grouping					
direct compatibility test					
direct Coombs test					
irregular antibody research					
other RBC antigen determination					
Rhesus factor determination					
Rhesus phenotype determination					
thrombocyte grouping					

Bacteriology

Analysis name	PHC	DIS	REG	REF	ABR
anal cyto-bacteriology (cytology + ID)					
antibiotic seric concentration determination					
antibiotic susceptibility testing (1 germ)					
antigen detection Yersinia					
antituberculosis sensitivity testing					
articulation overflow cyto-bacteriology					
basic sample cytology (microscopy + staining)					
broncho alveolar washing cyto-bacteriology					
broncho pulmonary cyto-bacteriology					
catheter cyto-bacteriology					
CSF cyto-bacteriology					
dropsy overflow cyto-bacteriology					
eye sample cyto-bacteriology					
genital cyto-bacteriology (cytology + ID)					
Hemoculture					
MIC determination					
miscellaneous overflow cyto-bacteriology					
nose-ear-throat cyto-bacteriology					
pleural overflow cyto-bacteriology					
pus cyto-bacteriology					
research of bacterial toxin					
research of Chlamydia					
research of diphtheria					
research of mycobacteria (ZN stain + culture)					
research of mycobacteria (ZN stain)					
research of mycobacteria species (biochemistry)					
research of mycoplasma					
research of pertussis					
research of rickettsia					
research of specific aerobic bacteria					
research of specific anaerobic bacteria					
research of specific bacteria (immunofluorescence)					
research of spirochetes					
serology borrelia					
serology brucella					
serology Chlamydia					
serology coxiella burnettii					
serology francisella					
serology leptospira					
serology pasteurella					
serology streptococcus					

serology syphilis					
serotyping of bacterial strain					
skin cyto-bacteriology					
sperme cytobacteriology					
stool cytobacteriology					
urinary cyto-bacteriology (AS + cytology + ID)					
urinary strip analysis (2 parameters)					
urinary strip analysis (full parameters)					
wound cyto-bacteriology					

Mycology

Analysis name	PHC	DIS	REG	REF	ABR
dermatophytes identification					
exotic fungi identification					
filamentous fungi identification					
fungi microscopy					
fungi sensitivity testing					
Malassezia furfur identification					
yeast identification					

Parasitology

Analysis name	PHC	DIS	REG	REF	ABR
stool parasite research (microscopy)					
stool parasite research (microscopy + concentration)					
parasitic stool larva identification					
malaria diagnosis (microscopy)					
malaria diagnosis (immunological)					
other blood borne parasites diagnosis					
derma/skin parasites diagnosis					
antigen detection aspergillus					
antigen detection candida					
antigen detection Cryptococcus					
antigen detection distomatosis					
antigen detection echinococcus					
antigen detection histoplasma					
antigen detection leishmania					
antigen detection toxoplasma					
antigen detection trichinella					

Immunology

Analysis name	PHC	DIS	REG	REF	ABR
antiDNA soluble antibodies determination					
antiDNAn antibodies determination (IF)					
antihistones antibodies determination					
antimitochondry antibodies determination					
antineutrophil antibodies determination					
antinuclear antibodies determination (IF)					
antiphospholipid antibodies determination					
IgE specific determination					
IgE total determination					
rhumatoid factor determination (Waaler-Rose)					

Virology

Analysis name	PHC	DIS	REG	REF	ABR
antigen detection adenovirus					
antigen detection rotavirus					
antigen detection rotavirus					
antigen detection RSV					
serology adenovirus					
serology arbovirus					
serology cytomegalovirus					
serology EBV					
serology enterovirus					
serology H delta V					
serology HAV					
serology HBV					
serology HCV					
serology HEV					

serology HIV					
serology HSV (1&2)					
serology HTLV					
serology influenza					
serology measles					
serology mumps					
serology parvo B19					
serology rabies					
serology RSV					
serology rubella					
serology VZV					
viral culture diagnosis (generic)					

Dynamic trials

Analysis name	PHC	DIS	REG	REF	ABR
creatinine clearance					
induced hyperglycemia					
urea clearance					
urine concentration trial					
urine dilution trial					

Hormons

Analysis name	PHC	DIS	REG	REF	ABR
17 OH corticosteroids					
17 OH pregnenolone					
25 OH D3					
ACTH					
ADH					
androstendiol					
C peptide					
calcitonin					
corticosteron					
cortisol					
cortison					

CRH					
desoxycortisol					
DHA					
E2					
E3					
erythropoietin					
FSH					
gastric					
GH					
glucagon					
GRH					
insulin					
LH					
LHRH					
melatonin					
osteocalcin					
P substance					
parathormon					
plasmatic cathecolamin					
plasmatic CGH					
pregnenolone					
pro insulin					
progesterone					
prolactin					
PTH					
renin					
serotonin					
T3, FT3, total T3					
T4, FT4, total T4					
TBG					
testosterone					
transcortin					
trypsin					

TSH					
urinary 17-cetosteroids					
urinary 6 beta OH cortisol					
urinary aldosteron					
urinary CGH (pregnancy)					
urinary estrogens					
urinary free cortisol					
urinary OH indol acetic acid					
urinary total catécholamin					
urinary vanylmandelic acid					

Enzymes

Analysis name	PHC	DIS	REG	REF	ABR
5' nu					
aldolase					
ALP					
amylase					
CKMB					
CPK					
G6PD					
GGT					
GO					
GP					
LDH					
lipase					

Proteins

Analysis name	PHC	DIS	REG	REF	ABR
albumin					
alpha 1 antitrypsin					
alpha 2 macroglobulin					
apoprotein A1					
apoprotein B					
beta 2 microglobulin					

C3					
C4					
CRP					
cryoglobulin research					
electrophyoresis of proteins					
ferritin					
fructosamin					
haptoglobin					
HbA1c					
hemolytic complement 50					
hemopexin					
hyaluronic acid					
Lp (a)					
monoclonal dysglobulinemia diagnosis					
myoglobin					
orosomucoid					
prealbumin					
procalcitonin					
total IgA					
total IgG					
total IgM					
total proteins					
troponin					

Vitamins

Analysis name	PHC	DIS	REG	REF	ABR
folic acid					
vitamin A					
vitamin B1					
vitamin B12					
vitamin B2					
vitamin B6					
vitamin E					

vitamin P						uric acid					

Tumor markers

Analysis name	PHC	DIS	REG	REF	ABR
AFP					
CA 125					
CA 15-3					
CA 19-9					
CA 50					
CEA					
PSA					

Gazometry

Analysis name	PHC	DIS	REG	REF	ABR
2-3 diphospho glycerate					
carbon monoxyde					
methemoglobin/hemoglobin					
pCO2					
pH					
pO2					
SaO2					

Biochemistry (blood, urine, CSF…)

Analysis name	PHC	DIS	REG	REF	ABR
ammoniac					
bicarbonats					
bilirubin (tot., free, conj.)					
calcium					
chlore					
cholesterol					
copper					
creatinin					
glucose					
iron					
iron fixation capacity					
lactic acid					
lithium					
magnesium					
osmolarity (measured)					
phosporus					
potassium					
sodium					
triglycerides					
urea					

Drug & toxic

Analysis name	PHC	DIS	REG	REF	ABR
alcool					
amikacin					
aspirin					
barbiturics					
benzen					
benzodiazepin					
canabis					
carbamazepin					
ciclosporin					
cocain					
digoxin					
INH					
lead					
methotrexate					
morphin/morphinics					
paracetamol					
phenytoin					
theophyllin					
tricyclic drugs					
vancomycin					

Molecular biology

Analysis name	PHC	DIS	REG	REF	ABR
CCHF					
Chlamydia					
HBV, viral DNA					
HCV, viral RNA					
HIV viral load					
mycobacteria					
SARS virus diagnosis					

Annex E. Equipment by Level of Laboratory

The minimal and optimal quantity of equipment that should be available in the different types of laboratory that are listed below in Table E-1.

Please note that this list covers bacteriology, virology, serology, parasitology, biochemistry, hematology and molecular biology.

Once analysis by level is defined (including methodology that should be used at the different levels), this list should be filled in order to enable laboratories to perform the set of analyses planned, using the methodology planned.

"Mini" and "opti" refer to the MINImal stock that should be available to perform the analysis decided for the considered level, when OPTImal will show the comfortable amount of stock that should be provided to the considered lab.

Table E-1: List of Equipment to be Filled in, by Level

	PHC		district		intermed.		reference	
	mini	opti	mini	opti	mini	opti	mini	opti
autoclave, 120 litres								
autoclave, 60 litres								
automated cell counter								
automatic pipetters 0-20 µl								
automatic pipetters 200-1000 µl								
automatic pipetters 20-200 µl								
biochemistry autom. analyzer								
blood gas analyzer								
blood grouping plates								
candle jar for culture								
centrifuge basic								
centrifuge cooled								
centrifuge hematocrit								
CO2 incubator								
coagulometer								
computer (complete)								
electrophoresis equipment								
ELISA equipment (W/I/R)								
ESR system								

flame photometer								
freezer-20°								
freezer-70°								
fridge								
gel pulse electrophoresis								
glassware kit, set *								
heated magnetic agitator								
immunoanalysis autom. analyzer								
incinerator basic								
incinerator large								
incubator, 30°								
incubator, 37°								
incubator, 42°								
Internet connection (year)								
laboratory information system								
mallassez cell + dil. pipette								
manipulation box								
McFarland photometer								
McFarland scale								
media dispenser								
microscope binocular								
microscope fluorescence								
microscope inverted								
nephelometer/turbidimeter								
oven								
pH meter								
photometer, basic								
pressure cook, 12 litres								
printer (laser)								
protective Plexiglas screen								
rotative agitator								
safety cabinet class II								
safety cabinet class III								
scale basic (0,1 g)								
scale precision (0,1 mg)								
slide stainer (hematek)								
spectrophotometer								
thermocycler								
vortex agitator								
water distiller								
waterbath								

For the specific purpose of VPDs, a list has been defined in 2003 following a workshop attended by several key persons from Georgia (MoLHSA, NCDC, WHO, etc.) but only including 3 levels of laboratories (without PHC level). This list only covers VPDs needs (no biochemistry or hematology).

Table E-2. Illustrative List of Equipment by Level (used by VPDs surveillance program)

Equipment	Level III laboratories		Level II laboratories		Level I laboratories	
	min.	opt.	min.	opt.	min.	opt.
autoclave	3	5	2	3	1	2
basic scale	1	2	1	1	0	1
binocular microscope	5	10	3	5	2	3
candle Jar	3	5	1	3	0	0
clothes washing machine	1	1	0	1	0	0
CO2 incubator	1	2	0	0	0	0
computer+printer	2	4	1	2	0	1
diluter	1	2	0	1	0	0
dryer	2	3	1	1	0	1
electrophoresis equipment	1	2	0	0	0	0
ELISA equipment (W/I/R)	2	3	1	2	0	0
emergency power supply	1	1	1	1	0	0
fluorescence microscope	1	2	1	1	0	0
freezer -20°	3	5	1	2	0	1
freezer -70°	1	2	0	1	0	0
fridge	4	8	2	5	1	2
gel pulse electrophoresis	1	1	0	0	0	0
glassware kit	1	1	1	1	1	1
heated magnetic agitator	1	2	1	1	0	0
incubator, large sized	2	4	0	1	0	0
incubator, small sized	3	5	1	2	0	0
Internet connection	1	1	1	1	0	1
manipulation box	0	0	1	2	0	1
Mc Farland photometer	1	2	1	1	0	0
media dispenser	1	2	1	1	0	0
oven	2	3	1	2	1	1
photographic equipment	1	1	0	0	0	0
plexiglass screen	3	5	2	4	1	2
precision scale	1	2	1	1	0	0
rotative agitator	1	2	1	1	0	0
safety cabinet class II	2	4	0	1	0	0
safety cabinet class III	1	2	0	0	0	0
slide dryer	1	3	0	1	0	1
thermocycler	1	3	0	0	0	0

vortex	3	3	1	2	0	1
washing machine	1	1	0	1	0	0
water distiller	2	2	2	2	1	1
waterbath	2	4	1	2	1	1

Annex F: List of Procedures to be Developed for QA

Premises and generic procedures

1. QA responsible designation procedure
2. Global map of the laboratory
3. Restricted areas procedures
4. Electrical, watery, gas and other fluids pathway
5. Arrows, signs and labels in the laboratory
6. Thermal area procedures (air conditioning, heater, cold rooms)
7. Emergency evacuation procedure
8. Procedures in case of fire, chemicals problem, electrical hazard, biohazard
9. Cold chain procedures
10. Decrees or official texts ruling the laboratory
11. List of analysis performed in the laboratory
12. Restrictive list to be performed at night & weekend

Staff management & organization procedures

13. List of the staff, including flow chart & responsibilities
14. One page by staff: address, background, initial training, continuous training attended & to be attended, job description, acting person if absent
15. Working hours & workload
16. Daily organization procedure
17. Night shift & weekend shift procedures
18. Communication procedures between staff (notes, regular meetings …)

Sample procedures

19. Sampling rooms
20. Sampling material
21. Sample rejection or acceptation criteria
22. Blood sampling (peripheral & capillary)
23. Stool sampling
24. Urine sampling
25. Vaginal sampling
26. Urethral sampling
27. STD sampling
28. Sputum sampling
29. Induced expectoration sampling
30. Wound sampling
31. Ear sampling
32. Nose sampling
33. Throat sampling
34. Dropsy overflow sampling
35. Pleural overflow sampling
36. CSF sampling
37. Ganglion sampling
38. Mycological sampling
39. Medullar sampling

Sample transportation procedures

40. Transport media general procedure
41. International transportation rules (IATA/other)
42. Sending specimen procedure
43. Receiving specimen procedure

44. Cary-Blair media
45. Alcalin pepton water media
46. TransIsolate media
47. Portagerm media
48. Other transport media
49. Particular cases: HIV, hepatitis, poliomyelitis, haemorrhagic fever

Sterilization, hygiene & security procedures

50. Sterilization by the dry heat
51. Sterilization by the wet heat
52. Chemical cold sterilization
53. Disinfectants, disinfections
54. Vaccination required for laboratory staff
55. Clothes required in the laboratory
56. Lab-coat, napkins & tissues washing
57. Hand washing
58. Laboratory washing, including floor & benches
59. Safe manipulation procedure
60. Procedures in case of injury (chemical, wound, burning)
61. Procedure in case of biohazard injury (incl. HIV+ exposure)

Staining procedures

62. Smears, films & slides performing
63. Quality control of staining methods
64. Methylene blue staining
65. Gram staining
66. Ziehl Nielsen staining
67. India ink staining
68. Giemsa staining
69. May Grünewald Giemsa / field staining
70. Lugol staining
71. Trichrome staining
72. Lactophenol blue staining
73. Weber staining
74. Gomori Grocott staining

Media procedures

75. Media ordering procedures
76. Media location in the laboratory
77. General procedure on media preparation
78. General procedure on media conservation
79. Culture media decontamination & elimination
80. Incorporation of ATB into Used culture media
81. Conservation and control of culture media
82. Non selective agar
83. Hektoen culture media
84. Salmonella Shigella culture media
85. BCYE culture media
86. Blood agar culture media
87. Chocolate culture media
88. Mc Conkey culture media
89. Sabouraud culture media
90. TCBS culture media
91. Chapman culture media
92. Kliegler culture media
93. Simmons citrate culture media
94. Löwenstein Jensen culture media
95. Coletsos culture media
96. Basic nutritive broth
97. Brain heart broth
98. Schaedler broth

Reagent procedures

99. Reagent ordering procedures
100. Reagent stock management
101. Reagent global use, quality control and storage
102. Reagent location in the laboratory

103. Reagent fabrication

Sample culture procedures

104. Stool culture
105. Urine culture
106. CSF culture
107. Blood culture
108. Swab specimen culture
109. Sputum culture (general)
110. Sputum culture (tuberculosis research)
111. Overflows culture
112. Culture for mycological research

Identification of a micro-organism

113. Identification of a gram positive cocci
114. Identification of a gram positive rods
115. Identification of a gram negative cocci
116. Identification of a gram negative rods
117. STDs diagnostics & culture

Antibiotic susc. testing procedures

118. Media preparation, control & use
119. AST general procedure
120. AST special feature procedure
121. MIC procedure

Quality assurance procedures

General QA procedures

122. Location of QA manual and documentation
123. Update of QA manual
124. Procedure flow inside the laboratory

Equipment procedures

125. General acquisition procedure
126. General resp. & organization toward equipment
127. Centrifuge use, control & maintain
128. Microscope use, control & maintain
129. Incubator use, control & maintain
130. Laminar flow use, control & maintain
131. Water bath use, control & maintain
132. Agitators use, control & maintain
133. Fridge use, control & maintain
134. Freezer use, control & maintain
135. Scale use, control & maintain
136. ELISA chain use, control & maintain
137. Colorimeter use, control & maintain
138. Spectrophotometer use, control & maintain
139. Turbidimeter use, control & maintain
140. Autoclave use, control & maintain
141. Oven use, control & maintain
142. Dryer use, control & maintain
143. Washing machine use, control & maintain
144. Water distiller use, control & maintain

Internal quality control procedures

145. What IQC is to be performed
146. Archiving IQC results
147. Corrective action to be taken following bad IQC results

External quality control procedures

148. What EQC is to be performed
149. Archiving EQC results
150. Corrective actions to be taken following a bad EQC result

Data management procedures

Recording & computerized procedures

151. Legal frame on what should be recorded for each patient
152. Global recording procedures
153. Availability of the manual of the computerized laboratory management software (CLMS)
154. Pre-analytical edition: working number,

labels, working sheets

155. Results filling & technical validation procedures
156. Criteria for re-analyzing an abnormal result
157. Access restriction for patient modification, result modification, biological validation

Archiving procedures

158. Global organization of archiving: what, where, how
159. Archives access restriction
160. Backup & copies of archived data
161. How long to archive data, logbooks and reports

Reporting procedures

Disease-specific procedures

For each disease

162. (some parts are not relevant for all the disease)
163. Causative organism
164. Specimen used
165. Collection, storage and transport. of specimens
166. Material needed
167. List of analysis to be performed, useless analysis
168. Macroscopic examination of the specimens
169. Staining procedures, microscopic examination
170. Analysis procedures
171. Serodiagnostic and other immunological tests
172. Other significant organisms isolated from the same specimen
173. Differential diagnostic, false positives, false negatives
174. Quality control
175. Antimicrobial susceptibility testing
176. Presumptive identification
177. Further analysis to be sent out of the laboratory
178. Reporting of the results, units of the results
179. Referral, links with Public Health authorities
180. Biosafety, waste elimination

Proposed list of diseases

181. Cholera
182. Shigella
183. Salmonella
184. Diphtheria
185. Typhoid fever
186. Pyogenic meningitis
187. STDs
188. Plague
189. Tuberculosis
190. Other respiratory diseases
191. Malaria
192. Viral hemorrhagic fever
193. Hepatitis
194. HIV/AIDS
195. Fungal infections
196. Parasitic digestive infections

Annex G. Details on Costing Issues

Note: all tables and graphs (included as pictures) are also available in MS Excel® format.

Price of Equipment and Sampling Consumables

Figure E-1 shows the details about:

- Price of small equipment (**included** in the network budget)
- Price of sampling consumables (**not included** in the network budget as included in the hospital budget)

This sampling equipment represents quite a large amount of money, and is regularly a limiting factor of sampling quality and quantity. It has not been included into the yearly budget, as already supported by a large variety of programs and institutions.

Figure G-1. Details on Sampling Equipment and Consumables Costing

Small equipment

	# per PHC	# of PHC	# per district	# of districts	# per region	#of regions	total units	unit price	total price
triple package (large size)	4	488	8	61	16	11	2616	$ 20	$ 52 320
external cold box	2	488	4	61	8	11	1308	$ 4	$ 5 232
ice pack, average	8	488	16	61	32	11	5232	$ 0,5	$ 2 616
sampling guideline	3	488	10	61	10	11	2184	$ 2,0	$ 4 368

Total $ 64 536

renewal of the set every 4 years --> yearly cost **Yearly $ 16 134**

Sampling consumables

	# per PHC	# of PHC	# per district	# of districts	# per region	#of regions	total units	unit price	total price
vaccutainer tubes ("dry")	1000	488	3000	61	6000	11	737000	0,2	$ 147 400
vaccutainer tubes ("EDTA")	500	488	2000	61	4000	11	410000	0,2	$ 82 000
urine vial	2000	488	2000	61	4000	11	1142000	0,1	$ 114 200
cary-blair (stool transportation)	300	488	1000	61	2000	11	229400	0,05	$ 11 470
swabs, set of 100	10	488	30	61	60	11	7370	7	$ 51 590
slides, set of 50	20	488	40	61	80	11	13080	3	$ 39 240
hemoculture bottles	200	488	1000	61	2000	11	180600	0,7	$ 126 420
request forms (set of 100)	20	488	50	61	100	11	13910	2	$ 27 820
CSF collection kit	0	488	100	61	500	11	11600	10	$ 116 000

Yearly total $ 716 140

Price of Training

Figure G-2. Training Costs

Training issues			
Preparation of the training			
	unit cost	# units	total cost
material developement	$ 3 000	1	$ 3 000
writing guideline	$ 2 000	1	$ 2 000
field test	$ 2 000	2	$ 4 000
definitive version	$ 2 000	1	$ 2 000
		total	**$11 000**
training of regional lab	3 participants per regions		
	11 regions		
	unit cost	# units	total cost
perdiem participants	$ 50	33	$ 1650
set of material	$ 10	33	$ 330
		total	**$ 1 980**
training of district labs	2 participants per districts		
	61 districts		
	unit cost	# units	total cost
perdiem participants	$ 25	122	$ 3 050
set of material	$ 10	122	$ 1 220
		total	**$ 4 270**
training of PHC	1 participants per PHC		
	488 PHC		
	unit cost	# units	total cost
perdiem participants	$ 10	976	$ 9 760
set of material	$ 10	488	$ 4 880
		total	**$14 640**
		grand total training	**$31 890**
		if every 2 years --> yearly cost	**$15 945**

Use of the Costing Tool for Laboratories

The Costing Tool for Laboratories (CTL) is a tool being developed by WHO/CSR/Lyon. It will help in the development of a global budget to support national public health laboratory systems in their basic laboratory surveillance activity.

This CTL is designed for various professionals including:

- Policymakers
- Health economists
- Administrators

- MoH representatives
- Laboratory coordinators
- Reference laboratory directors

The CTL can be used by the aforementioned professionals to:

- Calculate global costs for a laboratory network organization in their country
- Calculate costs for a specific disease syndrome
- Calculate costs for a specific type of laboratory
- Calculate costs for a specific type of analysis

In addition, this CTL can be used in the development of a national strategic plan that explores the following:

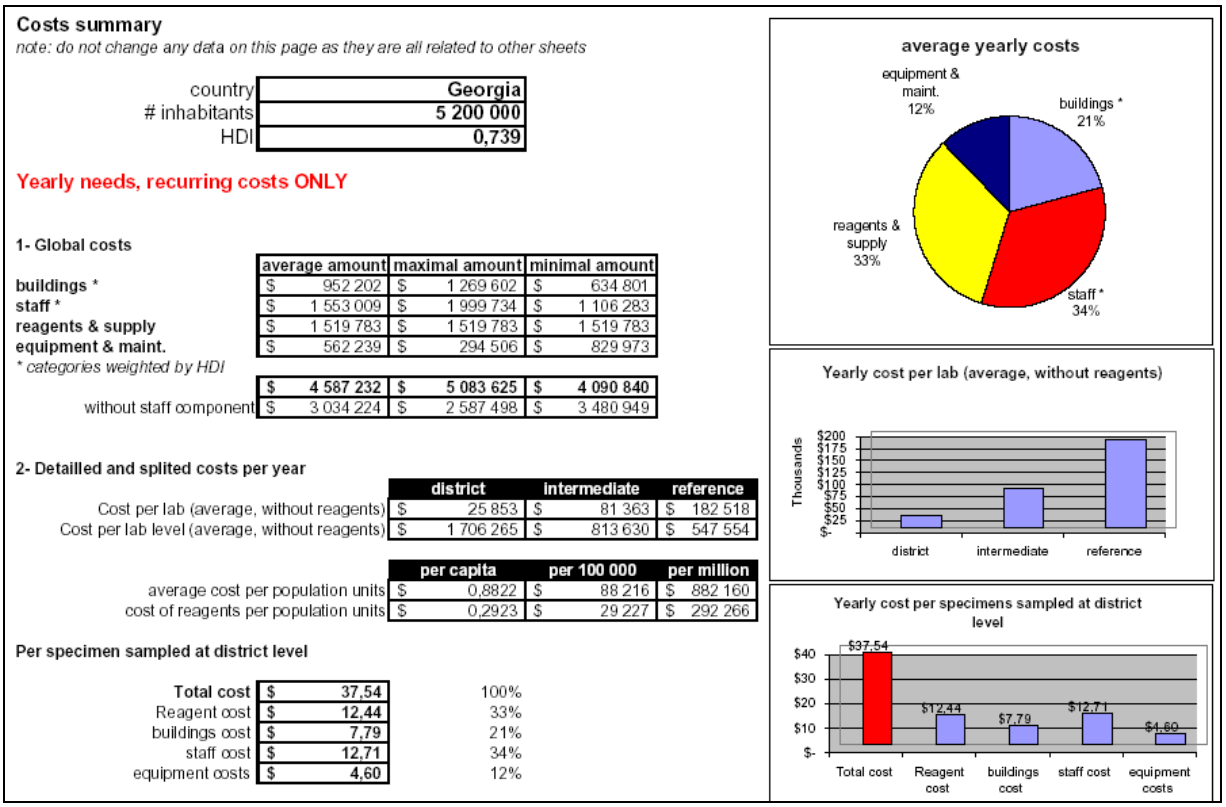
- How to screen/diagnose/confirm a specific disease
- How to organize and manage a laboratory network in a country
- How to determine the type of analysis that should be available at each level of the laboratory network
- How to determine the number of staff required at each laboratory level
- How to determine the amount of equipment needed at each laboratory level

This tool can be used in two different ways:

1. The **rapid** method uses automated calculations with no or few refinements in the calculations.
2. The **precise** method refines several of the indicators used for calculations when completing the tool. This method is more accurate; however, it is also a more time-consuming process.

Important note: this tool is still under development and Georgia was one of the first countries for field-testing of the tool. We are only providing a screenshot of the result.

Figure G-3. Screenshot of the Preliminary Laboratory Network Costing Tool (WHO/CSR/Lyon)



Costs summary

note: do not change any data on this page as they are all related to other sheets

country	Georgia
# inhabitants	5 200 000
HDI	0,739

Yearly needs, recurring costs ONLY

1- Global costs

	average amount	maximal amount	minimal amount
buildings *	$ 952 202	$ 1 269 602	$ 634 801
staff *	$ 1 553 009	$ 1 999 734	$ 1 106 283
reagents & supply	$ 1 519 783	$ 1 519 783	$ 1 519 783
equipment & maint.	$ 562 239	$ 294 506	$ 829 973
** categories weighted by HDI*			
	$ 4 587 232	**$ 5 083 625**	**$ 4 090 840**
without staff component	$ 3 034 224	$ 2 587 498	$ 3 480 949

2- Detailled and splited costs per year

	district	intermediate	reference
Cost per lab (average, without reagents)	$ 25 853	$ 81 363	$ 182 518
Cost per lab level (average, without reagents)	$ 1 706 265	$ 813 630	$ 547 554

	per capita	per 100 000	per million
average cost per population units	$ 0,8822	$ 88 216	$ 882 160
cost of reagents per population units	$ 0,2923	$ 29 227	$ 292 266

Per specimen sampled at district level

Total cost	**$ 37,54**	100%
Reagent cost	$ 12,44	33%
buildings cost	$ 7,79	21%
staff cost	$ 12,71	34%
equipment costs	$ 4,60	12%

Once this tool finalized, it will be possible to include all country parameters in order to get a very precise estimate.

Annex H: Documentation Provided/Gathered During Consultation

Documentation provided:

Note: a CD-ROM containing a large amount of documentation was burned and left with the director of the Licensing Unit.

- WHO/CDC Manual for the Laboratory Identification and Antimicrobial Susceptibility Testing of Bacterial Pathogens of Public Health Importance in the Developing World (English), 3 examples left (NCDC, Infectious Disease Hospital, Curatio International)
- Summary of the norm ISO 17025 (English), as the official document is not for free distribution
- Questionnaire for microbiology laboratory certification, French Committee for Antibiogramme (English & French)
- French Norms for Antibiogramme (English and French), free distribution
- Links to NCCLS (US standards), as distribution is not free
- Different types of Georgian maps (with regions and/or districts, with both, etc.), provided by the Health Mapping unit (WHO/Geneva)
- French "GBEA" (Guide de Bonne Execution des Analyses, Guide for good execution of analysis), sshort 25-page summary of French norms for laboratories
- Moldovan policy for "National External Quality Control Scheme in Bacteriology" (English)
- Policies and procedures of the WHO/NHLS external quality control for African laboratories of 43 countries (125 pages, in English)
- French nomenclature of analysis (free distribution)
- French official tests:
  - "Décret relative au contrôle de qualité des analyses de biologie médicale", décret 94-1049, 02/12/1994 (decree related to QC of analysis), decree that made compulsory participation to National EQC programme (in French)
  - "Missions et compétences de l'AFSSAPS", missions and objectives of the French FDA (in French)

Documentation gathered:

- "Organization of TB laboratory network and sputum transportation project in Georgia", with narrative, map, and laboratory list
- Presentation PowerPoint of the DTRA project/training week in Georgia
- "PHC Service Model for Kakheti region"

- World Bank Primary Health Care Development Project: “Project Appraisal Document” (94 pages)
- VPD Quality Assurance Manual (only in Georgian to-date)
- Georgian norms for laboratories (printed by NGO Genesis, only in Georgian to-date)
- Georgian railroad time table (useful for regular train transportation)

Note: an interactive CD-rom for network implementation is also available