

Policy and practice

NEW POLICY-FORMULATION METHODOLOGY PAVES THE WAY FOR SUSTAINABLE LABORATORY SYSTEMS IN EUROPE

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ABSTRACT

A newly developed policy-formulation methodology carried out under the aegis of the World Health Organization Regional Office for Europe "Better Labs for Better Health" initiative was launched in 2012. The aim was to drive long-term planning and sustainability and ensure quality laboratory services. The methodology has already resulted in national laboratory policies in Republic of Moldova and Tajikistan and similar work is in progress in two other countries. National laboratory policy documents are developed over one year in three phases. Preparatory activities of

phase 1 include the establishment and formal endorsement of an intersectoral national laboratory working group (NLWG) which reflects the One Health concept and performs a laboratory system assessment. Development of the policy in phase 2 occurs over three workshops during which a vision for laboratory services is developed, policy topics are identified, policy statements are formulated and an inventory of documents pertaining to the laboratory system is established. Policy endorsement is sought during phase 3 through consultation with stakeholders

and submission of the draft policy to the government. Throughout all phases, the NLWG is mentored and trained in the evidence-informed, consensus-based policy development. The policies developed are nationally owned and consistent with other national policies in related fields. The NLWGs have become a critical platform of change-making senior laboratory experts and the information generated forms an essential resource for all those interested in supporting the improvement of laboratory services.

Keywords: NATIONAL LABORATORY POLICY, METHODOLOGY, SUSTAINABILITY, EUROPE

BACKGROUND

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 (1). The ongoing 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 (2). Within such a strong health system, effective high-quality (accredited) laboratories and response networks must be on the front line (3).

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 (4). 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 (5). 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 (6).

LOCAL CONTEXT

In recent years, investments in laboratory services in countries of eastern Europe have been in so-called vertical programmes targeting single diseases, such as polio eradication or measles elimination, rather than benefiting the laboratory system as a whole (7). 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 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 (8). For these reasons, and in view of the WHO global vision, in 2012 the WHO Regional Office for Europe initiated the Better Labs for Better Health (BLBH) initiative – a sustainable, horizontal approach to improve the quality of all laboratories that deal with health. For each country, the first BLBH step is the development of a national laboratory policy (NLP), the methodology for which is described in this paper and the development of which started in the Republic of Moldova and Tajikistan in 2013.

APPROACH

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 driving seat. Such a policy is essential for developing sustainable services (9); providing criteria for accepting or refusing activities; and ensuring

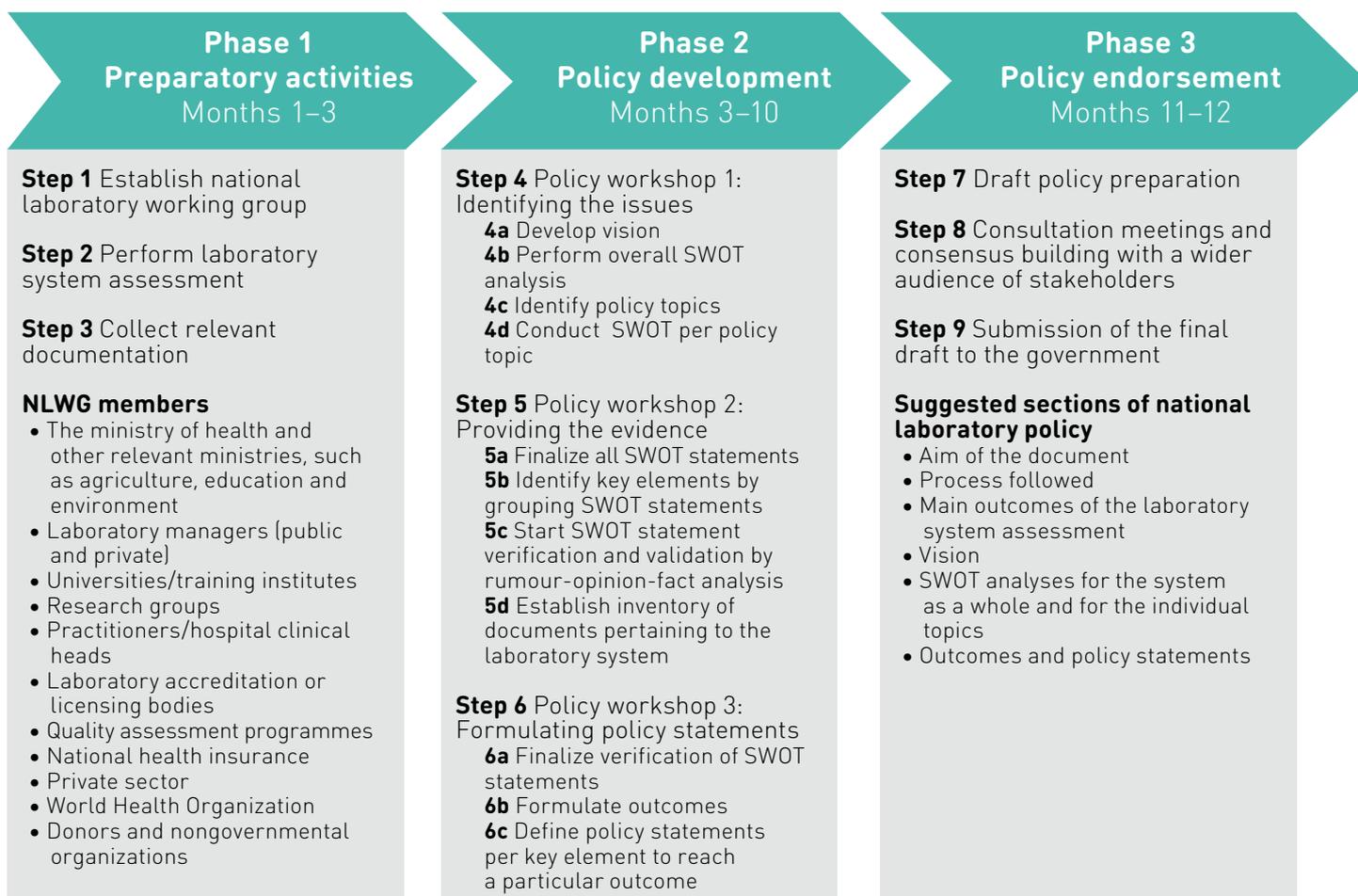
optimal use of scarce resources. The policy should be consistent with other national policies in related fields; aligned to ongoing country laboratory initiatives and wider health system reforms; and based on broad consensus. NLP development described here pertains to all laboratories dealing with health 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” (10). Laboratories for prevention and management of acute and chronic diseases; control of outbreaks; antimicrobial resistance; 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 (11).

The NLP is developed over a period of about 1 year (Fig. 1) through a facilitated, country-tailored, step-by-step approach under the umbrella of a formally recognized national laboratory working group (NLWG). The methodology is based on examples from other countries (12, 13) and WHO regions (14), 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). These components of NLP development are summarized in Fig. 1 and described below.

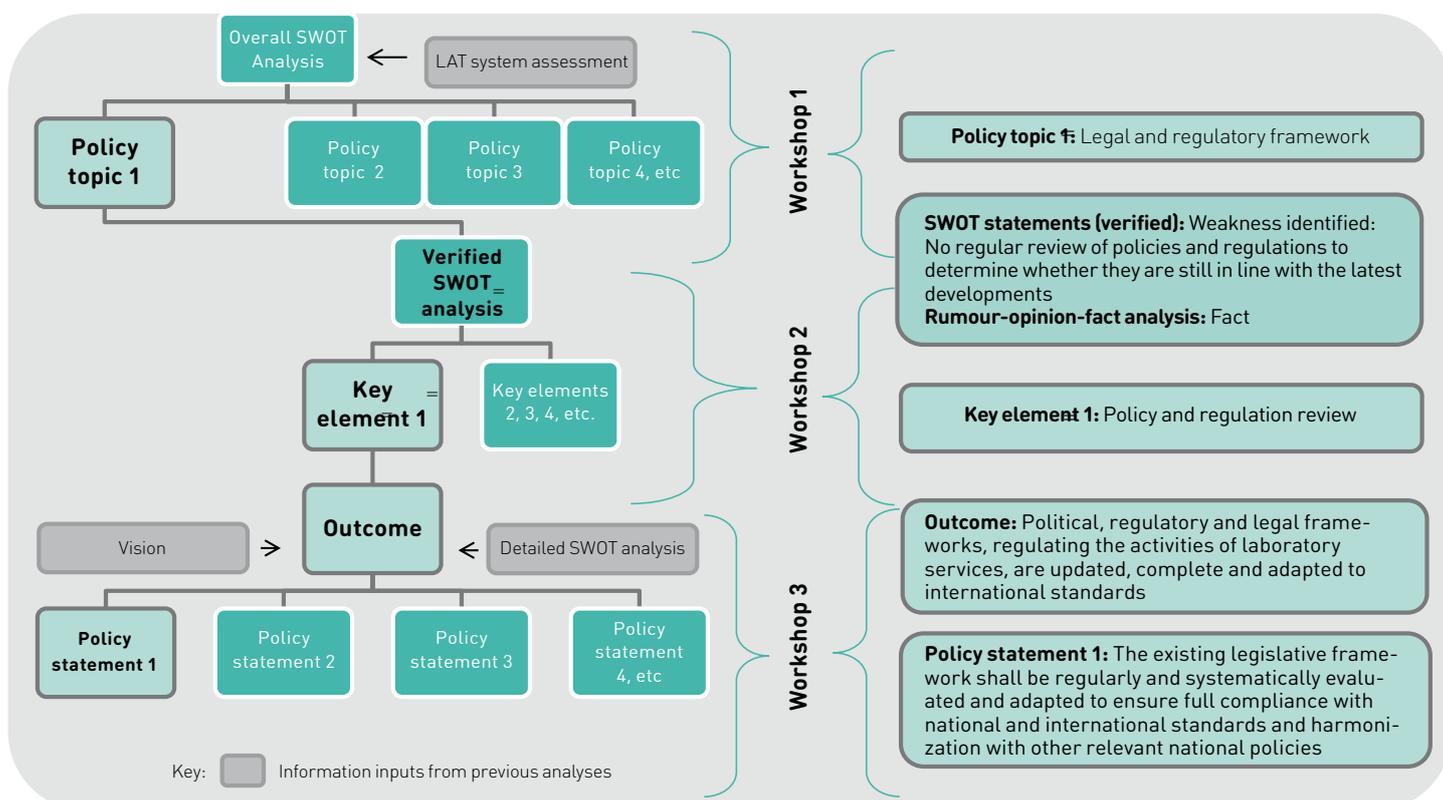
PHASE 1: PREPARATORY ACTIVITIES

In step 1, the NLWG is formally established, consisting of a core group of 15–20 persons, a chairperson and an executive secretary and including representatives as shown in Fig. 1. In step 2, the NLWG performs a laboratory system assessment using the WHO laboratory assessment tool, which enables calculation of a score for each of the key components of a laboratory system (15). Ideally, laboratories at different tiers of the health-care system are also assessed to

FIG. 1. NATIONAL LABORATORY POLICY DEVELOPMENT PROCESS



Phase 2 process



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

obtain a more complete overview. The results (Fig. 2), together with documents relevant to the laboratory sector identified through the laboratory assessment tool (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.

PHASE 2: POLICY DEVELOPMENT

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

Policy workshop 1 (step 4) identifies the issues by developing a long-term vision for laboratory services (Box 1), performing a stakeholder analysis and situational SWOT analysis of the overall laboratory system. This identifies major themes for the NLP which are categorized under 10–14 policy topics (Table 1). All policy topics are 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.

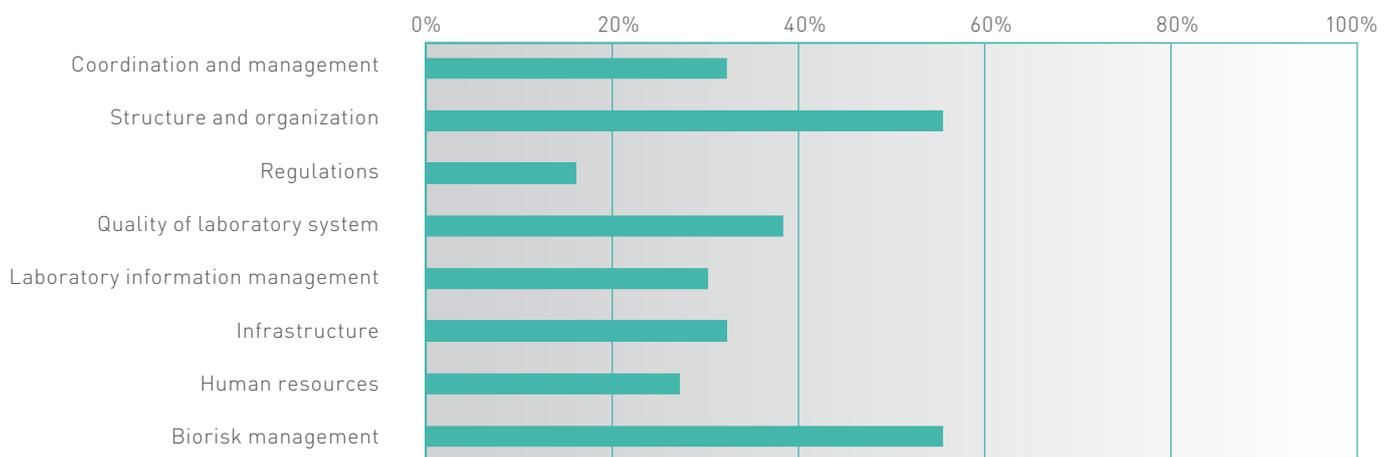
Policy workshop 2 (step 5) provides the evidence by reviewing and improving the detailed SWOT analyses for all policy topics and by making a final list of all SWOT statements for each policy topic. To provide structure where necessary, SWOT statements may be grouped to form subgroups per topic called key elements. The complete list of SWOT statements is subjected to verification and validation 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.

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.”

By policy workshop 3 (step 6), the NLWG has verified all the SWOT statements and determined which parts

FIG. 2. EXAMPLE OF INDICATOR RESULTS FROM A LAB LABORATORY SYSTEM ASSESSMENT



to keep and which parts to remove. The verification process results in an inventory of documents pertaining to the laboratory system. 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) (Table 1), the NLWG starts to define policy statements for the SWOT statements and/or key elements. One outcome is formulated per SWOT statement or key element and the policy statement is formulated to reach that outcome. The typical

TABLE 1. EXAMPLES OF NATIONAL LABORATORY POLICY TOPICS

Category	Policy topics
System inputs	<ul style="list-style-type: none"> • Legal and regulatory framework • Organization and management of services • Accessibility of services including community perspective • Partnerships, coordination and scientific collaboration
Structural inputs	<ul style="list-style-type: none"> • Human resources • Finance • Infrastructure • Procurement, equipment and logistics
Support inputs	<ul style="list-style-type: none"> • Biosafety and waste management • Communication and information system • Quality management

structure of a policy statement is: “There shall be ... to ensure” Normally, two to five policy statements per key element 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 all remaining policy statements. The Executive Secretary of the NLWG consolidates all outcomes into a draft NLP (step 7). The proposal follows local rules for content, structure and endorsement of a policy paper 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 have to be implemented, through the development of strategic and operational plans describing responsibilities, budgets and timelines. This step is already ongoing in Republic of Moldova and Tajikistan.

RELEVANT CHANGES

NLP are being developed in four WHO European Region countries (Kyrgyzstan, Republic of Moldova, Tajikistan and Uzbekistan). In the Republic of Moldova and Tajikistan, policies have been finalized and are undergoing formal endorsement. A national coordinated approach to laboratory system strengthening is legitimate in low- and middle-income countries in the European Region, as it is in such countries in other regions where health is still chiefly the responsibility of the public rather than the private sector. Particularly in this setting, NLP provides direction for strategic planning and implementation of improvements, with ultimately better-informed use of scarce government and donor resources. Improvements implemented in laboratory-quality systems following NLP development in Uganda are encouraging (16). Integrating laboratory functions in a more horizontal system will result in cost-savings: for example, molecular detection or serological assays can be run for multiple pathogens in the same laboratory rather than certain diseases having separate, designated laboratories. In parallel with policy and strategy development, the BLBH initiative is helping countries to improve the quality of their laboratories by providing training in laboratory-quality implementation to the NLWG and other senior laboratory staff in the four countries, as well as to staff from national laboratories in more than 20 eastern and south-eastern European countries.

The approach described here resulted in the establishment of NLWG's that are led by persons responsible for laboratory services at national level and that have gone through a process of consensus building during laboratory policy development. The NLWG are thus a critical platform and resource for change in the four countries since they provide advice to the governments on laboratory issues; enhance collaboration and sharing of expertise and resources among laboratories, sectors and international

partners; and are trained in evidence-informed policy development. The inventory of documents pertaining to the laboratory system in a country is a critical resource, consisting of laws, rules and regulations, government decisions and strategies and forms the evidence base for the policy and plan.

By including laboratories for all sectors dealing with health, the NLWG is poised to enhance One Health strategies, such as: integrated programmes for surveillance and laboratory systems spanning human and animal health; public health programmes run by veterinary colleges; biomedical research involving animal models of disease; and integrated diagnostics across human and animal health laboratory networks.

LESSONS LEARNED

The key actors for change in the four countries have been the ministries of health, which have recognized the need for better coordination and oversight of laboratory services as drivers for sustainability and change. WHO has an important role in advocating for the establishment of NLWG that are intersectoral, and for providing mentoring and training, leading to consensus building and evidence-based policies. NLP's are nationally owned, since their development is based on consensus. Inclusion of laboratories from sectors other than health as well as the private sector in the policy development was readily agreed to by the relevant ministries in Tajikistan. However, during the policy development workshops, it was necessary to explain to all NLWG members the relevance of including sectors other than human health in order to build consensus. In the Republic of Moldova, the inclusion of other sectors and stakeholders will occur during strategic plan development. Inclusion of other external partners in policy development provides additional support and will enhance coordination within, between and among governments and donor organizations in the implementation phase of national laboratory strategies, as it has in other countries (6).

NLPs must be constructed such that their format and content are aligned with other national documentation. Inclusion of all relevant stakeholders to endorse the NLP is critical; activities may include a public event to collect final feedback, improve transparency and advocate for inclusion of other sectors. Government endorsement of the NLP may require inclusion of budgeted action

plans, since changes to the system will have significant resource implications. High-level national laboratory coordination committees established in Tajikistan and Kyrgyzstan are facilitators of NLP endorsement.

WHO encourages countries to publish their NLPs, to inform all stakeholders and to be an example for other countries (17). The BLBH initiative is gaining momentum in the WHO European Region (7) and the methodology described here to develop NLP can be applied in any country, as is already occurring in several countries of the WHO Eastern Mediterranean Region (17). All materials developed to facilitate NLP development (NLP facilitators' guide and training materials) are available in English and Russian.

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REFERENCES

- Kessel M. Neglected diseases, delinquent diagnostics. *Sci Transl Med*. 2014;6(226):226ed6.
- Oleribe OO, Salako BL, Ka MM, Akpalu A, McConnochie M, Foster M et al. Ebola virus disease epidemic in West Africa: lessons learned and issues arising from West African countries. *Clin Med*. 2015;15(1):54–7.
 - Pereyaslov D, Rosin P, Palm D, Zeller H, Gross D, Brown CS et al. Laboratory capability and surveillance testing for Middle East respiratory syndrome coronavirus infection in the WHO European Region. *Euro Surveill*. 2014;19(40):20923.
 - Joint WHO–CDC conference on health laboratory quality systems. Geneva: World Health Organization; 2008 (<http://www.who.int/csr/ihr/lyon/report20080409.pdf?ua=1>, accessed 23 May 2015).
 - The Maputo Declaration on Strengthening of Laboratory

- Systems. Brazzaville: WHO Regional Office for Africa; 2008 (http://www.who.int/diagnostics_laboratory/Maputo-Declaration_2008.pdf, accessed 23 May 2015).
5. Olmsted SS, Moore M, Meili RC, Duber HC, Wasserman J, Sama P et al. Strengthening laboratory systems in resource-limited settings. *Am J Clin Pathol.* 2010;134:374–80.
 6. Report of the WHO regional meeting on strengthening laboratory capacities to support national programmes in eastern Europe and central Asia. Copenhagen: WHO Regional Office for Europe; 2014 (http://www.euro.who.int/__data/assets/pdf_file/0018/262611/Report-of-the-WHO-Regional-meeting-on-strengthening-laboratory-capacities-to-support-national-programmes-in-eastern-Europe-and-central-Asia-Eng.pdf?ua=1, accessed 23 May 2015).
 7. Health system reviews (HiT series) [online database]. Brussels: European Observatory on Health Systems and Policies; 2015 (<http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits>, accessed 23 May 2015).
 8. Nkengasong JN, Mesele T, Orloff S, Kebede Y, Fonjongo PN, Timperi R et al. Critical role of developing national strategic plans as a guide to strengthen laboratory health systems in resource-poor settings. *Am J Clin Pathol.* 2009;131:852–7.
 9. One health initiative task force. One health: a new professional imperative. Washington (DC): American Veterinary Medical Association, 2008 (https://www.avma.org/KB/Resources/Reports/Documents/onehealth_final.pdf, accessed 23 May 2015).
 10. Health 2020: the European policy for health and well-being [website]. Copenhagen: WHO Regional Office for Europe; 2015 (<http://www.euro.who.int/en/health-topics/health-policy/health-2020-the-european-policy-for-health-and-well-being>, accessed 23 May 2015).
 11. Uganda national health laboratory services policy. Kampala: Ministry of Health; 2009 (<http://www.ahpc.ug/UGANDA%20NATIONAL%20HEALTH%20LABORATORY%20SERVICES%20POLICY.pdf>, accessed 23 May 2015).
 12. A guide to policy development. Winnipeg: Office of the Auditor General Manitoba; 2003 (<http://www.oag.mb.ca/wp-content/uploads/2011/06/PolicyDevelopmentGuide.pdf>, accessed 23 May 2015).
 13. 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; 2011 (http://apps.searo.who.int/PDS_DOCS/B4725.pdf, accessed 23 May 2015).
 14. Laboratory Assessment Tool. Geneva: World Health Organization; 2012 ([http://www.who.int/ihr/publicationslaboratory assessment tool./laboratory_tool/en/](http://www.who.int/ihr/publicationslaboratory%20assessment%20tool/laboratory_tool/en/), accessed 23 May 2015).
 15. Hiwot TM, Ayana G, Mulugeta A, Kassa GB, Kebede Y, Fonjongo PF et al. Laboratory system strengthening and quality improvement in Ethiopia. *Afr J Lab Med.* 2014;3(2); 6 pp. doi:10.4102/ajlm.v3i2.228.
 16. Report on the consultative meeting to develop a strategic public health laboratory plan. Cairo: WHO Regional Office for the Eastern Mediterranean; 2014 (http://applications.emro.who.int/docs/IC_Meet_Rep_2014_EN_15354.pdf?ua=1, accessed 23 May 2015).