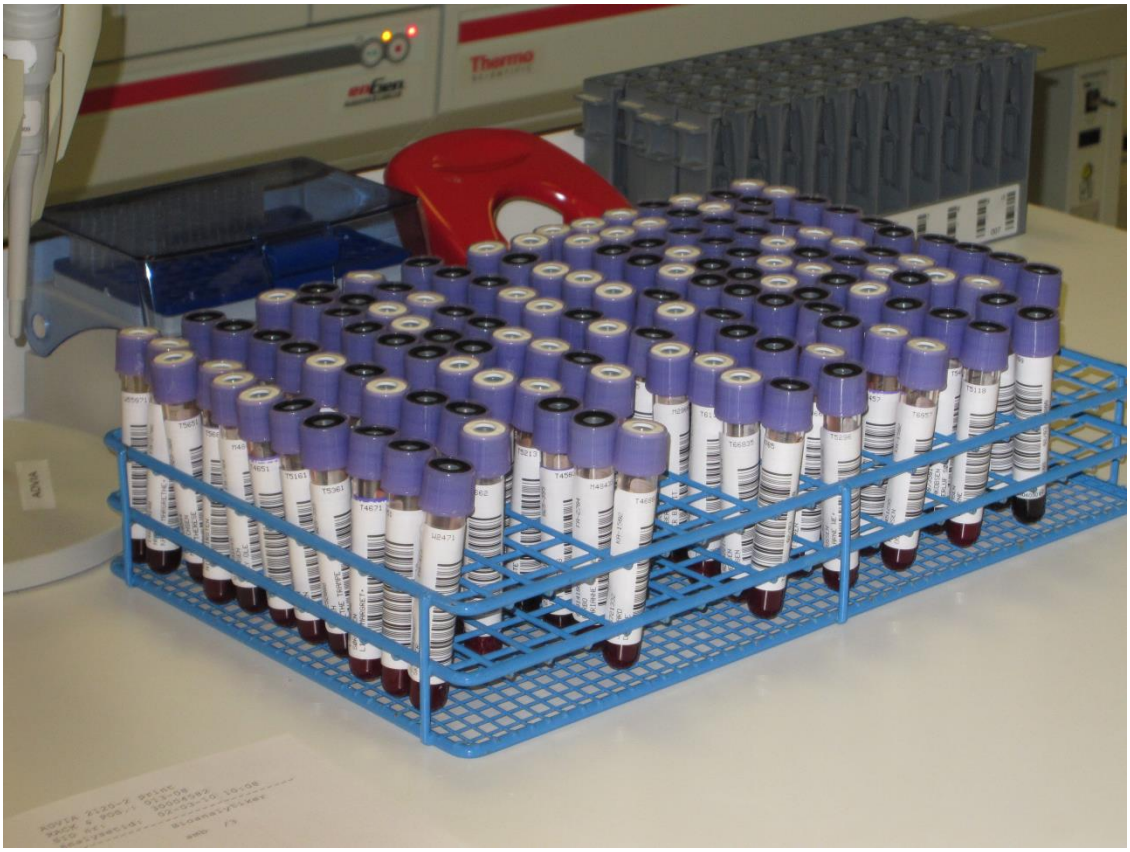
World Health Organization
REGIONAL OFFICE FOR Europe

KIT | Health

Development of national laboratory policies

Best practices document and facilitators' guide



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Contents

List of abbreviations

BLBH	Better Labs for Better Health
CDC	Centers for Disease Control and Prevention – USA
GAVI	Global Alliance for Vaccines and Immunization
IHR	International Health Regulations (2005)
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
KIT	Royal Tropical Institute
LAT	Laboratory Assessment Tool
MoH	Ministry of Health
NGO	Nongovernmental organization
NLP	National laboratory policy
NSP	National (laboratory) strategic plan
NLWG	National laboratory working group
PEST	Political – Economic and Environmental – Social – Technological
PPT	PowerPoint presentation (or presentation made with similar software)
ROF	Rumour – Opinion – Fact
SOP	Standard operating procedure
SWOT	Strengths – Weaknesses – Opportunities – Threats
WHO	World Health Organization

Acknowledgments

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It was authored by Linda Oskam (KIT), and developed based on methodology devised by Stella van Beers and Linda Oskam, with input from Paul Klatser (KIT).

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Scope of the document

This document provides guidance to the activities needed to develop a national laboratory policy.

Section 1 provides governments, participants and facilitators with an overview of the activities needed to develop a national laboratory policy that is nationally owned and widely supported.

Section 2 provides information on the main actors and their roles and responsibilities (Zwetyenga et al, 2015).

Section 3 provides a practical guide for facilitators of the workshops to develop a national laboratory policy. The facilitators' guide includes detailed, step-by-step agendas, complete with

descriptions of the activities, exercises, presentations and example outcomes that can be used for the facilitation of the workshops.

The document contains four annexes with detailed information. Template PowerPoint presentations and exercises, and a repository of policy statements from 10 different countries are available on request from the Better Labs for Better Health initiative (eulab@who.int).

Section 1: Background and approach

Background

The below text is based on the publication "New policy-formulation methodology paves the way for sustainable laboratory systems in Europe" (Brown et al., 2015).

Laboratories are an essential and fundamental part of all health systems and their goal to improve health. Reliable and timely laboratory-investigation results are fundamental elements in decision-making in almost all aspects of health services and so directly affect the health and well-being of individuals and countries. Reliable and timely laboratory services are also crucial to a nation's health security and economy and its ability to meet obligations such as the International Health Regulations. Approximately 60–70% of medical decisions are based on laboratory results (Kessel, 2014). The 2014–2016 outbreak of Ebola virus disease in West Africa has highlighted not only the crucial role of a strong health system in responding to public health emergencies but also the immense cost of ignoring this need (Oleribe et al, 2015). Within such a strong health system, effective high-quality (accredited) laboratories and response networks must be on the front line (Pereyaslov et al, 2014).

The 2008 global vision of the World Health Organization (WHO) and technical partners is that laboratory strengthening must be based on the implementation of national laboratory-quality standards (WHO, 2008). Implementation of these standards requires trained staff, appropriate infrastructure, equipment, reagents and consumables. All these components should be provided and coordinated by the national authority and informed and driven by national policies and strategies for health laboratory services (WHO, 2008a). Experience from resource limited settings in several countries shows that sustainable laboratory system strengthening is driven by coordinated efforts of country governments and their external funding partners around a host country's own national laboratory plan (Olmsted, 2010).

In recent years, investments in laboratory services in many low and middle income countries have been in disease-specific programmes targeting single diseases, such as polio or measles, rather than aimed at benefiting the laboratory system as a whole (WHO, 2014). Even within well-funded targeted programmes, such as HIV, tuberculosis and vaccine-preventable diseases, sustainability becomes a challenge once a country's economy improves and it is no longer eligible for funding from donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria or the GAVI Alliance. There has been relatively little attention paid to national coordination and oversight and often neither laboratory policies nor strategies have been developed at the national level (European Observatory on Health Systems and Policies, 2015). For these reasons, and in view of the WHO global vision, in 2012 the WHO Regional Office for

Europe launched the Better Labs for Better Health (BLBH) initiative – an intersectoral approach aimed at improving the quality of all laboratories that deal with health (Zwetyenga et al, 2015). For each country, the first step is the development of a national laboratory policy (NLP), followed by the development of a national strategic plan (NSP) and operational plans based on the NLP. A standardized methodology was developed for the formulation of NLPs and NSPs which has been implemented in the WHO European Region and is currently being rolled out by other WHO Regional Offices.

Approach for the development of a national laboratory policy

The below text is based on the publication "New policy-formulation methodology paves the way for sustainable laboratory systems in Europe" by Brown et al. (2015).

A national policy is a deliberate system of principles that guides future activities in a particular field, signals political commitment and puts the country in the driver's seat. Such a policy is essential for developing sustainable services (Nkengasong et al., 2009), providing criteria for accepting or refusing activities and ensuring optimal use of scarce resources. The policy should be consistent with other national policies in related fields, aligned to ongoing country laboratory initiatives and wider health system reforms, and based on broad consensus. NLP development described here pertains to all laboratories dealing with health as in the One Health approach, which is "the collaborative effort of multiple disciplines—working locally, nationally and globally—to attain optimal health for people, animals and the environment" (One health initiative task force, 2008). Laboratories working in prevention and management of acute and chronic diseases, control of outbreaks, antimicrobial resistance or adverse events associated with pharmaceutical or vaccine use, food, water and biological product safety, control of animal health and monitoring the environment should all be included, as should the private sector. The NLP is developed in line with Health 2020, the European policy for health and well-being (WHO, 2015).

The NLP is developed over a period of several months (Fig. 1) through a facilitated, participatory, country-tailored, step-by-step approach under the umbrella of a formally recognized national laboratory working group (NLWG[1]). This approach is taken with a view to creating national ownership of the NLP and NSP.

[1] http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/better-labs-for-better-health/national-laboratory-working-groups

The methodology is based on examples from other countries (Ministry of Health of Uganda, 2009; Office of the Auditor General Manitoba, 2003;) and WHO regions (WHO, 2011), and uses analyses such as: strengths, weaknesses, opportunities and threats (SWOT); political, economic, social and technological (PEST); root-cause; and rumour-opinion-fact (ROF) to collect and evaluate the evidence. The NLWG members are trained in the use of these techniques during the policy development workshops.

There are nine steps in the NLP development and each of these involves three steps divided over three phases:

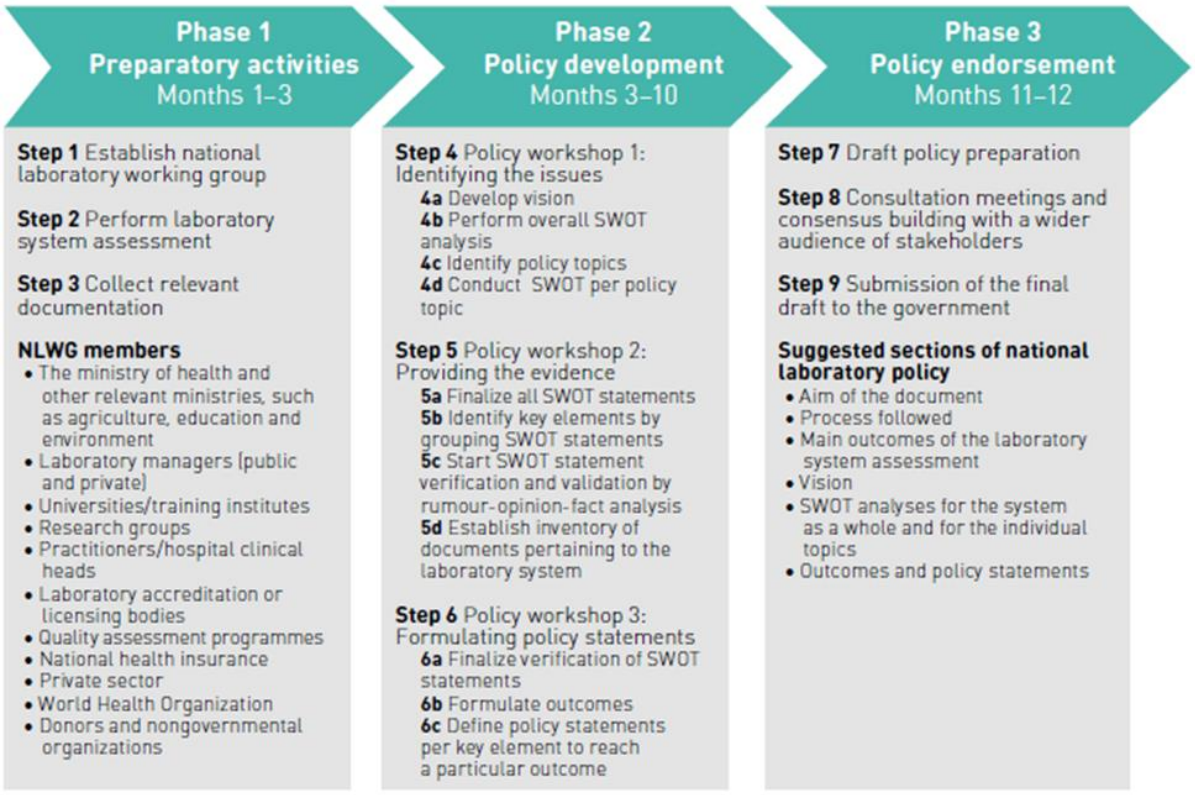
- phase 1 (steps 1–3) covers preparatory activities;
- phase 2 (steps 4–6) covers policy development; and
- phase 3 (steps 7–9) covers policy endorsement.

These components of NLP development are summarized in Fig. 1 and described below. Please note that the exact approach (including elements such as NLWG composition, number of workshops etc.) can be tailored to each country's situation and needs.

Phase 1: Preparatory activities

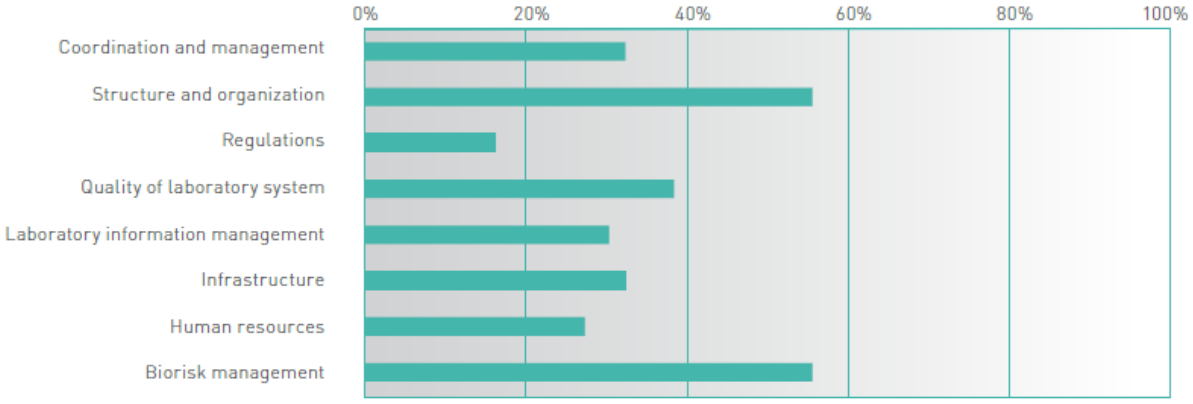
In step 1, the NLWG is formally established, consisting of a core group of about 15–20 persons, a chairperson and an executive secretary and including representatives as shown in Fig. 1.

Fig. 1. National laboratory policy development process



In step 2, the NLWG performs a laboratory system assessment using the WHO laboratory assessment tool (LAT), which enables calculation of a score for each of the key components of a laboratory system (WHO, 2012). Ideally, laboratories at different tiers of the health-care system are also assessed to obtain a more complete overview. The WHO Facility-level LAT can be used for this purpose. The results (Fig. 2), together with documents relevant to the laboratory sector identified through the LAT (step 3), are made available to the full NLWG and facilitators before the first workshop. Relevant documents include national health policies and other relevant policies, laws, ministerial orders and decrees, strategic plans and data on laboratories such as numbers, locations, staffing, uses and finances.

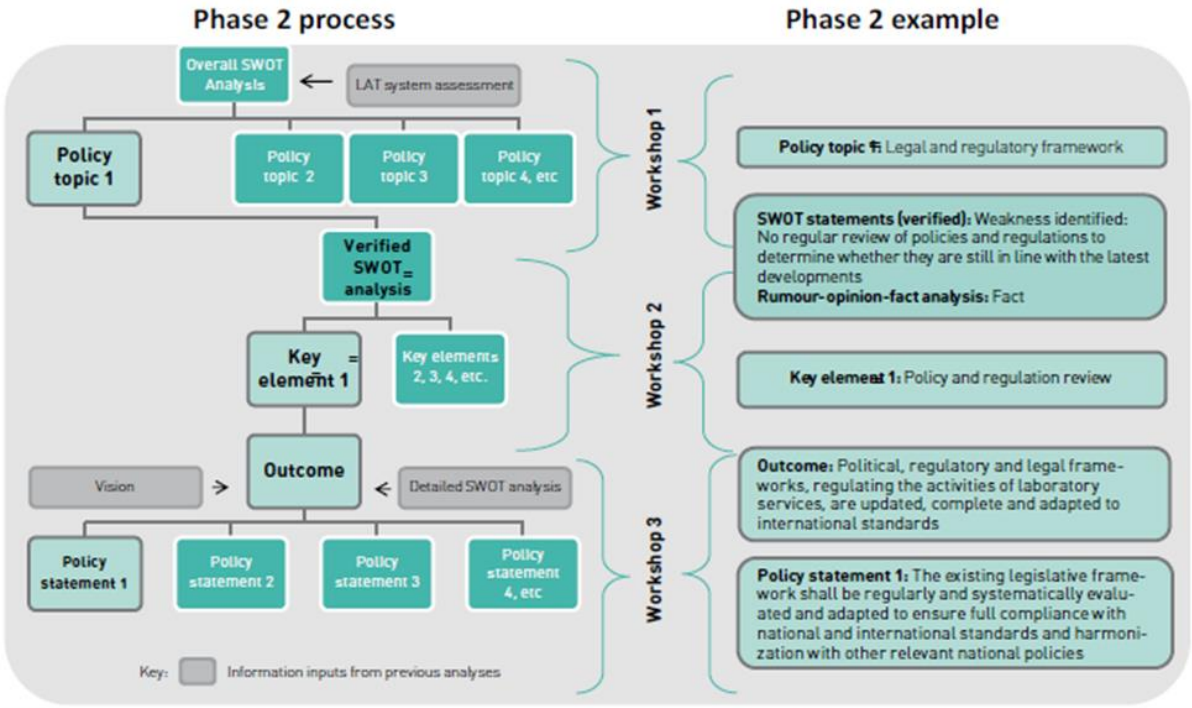
Fig. 2. Example of indicator results from a laboratory system assessment



Phase 2: Policy development

In phase 2 (see Fig. 3 for an example), three 3-day workshops comprised of exercises and group-work are conducted by international, experienced facilitators with laboratory quality backgrounds. The outputs from the workshops are based on consensus, which fosters nationally owned policies. In between workshops, the NLWG convenes to collect the information required for the next workshop.

Fig. 3. Example of the activities during phase 2



NLWG: national laboratory working group; SWOT: strengths, weaknesses, opportunities and threats; LAT: World Health Organization laboratory assessment tool.

Policy workshop 1 (step 4) identifies the main themes for the NLP by developing a long-term vision for laboratory services (Box 1), performing a stakeholder analysis and conducting a situation analysis of the overall laboratory system. The themes are categorized under 10–14 policy topics (Table 1).

Box 1. Example of a vision

"By 2020, the country shall have affordable, well-governed and well-managed quality laboratory services with strong leadership from the government and a rationally designed laboratory network structure with certified laboratories that are well funded and financially independent of donors. A comprehensive quality management system ensures that laboratories conform to standards and comply with biosafety and security regulations. Valid results are produced by a specialized, well-trained, highly qualified, well-paid and stable workforce that effectively performs procedures using good equipment and making use of a centralized procurement unit."

Table 1. Examples of national laboratory policy topics

Category	Policy topics
System inputs	• Legal and regulatory framework • Organization and management of services • Accessibility of services including community perspective • Partnerships, coordination and scientific collaboration
Structural inputs	• Human resources • Finance • Infrastructure • Procurement, equipment and logistics
Support inputs	• Biosafety and waste management • Communication and information system • Quality management

All policy topics are subsequently subjected to detailed SWOT analyses, some are conducted during the workshop and the rest are conducted in between the first and second workshop by the NLWG.

To support the SWOT analyses, the NLWG members are taught the principles of root-cause analysis to help identify the factors that result in a particular problem.

During policy workshop 2 (step 5), the evidence is reviewed and improved. The NLWG also provides evidence by collecting documents pertaining to laboratories, the detailed SWOT analyses for all policy topics and a final list of all SWOT statements for each policy topic is prepared. To provide structure where necessary, SWOT statements may be grouped to form subgroups per topic called key elements. The complete list of SWOT statements is then subjected to verification and validation by ROF analysis in which rumours are discarded, facts retained and opinions retained if there is consensus. The NLWG may also add, remove or combine topics, key elements or statements or revise the vision.

By the time of policy workshop 3 (step 6), the NLWG has verified all the SWOT statements and determined which statements to keep and which to remove.

The verification process results in an inventory of documents pertaining to the laboratory system, as many verified SWOT statements can be supported by an existing document. Using one or two topics from system inputs (e.g. legal framework and organization of the networks) plus two or three from structural inputs (e.g. infrastructure, procurement or human resources) (Fig. 1), the NLWG starts to define policy statements based on individual or several related SWOT statements and/or key elements. First, outcomes are formulated per policy topic or key element and based on these outcomes, the policy statements are formulated to reach the outcome. The typical structure of a policy statement is: "There shall be … to ensure …." Normally, two to five policy statements per key element or five to eight policy statements per policy topic (in case of a topic which is not subdivided into key elements) are formulated.

Fig. 1 shows an example for one policy topic of how SWOT statements lead to the identification of a key element, outcome and policy statement.

Phase 3: Policy endorsement

Subsequent to the third workshop, the NLWG develops outcomes and policy statements for all remaining policy topics. The Executive Secretary of the NLWG consolidates all outcomes and statements into a draft NLP or NLP proposal (step 7). The NLP proposal should be structured according to national requirements for such documents and could include sections as shown in Fig. 1, phase 3. It is submitted by the Chair of the NLWG to the Ministry of Health and once there is agreement it is submitted to a wider range of stakeholders, including other ministries, for consultation and review to ensure that all elements are captured and that the policy statements

are supported by as wide an audience as possible (step 8). Based on the comments from the reviewers a final document is prepared by the NLWG and submitted to the government for endorsement (step 9).

Once endorsed, the NLP will be implemented through the development of strategic and operational plans describing responsibilities, budgets and timelines. A separate facilitator's guide for the development of an NSP is available. This ensures that the policy statements are translated into actions that are carried out in an integrated manner at a pace that is in-line with the country's managerial and financial resources.

Methods/methodology

During the workshops the facilitators use a variety of participatory and interactive methods including individual reflections, group work and plenary discussions. There are few PowerPoint presentations; these are short and mainly serve as background for the exercises and activities.

The facilitators' guide for the policy development is based on the three-workshop approach described above. However, it is possible to expedite this activity using a two-workshop approach with longer workshops. An alternative agenda for these workshops is also presented.

Section 2: Actors involved and their roles and responsibilities

The main in-country parties

The Government

The organization of laboratory services varies per country, but laboratory services that have an impact on human health often fall under a number of ministries.

Clinical and public health services fall under the Ministry of Health (MoH), but veterinary and /or agricultural food safety laboratories may fall under the Ministry of Agriculture and water hygiene under the Ministry of the Environment. Coordination of activities of the various laboratory services that have an impact on human health should be the role of the MoH and an intersectoral working group can provide advice on this. The NLWG can play this role.

Other Ministries may play a more or less indirect role in laboratory services. For example, the Ministry of Education may be responsible for the training of laboratory workers, the Ministry of Finance for the budget necessary to run the laboratory services (either directly or through the National Health Insurance system) and the Ministry of Economic Affairs for the regulation of public and private services through licensing. Inclusion of representatives from these ministries in the NLWG should therefore be considered. The involvement of ministries other than health may vary per country.

The national laboratory working group

To ensure that the national laboratory policy represents and suits the needs of the country, it is important that policy-makers and high-level laboratory managerial staff are involved from the beginning in its development. To this end a national laboratory working group (NLWG) is established and installed before the start of the activities. (See also Fig. 1.)

All important stakeholders in the national health laboratory services should be represented in the NLWG to ensure a broadly supported and nationally owned national laboratory policy. The NLWG may include representatives from:

- The Ministry of Health and other relevant ministries, for example Education, Agriculture, Food, Environment, Finance, or Labour (see also explanation above).
- Managers from national (and possibly regional) public laboratories or laboratory networks. There should be a broad representation of the various types of laboratories in the country such as clinical, public health, veterinary, food and water safety, agricultural, product safety, chemical and radionuclear laboratories.
- Managers from private health laboratories.

- Universities and other training institutes providing pre-service or in-service laboratory training.
- Laboratory accreditation, certification or licensing bodies.
- Quality assessment programs.
- National Health Insurance.
- World Health Organization.
- Donors and NGOs involved in laboratory services.
- Representatives from research groups.
- Practitioners and clinical heads of hospitals as the main customers of clinical laboratory services.

This list is not exhaustive and, depending on the organization of the laboratory services in the country, other stakeholders may be added. It is important to have stakeholder representatives not only from the capital, but also from other regions.

The NLWG develops a draft NLP under the guidance of experienced facilitators in a series of workshops. The optimal group size for the policy development workshops is about 15-20. When the NLWG has more members than this, it can decide to appoint a smaller core group of its members to participate in the workshops. These core group members should participate on ALL days of ALL the workshops, as new persons who are involved at different stages will need to be briefed, which will delay the work and be an inefficient use of the NLWG's time. Regular meetings with the full NLWG should be organized to report progress and receive feedback on the documentation that is developed.

In addition to its involvement in the development of the NLP and at a later stage the NSP, the NLWG can also serve as the main information body and discussion partner for the MoH and other ministries on issues directly or indirectly related to laboratory services in the country.

Roles and responsibilities

Ministry of Health

The MoH serves as the government's coordinating body for the policy development process. It formalizes the establishment of the NLWG and provides the NLWG with the authority to develop a draft NLP. The MoH appoints NLWG members from its own ministry and from the health services under its authority and invites representatives from other ministries and stakeholders outside the government (see list above) to participate in the NLWG.

The MoH monitors the progress of the policy development and at the end of the process is responsible for discussing the draft policy with all government bodies involved and formalizing it in a way appropriate to the country.

The national laboratory working group

The NLWG represents all stakeholders of the health laboratory services in the country. Its Terms of Reference are:

- When requested, the NLWG provides advice and expertise to the government on health laboratory matters.
- The NLWG (or a smaller core group) develops the draft national laboratory policy and at a later stage drafts the strategic and operational plans.
- The NLWG seeks advice from, and tries to reach consensus with, the community of stakeholders of the health laboratory system before submitting the draft documents to the government.
- The members of the NLWG actively explain and promote the importance of quality laboratory services in the country.

The members of the NLWG will appoint a Chairperson and Executive Secretary from within the group.

World Health Organization

Upon request by the country, the WHO Regional and/or Country Office facilitates the process of developing a national laboratory policy. Depending on the resources and expertise available to WHO, this can be in the form of advice, identification of (inter)national experts, participation in the NLWG and/or organization and facilitation of the policy development process.

Facilitators

For each workshop it is important to have two facilitators. The team of facilitators should be kept the same for all three workshops, if possible.

The facilitators should have a solid background in laboratory work and laboratory quality management, as well as broad international experience in laboratory system assessment and strengthening. Experience with policy development is an asset. They should preferably come from another country to provide an independent and fresh view on issues.

They introduce the various elements and methodology of the policy development process to the participants, monitor the process, ask critical questions and place the national experiences and input from the NLWG in a broader perspective to ensure that the national laboratory policy is based on current international best practice.

Section 3: Facilitators' guide for policy development

Practical organization of the workshops

Each workshop requires two facilitators and 15-20 participants for optimal results. Interpreters may be needed, in which case they should have a working knowledge of laboratory terminology. As the methodology is highly interactive with most of the work being done in small groups and relatively few and short presentations, it is more practical to have consecutive rather than simultaneous translation.

Tentative agendas for the three workshops are given in Annex 1A – Annex 1C. The exact length of the individual workshops will depend on the length of the discussions required, the information that the participants do or do not have available, and the need for translation of discussions for the facilitators.

It is possible to expedite the policy development process using a two-workshop approach with longer workshops. An alternative agenda for these workshops is presented in Annex 1D. The first workshop is then expanded to five days, which may in some contexts not be possible as the NLWG members are unavailable for routine work for such an extended period of time.

The workshops should be organized in a large, quiet room suitable for group discussions as well as plenary work. The room should preferably not be attached to the working place of one or more of the NLWG members to prevent distraction.

A computer, beamer/projector and flip-charts with marker pens in four colours are required, as are small items such as stationery, pens, A4 paper, sticky tape and medium and large-sized Post-it notes in various colours.

The report of the workshop should give extensive summaries of all exercises and should be made available for the workshop participants within two weeks of the end of the workshop, in order not to lose momentum and to inform the activities in between workshops.

Phase 1: Preparatory phase – Activities before Workshop 1

As soon as the NLWG has been established, it should meet for the first time to discuss the Terms of Reference, appoint a Chair and Executive Secretary. If the group is large, from the group, appoint 15-20 people with different backgrounds that will be directly involved in the workshops to develop the national laboratory policy.

Before the start of the first workshop, basic information to inform the participants should be collected. This includes:

- A laboratory system assessment should be performed using the system questionnaire of the WHO Laboratory Assessment Tool (LAT)[2], which is available in English, French, Russian and Spanish and can be modified to accommodate other languages. This can be done by an external consultant.
- The results of the laboratory system assessment should be analysed and the results should be made available to the NLWG before the first workshop.
- Documents relevant to the laboratory sector should be identified and made available to the NLWG. This is also part of the LAT system assessment. These may include:
    - National health policies.
    - Other policies relevant to the laboratory sector.
    - Laws relevant to the laboratory sector or to the development of policies in general.
    - Relevant ministerial or presidential orders and decrees.
    - Strategic plans.
    - Statistics on the laboratory system(s), including numbers, functions, types and locations of laboratories, staffing, usage indicators, finances.

The organizers of the meetings should arrange all meetings taking into account the points mentioned under Practical organization of the workshops.

A series of PPTs is given as attachments to this document. Whenever specific information needs to be included this is *[indicated in square brackets in italics].* Facilitators customize the PowerPoint presentations (PPTs) to reflect the specific situation.

[2] http://www.who.int/ihr/publications/laboratory_tool/en/

Phase 2: Policy development process

Workshop 1: National laboratory policy development

This workshop can be carried out in two full days. However, it is divided over three days, because the first day will need to end with the Vision 2025. An example agenda is given in Annex 1A.

Terms of reference

By the end of the workshop the participants will have:

- developed a Vision 2025 for the laboratory sector in the country;
- performed a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis for the laboratory sector in the country;
- performed a Political, Economic, Social and Technological (PEST) analysis for the laboratory sector in the country;
- identified major topics and themes for the national laboratory policy;
- conducted a detailed SWOT analysis for at least one of the policy topics;
- agreed on the way forward and the activities to be undertaken before the second workshop.

Description of activities

Day 1

Activity 1 – Workshop opening

The workshop starts with short opening speeches by representatives of the government, WHO and the organizer of the meeting (if other than MoH or WHO), describing the role of the NLWG, the importance of the policy that will be developed and the support the NLWG can expect.

A round of introductions of all participants and facilitators then takes place. Often not all participants know each other as they are from different sectors of the laboratory system.

Activity 2 – Presentation of the current situation

During this activity a representative of the NLWG and/or a representative of the team that performed the LAT system assessment (see Activities before Workshop 1) present the main outcomes and conclusions of the LAT system assessment analysis.

There will also be some room for discussion to verify whether the outcomes of the assessment coincide with the views and experiences of the participants, but most of the discussions can be held as part of activities 5-8.

Activity 3 – Discussion of workshop objectives

During this activity one of the facilitators presents the purpose of the meeting, describes what a policy is and what it is used for and gives an overview of the program of the workshop. An example of such a presentation is given in PPT 03 "General Introduction".

Activity 4 – Introductory session

The slides for this activity are given in PPT 04 "Expectations-methodology-commitment".

This activity consists of 3 exercises:

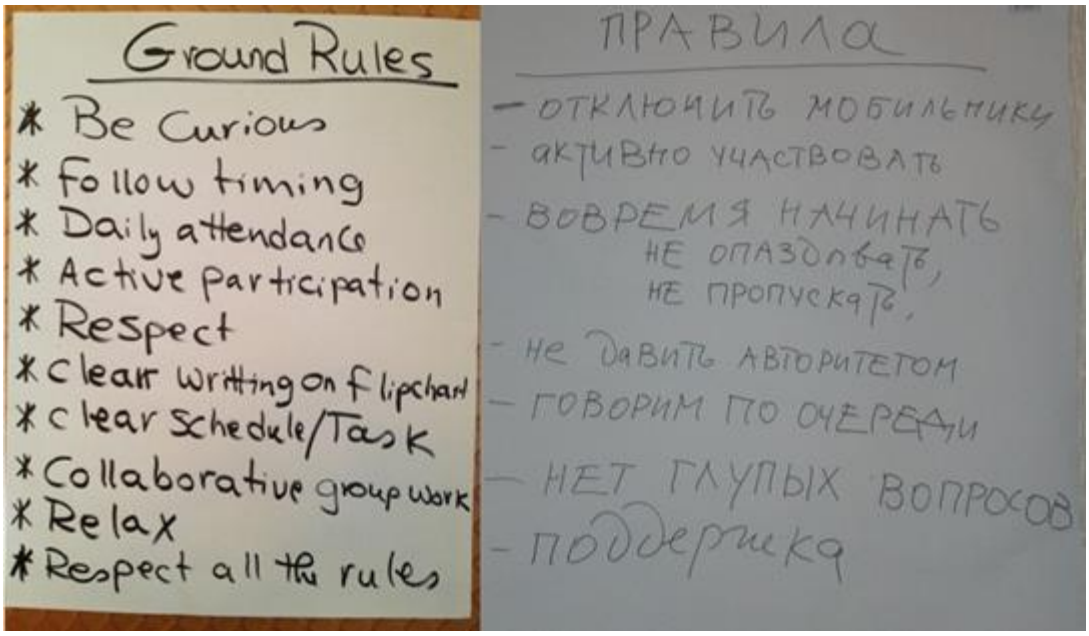
Exercise 1: (slide 2)

This exercise is meant to give the facilitators an idea of the expectations (questions 1 and 2) and worries (question 3) of the participants.

Ask the participants to write down the answer to the three questions and make an overview on a flip-chart page, which can be taped on the wall for reference at the end of the workshop if necessary.

From slide 2 it is easy to go to slide 3: ask each participant to write down one ground rule for attending a successful workshop. Write these on a flip-chart page and tape it to the wall for reference. Some examples are shown in Fig. 4.

Fig. 4. Examples of ground rules



- Switch off mobile phones.
- Actively participate.
- Start on time, do not be late, do not skip sessions.
- No one should use their (higher) position as an argument.
- Speak one at a time.
- There is no such thing as a stupid question (or topic).
- Support each other.

Exercise 2: slide 4

This exercise shows the participants the power of group work and also gives them the first exposure to group work, which forms the cornerstone of the workshop activities.

- Explain that a paperclip was originally intended for holding sheets of paper together. But people use it for many other things as well (do not give examples).
- Ask the participants to write on a Post-it as many uses of a paperclip as they can think of. Give them two minutes, with no conferring.
- Make an inventory on a flip-chart page of how many different uses people can think of. Calculate the average.

- Now ask the participants to work in pairs and see how many different uses they had between the two of them.
- Make an inventory of scores, calculate the average for the pair-work, and put this next to the average for the individual work.
- Now ask the participants to work in groups of about 6 people and see how many uses they had between all of them.
- Make an inventory of scores, calculate the average for the group-work and put this next to the averages for the individual and pair work.
- If time permits one can also make a plenary inventory. The general message is that two know more than one and groups know more than two etc., so that we need to use all the (different) experiences we have available in the group.

Exercise 3: slide 5

First ask participants individually to think about their experience with the laboratory sector from a personal perspective. Ask whether some participants are willing to share their experience with the group. This part of the exercise shows that laboratory services can make a difference at the individual level.

Exercise 3: slide 6

Now ask the participants what they are committed to and what the motivation behind that commitment is, i.e. what are they committed to and why. A good way to ask this is to ask how they want to be remembered: what should be emphasized in their retirement speech (or on their gravestone if they do not want to retire)?

Make an inventory on a flip-chart page and tape this to the wall.

Activity 5 – Planning for the future

During the previous activity the participants expressed their personal commitments and motivations. Now ask the participants for the commitments and requirements of the laboratory system as a whole.

Exercise 4

Give them five Post-its each and tell them a story using a text similar to the following:

"I ask you to dream now. Dream about the future of the laboratory services in your country. Suppose you travel out of the country now and return in [2025] with no contact in the meantime.

You come back in [2025]. In the meantime the laboratory sector has improved substantially. Please write down on the Post-its some characteristics of this improved laboratory system. Use one characteristic of 1-5 words per Post-it".

After about five minutes ask the participants to present the characteristics they came up with and try to categorize them into broader categories as you go.

This is the last exercise of the day. The facilitators take all the statements and build them into one Vision 2025 statement to be presented at the start of day 2. This can be done during the evening as it requires some time and reflection.

Some examples of Vision 2025 statements are:

"We shall have politically supported quality laboratory services that are rational, modern, comprehensive, accessible to all, trustworthy, competitive and in line with international standards giving timely results, that are reliable, compliant with standards, efficient, and cost effective, using modern good equipment and supplies, carried out by well-qualified staff, who are well–trained and competent."

AND

"By 2025 the country shall have affordable, well-governed and managed quality laboratory services with strong leadership from the government and a rationally-designed laboratory network structure with certified laboratories that are well-funded with financial independency from donors. A comprehensive quality management system ensures that laboratories conform to standards and comply with biosafety and –security regulations. Valid results are produced by a specialized, well-trained, highly qualified, well-paid and stable workforce that effectively performs procedures using good equipment and making use of a centralized procurement unit."

Day 2

Activity 6 – Vision 2025

The second day starts with a short overview of the main outcomes of the first day:

- Group work is useful.
- The individual commitments and motivations.

After this the Vision 2025 is presented and opened for discussion and improvement. At the end ask the participants to discuss and refine the Vision 2025 further during the activities in between Workshops 1 and 2.

Activity 7 – Stakeholder analysis

The slides for this activity are given in PPT 07 "Stakeholder analysis".

Exercise 5: slide 3

- Ask each participant to think about the first two questions on the slide. Invite a few participants to share their experiences.
- Ask the participants to discuss in groups questions 3 and 4. Invite a few groups to share their answers.

Exercise 6: slides 4-6

- Use a flip-chart page and follow the procedure described on slide 4.
- After this plenary discussion there should be an extensive list of stakeholders that may include patients, doctors, colleagues, other laboratories, government, training institutes, professional associations, regulatory bodies, companies, donors, insurance companies, media, customer right organizations etc.
- Ask the participants to answer the questions on slide 5. Ask the participants to identify which stakeholders are important for the national laboratory policy and whether they are included in the NLWG. If this is not the case they may need to be invited for the next meeting(s).
- Now ask the groups to complete the table on slide 6 for 5 important stakeholders.

Activity 8 – Situational analysis

The slides for this activity are given in PPT 08 "Situational analysis".

This activity starts with an overview of where we are in the process (slides 2 and 3):

Green indicates what has been done, orange what has partially been done, red what is going to be done now, and black what remains for the future.

Exercise 7: slides 4 and 5

Give the participants a stack of Post-its (if possible light green) and follow the process on slides 4 and 5. This identifies strong points of the system.

Exercise 8: slides 6 and 7

Give the participants a stack of Post-its (if possible pink or light red) and follow the process on slides 4 and 5. This identifies weak points in the system.

At the end the categories are combined into the major topics that are needed for the policy development as is indicated on slide 8. Examples of policy topics from other National Laboratory Policies are given in Annex 3 and in the repository, which is available on request.

Activity 9 – SWOT analysis

The situational analysis that was performed in the previous activity is already the start of a more formal SWOT analysis. During Activity 9, the participants will perform a formal SWOT analysis for the whole laboratory system of their country.

The slides for this activity are given in PPT 09 "SWOT analysis".

Slides 1-4 explain what a SWOT is and what it is for. The SWOT builds on the situational analysis that was performed in activity 8.

Exercise 9: slides 5 to 7

Put slide 5 on the screen.

- Ask the participants to discuss in small groups what the strong and weak points of the system are. They can use the situational analysis, the outcomes of the LAT assessment and their own knowledge, experience and information. They do not have to go into much detail (that comes later).
- Let each group first present the Strengths of the system. Ensure that they are indeed strengths and not Opportunities. Try to group statements as much as possible.
- Let each group now present the Weaknesses of the system. Ensure that they are indeed Weaknesses and not Threats. Try to group statements as much as possible.

NB. Strengths and weaknesses are factors internal to the laboratory system and opportunities and threats are factors external to the laboratory system.

Put slide 6 on the screen.

- Ask the participants to discuss in small groups what the opportunities and threats are using the PEST approach. They can use the situational analysis, the outcomes of the LAT assessment and their own knowledge, experience and information. They do not have to go into much detail (that comes later).
- Let each group first present the Opportunities for the system. Ensure that they are indeed Opportunities and not Strengths. Try to group as much as possible.
- Let each group now present the Threats to the system. Ensure that they are indeed Threats and not Weaknesses. Try to group as much as possible.

Put slide 7 on the screen.

- Ask the participants to discuss in groups to see whether there are things that need to be added to the Opportunities and Threats.
- After a plenary discussion the first version of the general SWOT for the whole laboratory system is now ready.

Present now slides 8 and 9 to explain why SWOTs are important and how they can be used to make informed decisions.

Activity 10 – Problem analysis

The slides for this activity are given in PPT 10 "Problem analysis".

Slides 1-3 explain root cause analysis: the perceived problem is often only an effect of an underlying problem. By identifying the underlying causes of the perceived problem one can work on the root causes instead of on the effects. There may be multiple root causes for the same problem, as one can see when more than one group carries out the root cause analysis.

Exercise 10: slides 4 to 7

The "5 Whys" exercise helps to identify the root causes. Slides 4-6 explain the "5 Whys" methodology, and provide an example. It may be that the root cause is already identified after 3 Whys or it may take 6 Whys. However, 5 Whys is a rule of thumb.

Slide 7 asks the participants to perform a root cause analysis in groups of about three persons. Explain that there is no "right answer". Participants can either use their imagination to make up a reason or use an example from their own experience.

"Pre-analytical examination steps" include sample collection, sample identification, sample registration, sample checking etc.

Let the groups perform the root cause analysis, then ask the groups to play out the root cause analysis: one person asks "Why?" five times, the other persons answer until they come to a root cause, then rotate within the group. It may be that different root causes are identified, even when one group performs the root cause analysis.

After the group work, go group by group and ask five times why to each group and write down the root cause(s) that were identified. This will also show that different groups may come to different root causes.

At the end, stress the importance to identify root causes instead of effects.

Day 3

Activity 11 – Identification of topics for the national laboratory policy

The third day starts with a short overview of the main outcomes of the second day by the facilitator:

- The stakeholders of the laboratory system.
- The situational analysis and SWOT analysis.
- Root cause analysis.
- From problem to challenge.

Now revisit the general SWOT of the whole laboratory system (Activity 9) with the participants. Are all strengths, weaknesses, opportunities and threats still valid or do you need to do a root cause analysis for some of them? Explain that if you do a root cause analysis, you may find that some perceived weaknesses have the same root cause. They can then be combined. You may also find that some weaknesses have multiple root causes, in which case they need to be split up.

At the end of this session, revisit the major topics that were identified during the SWOT analysis. Study the topics with the whole group and see whether the group still agrees with it or wants to change, regroup, revise, add or combine some topics. For examples of major topics identified in country policies, see Annex 3.

Activity 12 – SWOT analysis Human Resources

A highly qualified, motivated and well-functioning staff is crucial for quality laboratory services. Laboratories are part of the health system and as such are also suffering the consequences of the Human Resources for Health crisis: shortage of staff, retention problems, education problems and low remuneration are all challenges that are widely encountered all over the world. Human Resources is thus a topic that always shows up in National Laboratory Policies. During this activity the group will perform an in depth SWOT analysis for the Human Resources topic only.

The slides for this activity are given in PPT 12 "SWOT analysis HR". These are the same slides that were used during the original SWOT analysis, but the explanatory slides have been removed.

Ask the participant to first work individually, then in groups and conclude with a plenary session. Use Post-its. Start with the strengths, then the weaknesses and then the opportunities and threats. Ask them to also use the root cause analysis technique.

The facilitator should try to group as much as possible during the plenary discussion and use the root cause technique when s/he thinks that the group has not come to the root cause of the problem.

At the end of the SWOT analysis for human resources, explain that in between workshops the group will have to perform the SWOT analyses for the other policy topics that were identified.

Activity 13 – Planning the way forward

At the end of the workshop the facilitator explains the next steps. The slides for this activity are given in PPT 13 "The way forward". Some of the slides still need *[additional information]* or may need to be modified to reflect the local situation. If the NLWG members perform the SWOT analyses they may find that they still want to add, remove or combine topics or revise the Vision 2025. This is fine.

Also stress the importance of including all elements of the Vision 2025, the situational analysis and the general SWOT analysis into the detailed SWOT analyses.

Most important is to stress that the SWOT analyses for all topics have to be performed before a certain date to give the facilitators the opportunity to prepare for the second workshop.

Also, during Activity 7 "Stakeholder analysis" important stakeholders were identified that may need to be added to the NLWG. If this is the case, additional permission from the government may be required for this. This should be the task of the chairperson of the NLWG.

Activity 14 – Evaluation and closure

Refer to the flip-chart page of Activity 4 "Introductory session" to check whether the expectations of the group members are fulfilled and what they are expecting from the future. Ask which sessions they found more, or less, interesting or useful. If necessary, one can also perform an anonymous written evaluation.

Thank the participants and let the chairperson of the NLWG perform the formal closure of the workshop.

Activities in between Workshop 1 and Workshop 2

The report of the first workshop should be written by the facilitators or rapporteur immediately after the workshop and sent to all members of the NLWG as soon as possible as they may need it for reference. A template for the report is provided in Annex 2.

The activities should be organized and time frame monitored by the Executive Secretary and Chair of the NLWG. A representative from the WHO country office can monitor the process and can provide backstopping for any questions that may arise.

In between workshops the members of the NLWG should perform the in-depth SWOT analyses for all NLP topics. They may add, remove or combine topics or revise the Vision 2025.

If new members are invited to become members of the NLWG, they need to be informed and briefed in detail before the second workshop: the chairperson should take them through the process followed and outcomes generated during the first workshop in order to prevent the repetition of the process for the new members at the beginning of the second workshop.

At least one week before the start of Workshop 2 the outcomes of the in-depth SWOT analyses should be sent to the facilitators of the second workshop, which should preferably be the same facilitators as during the first workshop.

The facilitators should study the outcomes of the SWOT analyses and formulate critical remarks regarding grouping, topics, completeness, root causes, missing issues etc. It is also important to check whether factors mentioned are internal (strengths, weaknesses) or external (opportunities, threats). Also check that all elements of the Vision 2025, the situational analysis and the general SWOT analysis are reflected in the detailed SWOT analyses.

Workshop 2: National laboratory policy development

Terms of reference

By the end of the second workshop the participants will have:

- reviewed and further improved the detailed SWOT analyses for all policy topics;
- made a start with the verification of the SWOT statements for a number of the policy topics;
- agreed on the way forward and the activities to be undertaken before the third workshop.

Description of activities

An example agenda is given in Annex 1B.

Day 1

Activity 15 – Workshop opening

The workshop starts with short opening speeches by representatives of the government, WHO and the organizer of the meeting (if other than MoH or WHO).

Another round of introductions of all participants and facilitators may be necessary if new participants have been added to the NLWG.

Activity 16 – Discussion of the workshop objectives

First, the Chair of the NLWG has the opportunity to present the activities that have been performed by the members of the NLWG in between the two workshops.

Next, the facilitator gives an overview of what has been done in the first workshop and what will be done in this workshop. The slides for this activity are given in PPT 16 "Overview of activities and workshop objectives".

Restate the Vision 2025 (slide 5) and ask the participants whether they want to make any changes to the Vision 2025.

Restate the policy topics (slide 6) and ask the participants whether they want to make any changes to the policy topics.

It is important to ask participants to share their experience with the work they had to perform in between workshops (slide 8). Was it difficult? What was difficult? What was clear? What was not clear? If anything was not clear, explain them again.

Activity 17 – Review of SWOTs

Between the morning and the afternoon breaks, participants of the NLWG will present the outcomes of the SWOT analyses for discussion. Facilitators will use their preparation document (See Activities in between Workshop 1 and Workshop 2 above) to discuss the outcomes with the participants and together further refine the SWOT analyses.

As the discussion on the SWOT statements often leads to lengthy debates, it is important to allow sufficient time for all discussions. It is also important to start with topics which are closest to the daily work of the participants and with which they thus feel most comfortable, for example equipment, procurement, facilities, etc. Only after these have been covered move to the more complicated topics like legal framework, network organization etc.

Day 2

Activity 18 – Identification of key elements for all SWOTs

The slides for this activity are given in PPT 18 "Key elements".

The purpose of this activity is to determine whether the statements within the different SWOT analyses should be grouped: these subgroups per topic are called "key elements". They are subtopics within the major policy topics and are homogeneously addressing one major area within the policy topic under which several SWOT statements can be grouped.

Example:

Typical key elements for Human Resources are: training, career structure, retention and remuneration.

It is important to group the issues into key elements to provide structure, but too many key elements will make the situation unworkable as well. Consequently, two to five key elements per topic should be identified. In the case of relatively small (but important) or homogeneous policy topics it may be unnecessary to divide the topic up into key elements.

Exercise 12: slide 4

Let the participants work in four groups on the SWOT analyses to identify key elements. Give each group half of the topics, but make sure that no group has exactly the same set. This is the

final activity of the day and participants can continue until they have identified all the key elements.

During the evening the facilitators can also independently identify the key elements per topic as a background for the discussions on the next day.

NOTE:

In some of the development processes it was found that the introduction of key elements (or subtopics) caused confusion among the participants. If one finds this is the case, it is possible to leave out this further subdivision of the policy topics.

Day 3

Activity 18 – Identification of key elements for all SWOTs (continued)

If necessary the morning can start with continued group discussions. At the end of the discussions let the groups present which key elements they have identified, per topic. Compare results (also with the notes from the facilitators) and agree in a plenary discussion on the key elements per topic and group the SWOT statements per key element.

Check together whether there are any key elements missing.

Activity 19 – Rumour/opinion/fact

After the SWOT statements have been grouped into key elements per topic, it is time to determine which statements are based on facts, which are based on opinions and which on rumours. The slides for this activity are given in PPT 19 "Verification of statements".

Start with explaining the differences between rumours (R), opinions (O) and facts (F) (slides 2-4), and explain that you will conduct a so-called "ROF-exercise".

Exercise 13 – slide 5

Ask every participant to stand up. Explain to them that you are going to read out a story and that you want them to react according to the pictures if they hear a rumour, opinion of fact, i.e. hand at their mouth if they hear a rumour, hands on their head if they hear an opinion and thumbs up when they hear a fact.

Now read out the text given in the file "Exercise 13 ENG Rumour-Opinion-Fact". There are two versions of the text: the first version is for countries outside the tropics, the second one for

tropical countries. The facilitator should always read the text before the exercise and make changes to reflect the local situation as much as possible.

After each statement, check with the participants and explain why it is a rumour, opinion or fact if not everyone makes the same motion. Sometimes there is "opinion or fact" in which case it is important to explain that this depends on the absence or presence of supporting evidence.

Activity 20 – Review whether SWOT analysis/key element statements are evidence based

Divide the participants into 3-4 groups.

- Let each group work on one of the policy topics and decide per key element statement whether it is a rumour, an opinion or a fact.
- In case of a fact: ask them to write down the supporting evidence. In some cases they may need to identify additional evidence after the meeting. Explain that this is an outcome as well: facts can be divided into fact *with* supporting evidence and facts *without* supporting evidence. Ask them to collect the evidence in between workshops.
- In case of an opinion: ask them to write down whether this is a unanimous, majority or minority opinion of the NLWG.
- Now let each group present and discuss their categorization in a plenary session.
- The facilitators can also ask for additional supporting facts or ask the NLWG to perform certain reviews. For example: if the statement is that salaries in the public sector are too low, ask the NLWG to benchmark the salaries against the salaries paid in the private sector.

This review exercise can be repeated for a second set of topics if time permits.

Activity 21 – Planning the way forward

At the end of the workshop the facilitator explains the next steps. The slides for this activity are given in PPT 21 "The way forward 2". Some of the slides still need *[additional information]* or may need to be modified to reflect the local situation. If the NLWG members perform the ROF analyses they may find that they still want to add, remove or combine statements or revise the topics or Vision 2025. This is fine.

It is most important to stress that the ROF analyses for all topics have to be performed before a certain date to give the facilitators the opportunity to prepare for the third workshop.

Discuss again whether all important stakeholders were identified or who may need to be added to the NLWG. If this is the case, additional permission from the government may be required for this.

Activity 22 – Evaluation and closure

Refer to the flip-chart of Activity 4 "Introductory session" of workshop 1 to check whether the expectations of the group members are fulfilled and what they are expecting from the future. Ask which sessions they found more, or less, interesting or useful. If necessary, one can also perform an anonymous written evaluation.

Thank the participants and let the chairperson of the NLWG perform the formal closure of the workshop.

Activities in between Workshop 2 and Workshop 3

The report of the second workshop should be written by the facilitators or rapporteur immediately after the workshop and sent to all members of the NLWG as soon as possible as they may need it for reference. A template for the report is provided in Annex 2.

The activities should be organized and time frame monitored by the Executive Secretary and Chair of the NLWG. A representative from the WHO country office can monitor the process from a distance and can provide support for any questions that may arise.

In between workshops the members of the NLWG should try to verify all SWOT statements for all national laboratory policy topics. They should also decide which statements they want to keep (all that are fact and some that are (expert) opinions) and which they want to remove (rumours and some of the opinions). If they want they can still add, remove or combine topics, key elements or statements or revise the Vision 2025.

If new members are invited for the NLWG these need to be informed and briefed in detail before the third workshop: the chairperson should take them through the process followed and outcomes generated during the first and second workshops to avoid having to repeat the process for the new members at the beginning of the third workshop.

At least one week before the start of Workshop 3 the main outcomes and revisions should be sent to the facilitators of the third workshop.

The facilitators should study the outcomes of the SWOT statements verification exercise and formulate critical remarks regarding grouping, topics, key elements, completeness, root causes, missing issues etc. If time permits, they can still send this to the NLWG and ask the NLWG to collect additional information.

The facilitators should also decide which topics they want to include in the third workshop for policy statement development. Choose two or three topics from the internal laboratory services (for example topics similar to "infrastructure", "procurement" and "human resources") and one or two from a higher level (for example topics similar to "legal framework" and "organization of the networks").

Workshop 3: National laboratory policy development

Terms of reference

By the end of the third workshop, participants will have:

- revisited the SWOT analyses of the topics of the NLP presented in the second workshop;
- finalized and critically evaluated the verification results;
- made a start with defining policy statements for the key components;
- agreed on the way forward.

Description of activities

An example of an agenda is given in Annex 1C.

As the process is progressing, it becomes more and more difficult to give exact instructions to the facilitators as each national laboratory policy development process will have its own dynamics and intermediate outcomes along the way. A general approach to the activities of the workshop is presented here, but the facilitators will have to decide on the exact content and timing.

Day 1

Activity 23 – Welcome and introductions

The workshop starts with short opening speeches by representatives of the government, WHO and the organizer of the meeting (if other than MoH or WHO).

Another round of introductions of all participants and facilitators may be necessary if new participants have been added to the NLWG.

Activity 24 – Discussion of the workshop objectives

The facilitator gives an overview of what has been done in the first and second workshop and what will be done in this workshop. The slides for this activity are given in PPT 24 "Overview of activities and workshop objectives 2".

Restate the Vision 2025 (slide 5) and ask the participants whether they want to make any changes to the Vision 2025.

Restate the policy topics and key elements (slide 6, divide over multiple slides if necessary) and ask the participants whether they want to make any changes to the policy topics.

It is important to ask participants for their experience with the work they had to perform in between workshops (one but last slide). Was it difficult? What was difficult? What was clear? What was not clear? If anything was not clear, explain it again.

Activity 25 – Verification of statements

The Chair of the NLWG presents the outcome of the verification of statements activities that has been performed by the members of the NLWG in between the two workshops. The facilitators ask any critical questions that have come to their attention when analysing the outcomes and which have been prepared before the workshop.

The outcome is a further, refined SWOT analysis with verified statements for every topic and key element.

Activity 26 – Policy statement formulation

The facilitator explains the steps in formulating a policy statement. The slides for this activity are given in PPT 26 "Policy statement formulation".

The first step is to explain the process so far. This is indicated on slide 2. Next, describe the steps in the policy statement process (slide 3) and how the SWOT analysis can be used (slide 4). Slide 5 visualizes the whole process and shows the difference between the outcome (the future, ideal situation based on the Vision and also on elements of the SWOT analysis; the city on the horizon) and the policy statements (the steps that need to be undertaken to reach that future, ideal situation; the road to the city on the horizon).

Formulate first a desired outcome: for small policy topics this can be one outcome for the whole topic, for larger topics with multiple key elements, this will normally speaking be one outcome per key element. Try to combine the various elements of the outcome into one statement; these can be split up later in the individual policy statements. For example "an affordable, sustainable and easily accessible laboratory network" is one outcome.

NOTE:

Some countries may decide to include the outcomes in the policy document, as they provide a clear picture of the way forward. In the repository, this is for example the case for countries A-E.

Now the policy statements should be formulated and the rationale for the proposed statement can be formulated in the "to ensure" part of the statement. Not all statements will have a "to ensure statement" attached to it as sometimes it is very clear what a statement wants to ensure. Slides 6 and 7 give examples of policy statements.

A compilation of policy statements is available in the repository, available on request. Annex 4 gives a non-exhaustive list of example policy statements for quick reference and inspiration. These are not always formulated in the "There shall be … to ensure …" structure but they can serve as sources of information, inspiration and reference for the participants and the facilitators on topics, key elements and statements that were considered important in other countries.

EXAMPLE POLICY STATEMENT:
There shall be regularly reviewed and updated standards and regulations for importation, registration, use, storage and disposal of laboratory equipment and consumables to ensure high quality laboratory services.

Exercise 14 – slide 8

Ask the participants to divide into groups. Start with the first topic; choose a topic that is very familiar to the participants, for example the topic that includes equipment. Ask them to formulate the outcome for this topic or for the key elements. Discuss in plenary and summarize.

Now ask the participants to formulate one to four policy statements starting with "There shall be…" for the topic/key element based on the outcome they have formulated. Also ask them to define what this policy statement ensures, so "There shall be …. to ensure …".

In the plenary discussion the groups present their policy statements. Often policy statements from different groups can be combined. One facilitator asks questions and is actively involved in the discussion, the other facilitator serves as observer and at the end of the discussion (which is often very lively) summarizes what has been said into a draft policy statement for further refining by the participants. The time needed to formulate policy statements per topic or key element will vary, depending on the degree of agreement between participants, the experience and background of the participants and the importance of the topic/key element.

Sometimes discussions also cover other topics or key elements. If this is the case, formulate the policy statement and add it to the relevant topic/key element.

Day 1 and day 2

After the first policy topic has been discussed in this way, proceed for the rest of the day and up until the afternoon tea break of the second day with other policy topics. Choose topics of different abstraction levels and/or discuss with the participants which topics they want to include during the workshop.

Day 2

Activity 27 – Summary of the previous day

At the beginning of Day 2 revisit the policy statements that were formulated during the first day and discuss whether any changes/refinements are needed.

Activity 28 – Development of policy statements

Continue with the formulation of policy statements as described above.

Activity 29 – Planning the way forward

At the end of the workshop the facilitator explains the next steps. The slides for this activity are given in PPT 29 "The way forward 3". Some of the slides still need *[additional information]* or may need to be modified to reflect the local situation.

It is most important to stress that a wide consensus for the policy statements is essential prior to endorsement. Therefore the NLWG members should first seek the informal approval of the government and go through a round of consultations with all important stakeholders in the country. This can be in the form of a formal workshop or conference or as a series of consultation meetings.

Also stress that the document remains a draft until the relevant ministries/government have officially endorsed the policy: the NLWG role is to serves as the advisor to the government for the formulation of the national laboratory policy.

If the country has a format for policy documents, the Executive Secretary and Chairperson of the NLWG should reformat the national laboratory policy documentation into that format. A formal presentation of the draft national laboratory policy to a high official or a minister, preferably in the presence of the media, will further heighten the visibility of the document and the laboratory services in general.

Activity 30 – Evaluation and closure

Refer to the flip-chart of Activity 4 "Introductory session" of workshop 1 to check whether the expectations of the group members are fulfilled and what their expectations are. Ask which sessions they found more, or less, interesting or useful. If necessary, one can also perform an anonymous written evaluation.

Thank the participants and let the chairperson of the NLWG perform the formal closure of the workshop.

Workshop report

The report of the third workshop should be written by the facilitators or rapporteur immediately after the workshop and sent to all members of the NLWG as soon as possible as they may need it for reference. An example for the report is provided in Annex 2.

Phase 3: Policy dialogue and final draft preparation

Consultation process

After the third workshop the NLWG will consult representatives of all stakeholders associated with the national laboratory policy (see also Activity 29).

- The Executive Secretary of the NLWG will consolidate the draft national laboratory policy into a draft "Proposal of the Laboratory Working Group for a national laboratory policy for *[country]*".
- The proposal will be submitted to the MoH for a first informal consultation to determine whether this is roughly in agreement with the government's expectations.
- Upon agreement, the proposal will be submitted to a wider range of stakeholders, also including stakeholders from other ministries, for consultation and reviewing to ensure that all elements are captured and that the policy statements are supported by as wide an audience as possible.
- Based on the comments from the reviewers a final document will be prepared. When the comments are relatively minor, the final document can be prepared by the Executive Secretary; if the comments are more substantial it may be necessary to organize another meeting of the NLWG.
- Submission of the final proposal to the government.

Structure and content of the final document

It is important to use the required format for a National Policy if there is such a fixed format in the country. The Executive Secretary and Chairperson of the NLWG should reformat the national laboratory policy documentation into that format.

The Executive Secretary will consolidate all outcomes into a "Proposal of the National Laboratory Working Group for a national laboratory policy for *[country]",* which –if the format permits- will include the following elements:

- Aim of the document.
- Process followed.
- Main outcomes of the Laboratory System Assessment.
- Vision 2025.
- SWOT analyses for the system as a whole and for the individual topics.
- Policy statements.

Include as annexes the list of documents (evidence) for the consultation process. The final endorsed NLP will most likely contain these document annexes.

This document will be submitted by the Chair of the NLWG to the government for discussion and endorsement through the appropriate channels. WHO encourages countries to publish their national laboratory policies, to inform all stakeholders and to be an example for other countries.

Annex 1: Workshop agendas

All agenda times are tentative: this will depend on the length of the discussions, the start time of the workshops and the leftover activities from previous workshops. The number in the first column is the number of the activity; the files of the PowerPoint presentations also include the activity number.

Agenda for national laboratory policy development

1A: Workshop 1 agenda

Day 1 (13.00 – 17.00)		Objectives	Presenters and materials
1	Workshop opening – welcome and introductions	• Welcome the participants	MoH, WHO
2	Presentation of the current situation	• Describe the current laboratory system	Representative of NLWG and/or of team that performed the LAT system assessment
3	Discussion of workshop objectives	• Presentation on the purpose/process and focus of a national laboratory policy	PPT 03 – General introduction
4	Introductory session	• Introduction of participants • Explore expectations and discuss agenda • Workshop norms • Identify commitment for good laboratory services	PPT 04 – Expectations-methodology-commitment
Break			
5	Planning for the future	• Describe the characteristics of the laboratory system as it should ideally be by 2025	*[Facilitator's name]*

Day 2 (9.00 – 17.00)			
6	Vision 2025	• Summarize the previous day • Present and discuss the vision 2025	*[Facilitator's name]*
7	Stakeholder analysis	• Identify stakeholders, their concerns and interests	PPT 07 – Stakeholder analysis
Break			
8	Situational analysis	• Identify and categorize major weaknesses encountered in daily practice	PPT 08 – Situational analysis
9	SWOT analysis	• Perform SWOT analysis • Scan external environment using PEST tool	PPT 09 – SWOT analysis
Lunch			
	SWOT analysis (continued)		PPT 09 – SWOT analysis
Break			
10	Analysis of problems	• Analyse problems using root cause analysis	PPT 10 – Problem analysis

Day 3 (9.00 – 14.00)			
11	Identification of topics for the national laboratory policy	• Summarize major topics for national laboratory policy	*[Facilitator's name]*
12	SWOT analysis	• Perform SWOT analysis for the human resource topic	PPT 12 – SWOT analysis
Break			
	SWOT analysis	• Perform SWOT analysis for the human resource topic (continued)	
Lunch			
13	Planning the way forward	• Agree upon next steps • Identify how activities for next step will be implemented	PPT 13 – The way forward
14	Evaluation and Closure		

1B: Workshop 2 agenda

Day 1 (13:00 – 17:00)		Objectives	Presenters and methods
15	Workshop opening – welcome and introductions	• Welcome the participants	MoH and WHO
16	Discussion of workshop objectives	• Describe the activities performed in between the two workshops • Provide overview of where we are in the process of writing the policy, recap the first workshop and describe the purpose of this workshop	Chair of the NLWG PPT 16 – Overview of activities and workshop objectives
17	Review of the SWOTs	• Presentation of the NLWG on the SWOTs performed on each topic	Participants present their work
Break			
	Review of the SWOTs (continued)		

Day 2 (9:00 – 17:00)		Objectives	Presenters and methods
	Review of the SWOTs (continued)		
Break			
	Review of the SWOTs (continued)		
Lunch			
18	Identification of key elements	• Explain the concept of key elements • Identify the key elements for each policy topic and analyse if there are missing issues	PPT 18 – Key elements Group work
Break			
	Identification of key elements (continued)		Group work

Day 3 (9:00 – 16:00)			
	Identification of key elements (continued)		Plenary session
19	Rumour/opinion/fact	• Understand the difference between rumours, opinions and facts (ROF)	PPT 19 – Verification of statements Exercise 13: ROF
Break			
20	Review whether key element/ SWOT analysis statements are evidence based	• Review ROF classification for the concerned key element statements • Present and discuss group work • Identify key element statements which need additional information to be evidence based.	Group work and plenary discussions
Lunch			
	Review whether key element/ SWOT analysis statements are evidence based (continued)		Group work and plenary discussions
Break			
21	Planning the way forward	• Agree upon next steps • Identify how activities for next step will be implemented	PPT 21 – The way forward 2
22	Evaluation and closure		

1C: Workshop 3 agenda

Day 1 (9:00 – 17:00)		Objectives	Presenters and methods
23	Workshop opening – welcome and introductions	Welcome the participants	MoH and WHO
24	Discussion of workshop objectives	Provide overview of where we are in the process of writing the policy, recap the first and second workshops and describe the purpose of this workshop	PPT 24 – Overview of activities and workshop objectives
25	Verification of SWOT statements	Discuss the verification exercise performed in between the two workshops	Chair of the NLWG
Break			
26	Presentation on policy statement formulation	• Familiarize the participants with the process of policy statement development	PPT 26 – Developing policy statements
	Development of policy statements	• Development of policy statements per key element for 1 policy topic	Group work and plenary discussion
Lunch			
	Development of policy statements (continued)	• Development of policy statements per key element for 1 policy topic	Group work and plenary discussion
Break			
	Development of policy statements (continued)	• Development of policy statements per key element for 1 policy topic	Group work and plenary discussion

Day 2 (9:00 – 16:00)			
27	Summary of previous day	• Presentation and critical review of the policy statements formulated so far	Presentation and plenary discussion
Break			
28	Development of policy statements (continued)	• Development of policy statements per key element for 1 policy topic	Group work and plenary discussion
Lunch			
	Development of policy statements (continued)	• Development of policy statements per key element for 1 policy topic	Group work and plenary discussion
Break			
29	Planning the way forward	• Agree upon next steps • Identify how activities for next step will be implemented	PPT 29 – Finalizing the national laboratory policy
30	Evaluation and closure		

1D: Alternative agenda for national laboratory policy development – two-workshop approach

For more details on objectives of the various sessions, see Annex 1A – Annex 1C.

Workshop 1 agenda

Day 1		
09:00 – 09:30	Official opening and introduction of participants	
09:30 – 10:15	Presentation on objectives of the workshop and inventory of expectations	PPT03 and PPT04
10:15 – 11:00	Discussion on LAT system assessment outcomes	
11:00 – 11:30	*Coffee break*	
11:30 – 13:00	Discussion on LAT system assessment outcomes (continued)	
13:00 – 14:00	*Lunch break*	
14:00 – 15.30	Development of a Vision 2025	

Day 2		
09:00 – 09:30	Discussion on Vision 2025	
09:30 – 10:30	Stakeholder analysis	PPT07
10:30 – 11:00	Situational analysis	PPT08
11:00 – 11:30	*Coffee break*	
11:30 – 13:00	Situational analysis (continued), SWOT analysis and PEST analysis	PPT09
13:00 – 14:00	*Lunch break*	
14:00 – 15.00	SWOT analysis and PEST analysis (continued)	
15:00 – 15:30	Identification of policy topics	

Day 3		
09:00 – 09:30	Revisit SWOT analysis and policy topics	
09:30 – 10:00	Root cause analysis	PPT10
10:00 – 10:30	Perform detailed SWOT analysis (plenary)	PPT12
10:30 – 11:00	*Coffee break*	
11:00 – 11.30	Perform detailed SWOT analysis (plenary, continued)	
11:30 – 13:00	Perform detailed SWOT analysis (in groups)	
13:00 – 14:00	*Lunch break*	
14:00 – 15.30	Perform detailed SWOT analysis (in groups) (continued)	

Day 4		
09:00 – 10:30	Perform detailed SWOT analysis (in groups) (continued)	
10:30 – 11:00	*Coffee break*	
11:00 – 13:00	Perform detailed SWOT analysis (in groups) (continued)	
13:00 – 14:00	*Lunch break*	
14:00 – 15.30	Identification of key elements	PPT18

Day 5		
09:00 – 09:30	Rumour, opinion, fact	Exercise 13
09:30 – 11:00	Verification of SWOT statements	PPT19
10:30 – 11:00	*Coffee break*	
11:00 – 13:00	Verification of SWOT statements (plenary discussion)	
13:00 – 14:00	*Lunch break*	
14:00 – 15.00	Verification of SWOT statements (continued)	
15:00 – 15:30	The way forward	PPT21

Workshop 2 agenda

Day 1		
09:00 – 09:30	Official opening and introduction of participants	
09:30 – 09:45	Objectives of the workshop (presentation)	PP24
09:45 – 10:45	Discussion on progress of activities (plenary discussion)	
10:45 – 11:15	*Coffee break*	
11:15 – 11:45	Revisit Vision and policy topics (plenary discussion)	
11.45 – 13:00	Finalize verification of statements (plenary discussion)	
13:00 – 14:00	*Lunch break*	
14:00 – 14.15	Introduction to policy statement formulation (presentation)	PPT26
14:15 – 15:30	Policy statement formulation for topic 1 (plenary discussion)	

Day 2		
09:00 – 15.30	Policy statement formulation for topics 2-6 (plenary discussion)	

Day 3		
09:00 – 15.30	Policy statement formulation for topics 7-13 (plenary discussion)	
15.30 – 16:00	The way forward	PPT29
16:00 – 16:30	Formal closure	

Annex 2: Template for report

[Country name] – Planning for National Laboratory Policy development

REPORT OF THE *[number of days]*-DAY *[FIRST/SECOND/THIRD]* WORKSHOP FOR THE NATIONAL LABORATORY WORKING GROUP

Facilitators: ***[names, affiliations and e-mail addresses]*** ***If under APW or consultancy contract with WHO add the fact that you are a "WHO Consultant"***

[Optional: group picture]

[Place, country, dates]

Contents

Abbreviations

[List of abbreviations used in report]

Background

Well-functioning, sustainable laboratory services, operating according to international principles of quality and safety, are an essential part of strong health systems and are crucial to improving public health. The analyses they provide offer a reliable foundation for evidence-based control of disease outbreaks, robust surveillance of adverse events associated with pharmaceutical or vaccine use and earlier treatment of both acute and chronic diseases.

This mission/meeting is conducted as part of [*programme*] in [*Country*].

Concept for a National Laboratory Policy in *[Country]*

National policies and plans are essential for the efficient and high quality delivery of health services in a country. This also applies to laboratory services, whereby a national policy supported by appropriate strategies and operational plans to implement the policy, will ensure best use of scarce resources. The policy and plan should be developed by a national laboratory working group that has high level technical expertise and which is supported by the Ministry of Health, other relevant ministries and international partners.

Process to be followed in *[Country]*

The policy will be developed during a series of three workshops, mentored by experts from *[organization(s)].* In between workshops, the national laboratory working group will conduct additional analyses and develop the document. The type of analyses that will be done include:

1. Analyse available documentation of already existing policies and plans in which the lab sector is involved.
2. Conduct a general SWOT analysis of the laboratory system.
3. Define policy topics.
4. Conduct a SWOT analysis per topic.
5. Define key elements per policy topic.

From the situation/gap analysis, which is a synthesis of 1, 2 and 4 above, the following will be developed:

- Desired outcomes.
- Policy statements.

Suggested outline of a policy document (based on available country examples)

- Policy objective.
- Background.
- Situational analysis.
- Policies and strategies per topic.
- Conclusions.

Once the national laboratory policy has been endorsed, the next stage is to develop a national laboratory plan. The national laboratory strategic plan will have a maximum span of 5 years. The time-frame for implementation of the laboratory strategic plan will be harmonized with the time-frame of other planning mechanisms in the country, especially those of the Ministry of Health (MoH).

Timetable for three workshops to develop a national laboratory policy

[Give tentative time table with dates for all 3 workshops]

Workshop Format

A participatory process will be employed in which the participants will work in small groups, providing the opportunity to discuss, plan and interact with each other. This will answer the questions:

Where are we now? Where are we going? How will we get there?

Annex 1A and Annex 1B provide the program and the list of participants.

Expected results by the end of the *[first/second/third]* workshop

By the end of the workshop, participants will have:

[include Terms of Reference]

Outcomes of workshop *[1/2/3]*

The outcomes of the different exercises are given in Annex 2 and Annex 3.

[Add vision here]

Participants worked individually and in groups, discussing what is currently working well and what is not working well in the laboratory services to identify the main topics for the national policy. A total of *[number]* topics for the National Laboratory Policy were identified:

[Give list of policy topics here]

Action points

[Add list of action points here: who should do what by when]

Annexes

[As required, but at least: agenda, list of participants, major topics/key elements for the national laboratory policy, results of presentations and exercises]

Template for SWOT

STRENGTHS	WEAKNESSES
•	•
OPPORTUNITIES	**THREATS**
•	•

Annex 3: Examples of categories and topics from other national laboratory policies

Note: the lists provided below are not exhaustive. They serve as a resource list for facilitators. For each policy the facilitators will have to determine:

- Have all topics important to the country been covered?
- Is there a certain grouping of topics into categories possible to enhance the structure of the Policy document?
- Are there any themes that appear in multiple topics?

Laboratory policy development guides

The following resources were consulted:

- Office of the Auditor General Manitoba. A guide to policy development. Winnipeg: 2003.
- WHO 2011. Development of national health laboratory policy and plan. New Delhi: WHO Regional Office for South-East Asia, Manila: WHO Regional Office for the Western Pacific.
- Ministry of Health Uganda. Uganda national health laboratory services policy. Kampala: Ministry of Health; 2009.

Apart from these documents, 10 other policies were consulted, which can be found in the repository, available on request.

Table 2. National laboratory policy categories and policy topics

Category	Policy topics
System inputs	Legal and regulatory framework
	Organization and management of services/Laboratory network(s)
	Accessibility of services including community perspective
	Partnerships, coordination and scientific collaboration
Structural inputs	Human resources
	Finance
	Infrastructure
	Procurement, equipment and logistics

Category	Policy topics
Support inputs	Biorisk management and waste management
	Communication and information systems
	Quality management
	Ethics
	Research

National laboratory policy themes

Sometimes recurring themes appear when discussing various topics. This is often already seen at the overall system SWOT analysis (activity 9). It is important at least to identify these themes and ask the participants whether they play a role in certain topics when performing the SWOT analyses for the individual policy topics. If so, they should be taken into consideration for relevant topics. Examples of themes may be:

- The need to modernize.
- The need to enhance the status of laboratory services within the health system.
- Sustainability.
- Quality.
- (Bio)safety.

Sometimes these themes are also identified as separate topics or key elements.

Annex 4: Compilation of example policy statements

Ten national laboratory policies were consulted, which can be shared on request. For easy reference and inspiration, a list of example policy statements and outcomes is given below based on these policies

Legal and regulatory framework

- There shall be a resolution of the Government of the Country on the reform of laboratory services.
- There is an independent intersectoral laboratory coordination committee with representatives from all laboratory sectors that shall coordinate and guide the laboratory reform process.
- There shall be an update of public health laws in the field of laboratory services.
- Laws and regulations shall be fed by trained and competent laboratory experts.
- Laws and regulations shall take into consideration internationally accepted ethical standards.
- There shall be a strictly enforced regulation regarding licensing to practice.
- There shall be a mechanism to regularly review and update all laboratory-related laws, regulations and technical standards.
- The existing legislative framework shall be regularly and systematically evaluated and adapted to ensure full compliance with national and international standards and harmonization with other relevant national policies.
- Normative instruments shall be updated including licensing, control and pricing of laboratory services as needed with the same rules and standards applying to both public and private laboratories.

Organization and management of services/laboratory network(s)

- There shall be a comprehensive review of the current laboratory system and needs assessment taking into account (among other) epidemiological and geographical parameters, workload, the state of the facilities, available staff, the characteristics of the population served, of livestock and the environment.
- There shall be a structured, sustainable, accessible and rational laboratory network designed with roles and responsibilities described for each laboratory level in accordance with national and international standards.
- There shall be dedicated staff responsible for laboratories in the Ministry of Health.

- The design of the laboratory system shall include integration and best use of capacities developed as part of vertical programs (e.g. programs focused on specific diseases or area).
- There shall be a harmonized package of services defined for each laboratory level to ensure complementarity of services and effective use of resources.
- There shall be comprehensive guidelines to ensure appropriate referral and communication between the different laboratory levels.
- Sustainable and efficient sample collection and transportation systems shall be designed to ensure accessibility to laboratory services for the whole population of the country, and serve all other sectors.
- There shall be a national laboratory sample and data management program to ensure efficient sample and data handling.
- There shall be a system in place for regular monitoring and evaluation of the functioning of the referral network.
- There shall be training of laboratory staff on the national laboratory sample management program.
- Testing algorithms for principal diseases shall be defined for primary and confirmation tests.
- New test methods for existing and new or emerging infections and diseases shall be validated by the corresponding reference laboratory before being introduced into the laboratory network.

Accessibility of services including community perspective

- Advocacy and educational work shall be carried out among all stakeholders (at the level of the government, ministries and departments, local authorities, clinical staff and population in general) to explain the role of the laboratory in the protection of human and animal health, namely, the importance of laboratory data for the diagnosis and prevention of diseases and safety of food, environment and consumer goods.
- Activities shall be undertaken to raise the awareness of the general population and the professional community about existing laboratory services.
- A website about the laboratory services in the country shall be created and regularly updated to provide general information for customers and collaborators.
- A system shall be set up to inform specialists about the availability and interpretation of test (results) of the laboratory services.
- In every laboratory network interaction with customers shall be established, also obtaining customers' feedback.

- Accessibility of laboratory services shall be taken into account during centralization of the laboratory network.
- A system shall be created to ensure direct communication with all laboratories, and especially in remote districts, is operational. Direct communication with laboratories is available 24/7 where needed.

Partnerships, coordination and scientific collaboration

- Effective linkages shall be established between the public and private sector with respect to national surveillance, notification and statistics systems.
- There shall be a mechanism for cooperation between national reference laboratories.
- Exchange of expertise, knowledge and capacities among different laboratory sectors shall be encouraged to ensure efficient use of resources and information and data sharing.
- The collaboration with international (accredited) laboratories and laboratory networks shall be promoted.
- The country's specialized laboratories shall be integrated within international laboratory networks with appropriate profiles.
- There shall be advocacy activities developed to mobilize support for the laboratory network from communities, NGOs and the private sector.

Human resources

- There shall be an effective human resources management program to plan for the development of laboratory professionals in coordination with universities, vocational training institutes and other relevant stakeholders.
- There shall be an update of the curricula of academic and vocational education to harmonize them with current needs of laboratories.
- Educational institutions providing undergraduate and postgraduate training shall have appropriately equipped facilities in order to provide a comprehensive theoretical and practical training of laboratory specialists.
- Training of laboratory staff shall be based on training need assessment and according to their job specification.
- The job description of laboratory managers shall give the laboratory manager a clear mandate to take decisions for running the laboratory.
- Laboratory managers shall be laboratory professionals that are technically qualified and have the necessary management skills.

- There shall be regular participation in national and international training programs to ensure experience exchange and to offer opportunities for benchmarking.
- There shall be training opportunities for laboratory staff on planning, M&E, leadership and management.
- There shall be clear and regularly updated qualification standards and job descriptions available for each position in the public laboratory service.
- Remuneration of staff shall be based on the level and position of the staff and shall take into account the health risks of the work to the staff to ensure employee satisfaction.
- There shall be procedures developed to account for attrition while having new intakes to ensure the availability of qualified staff.
- There shall be a non-financial motivation package developed to ensure staff commitment and motivation.
- There shall be a clear and transparently structured career perspective based on key qualifications, with corresponding remuneration packages.

Finance

- There shall be dedicated adequate budget lines based on need assessments made available on a regular basis for laboratory services at all levels.
- The laboratory budget shall cover laboratory running, management and development costs.
- A transparent and efficient system shall be in place to ensure programmatic and financial accountability of the laboratory service providers.
- Essential laboratory services shall be included in the list of the free of charge services funded by the government.
- The pricing of paid services by public laboratories shall be based on actual costs that are regularly updated.
- There shall be a financial contribution from the national health insurance fund to support laboratory services to ensure sustainability of services provided for the health insured population.
- The costs and ensure intersectoral cooperation in financing laboratory services in emergencies shall be calculated, including public health events of international concern according to IHR.
- There shall be a coordination mechanism between the government and donors to ensure efficient and effective use of financial resources.
- Financial support from (inter)national donors shall be in line with the national laboratory policy and its implementation plans.

Infrastructure

- National minimum standards and guidelines for laboratory construction and design according to function and level requirements shall be developed.
- All laboratories shall be provided with uninterrupted supply of water and electricity, ventilation, sanitation, heating, telecommunication and internet.
- Laboratory facilities shall be designed in a standardized manner for different levels of laboratory system/network and in accordance with national and international standards and suitable for the services that are being provided.
- There shall be safety guidelines developed to ensure compatibility of laboratory building with safety levels requirements.
- A mechanism shall be in place to ensure compliance of laboratories to these national standards and guidelines.
- A mechanism and financial plan shall be in place for professional preventive and corrective maintenance of laboratory premises.

Procurement, equipment and logistics

- There shall be regularly reviewed and updated standards and regulations for importation, registration, use, storage and disposal of laboratory equipment and consumables to ensure high quality laboratory services.
- There shall be purchasing guidelines to ensure that equipment and supplies shall only be purchased from qualified and certified companies and equipment contracts shall contain maintenance and training.
- Laboratory staff shall be adequately trained for proper operation and basic maintenance of equipment.
- There shall be an efficient and effective equipment inventory system, including proper documentation.
- There shall be an efficient system for regular servicing, calibration and maintenance of equipment.
- A centralized, certified maintenance body shall provide high quality preventive maintenance and repair services.
- There shall be a system for disposal and de-commissioning of all laboratory equipment.
- All donations of equipment shall comply with the equipment purchasing guidelines and shall be need-based.
- There shall be a regulated efficient supply system with guidelines functioning at national and state level meeting the needs of the beneficiaries.

- Laboratory representatives shall be trained in procurement procedures and shall participate in tender committees conducting purchasing of the materials for laboratories.
- There shall be well-trained and qualified supply management staff.
- There shall be a proper documentation system to support the supply system (electronic and/or paper based).
- There shall be a mechanism in place to regularly monitor and evaluate the supply system.

Biorisk management and waste management

- There shall be a regulation to protect laboratory workers, the community and the environment against all types of laboratory hazards.
- There shall be national laws to regulate the use and disposal of radiological, chemical and biological materials and other waste in compliance with international regulations.
- Inspection mechanisms shall ensure the implementation of the regulations and laws.
- There shall be a universally enforced waste management system that ensures the collection, transportation and disposal of all kinds of waste including obsolete equipment, separated domestic, medical, chemical and radiological waste.
- A national waste management system shall regulate safe disposal of hazardous materials.
- There shall be standardized and harmonized guidelines, manuals and Standard Operating Procedures (SOP) developed to minimize hazard exposure and ensure safety.
- Each laboratory shall have a safety policy and guidelines, manuals and SOPs that are adapted to its own situation.
- A risk assessment shall be conducted in each laboratory to implement appropriate risk detection and mitigation measures.
- A standardized, harmonized and regularly updated comprehensive (bio)safety training package shall be developed for different categories of laboratory workers.
- Laboratories shall be adequately supplied with safety equipment for staff and premises.

Communication and information systems

- There shall be an effective and efficient standardized and harmonized reporting system for laboratories at different levels.
- All laboratory facilities shall have access to electronic databases relevant to their scope of work.

- All databases and data exchange mechanisms shall be designed to ensure patient data confidentiality.
- In the process of computerization of the laboratories, laboratory staff shall be trained in computer literacy.
- There shall be a system in place for information sharing and exchange between laboratories and health authorities.
- There shall be a mechanism in place for regular analysis of laboratory information to improve planning and decision-making.
- There shall be an integrated LIMS at national level that is fed by information from lower levels.
- The LMIS infrastructure shall be based on state of the art information technology with proper data storage and back up.
- There shall be guidelines for unified disease laboratory surveillance.
- The LIMS shall have adequate numbers of skilled staff enabling effective data collection and reporting, information analysis and reporting to decision-makers.

Quality management

- There shall be unified, clearly written, updated, communicated (to all laboratory levels) technical standards for facilities, service provision, quality, safety and human resources.
- Regularly reviewed and updated national quality standards for each laboratory level shall be developed on the basis of international standards to improve quality of laboratory services.
- A system of regulation and supervision ensuring compliance to the national quality standards shall be developed.
- Support to quality standard implementation shall be provided through standardized trainings and harmonized technical guidelines and tools.
- The position of quality manager shall be introduced in the staffing of laboratories.
- There shall be an auditing and validation system to ensure compliance to quality standards.
- There shall be sets of quality indicators for the different types and levels of laboratories to be able to objectively assess the quality of the work of the laboratory.
- Laboratories shall be stimulated to participate in External Quality Assurance programs nationally and internationally.
- The curricula of academic and vocational training institutes shall be updated to include modules on quality aspects.

- Through ISO 17011 accreditation, the national accreditation body shall become at least an associate member of the International Laboratory Accreditation Cooperation (ILAC) to ensure the availability of a national accreditation body for ISO 17025 (veterinary, food and other laboratories) and ISO 15189 (medical laboratories).
- The National Accreditation Council for Health Facilities shall seek to become a full member of ILAC.
- A financial system shall be developed to make the accreditation/certification body self-sustained.

Ethics

- All laboratory staff shall work in accordance with public service, ethical, safety and professional code of conduct.
- Ethics shall be included in the pre-service training and education of laboratory specialists.
- Ethical standards and rules shall be developed and implemented in accordance with international requirements.
- All laboratory workers shall sign in agreement to comply with patient data confidentiality before they can start working with patient data.

Research

- A national research committee with representatives from different stakeholders shall supervise research priority setting and ensure coordination and collaboration with relevant stakeholders.
- There shall be a system of continuous training and education for research personnel to improve their research skills, including research methodology and ethics.
- Research forums shall be established to ensure communication of research results with stakeholders.
- A national laboratory research database shall be developed in collaboration with concerned stakeholders to ensure overview of research activities and prevent duplication.
- The national research committee shall work in collaboration with partners to mobilize national and international resources for research.
- There shall be a separate budget line for research within laboratory annual plans.

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The WHO Regional Office for Europe

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