

## Policy and practice

# BETTER LABS FOR BETTER HEALTH: INTERSECTORAL CHALLENGES AND SOLUTIONS FOR LABORATORY SYSTEMS STRENGTHENING

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## ABSTRACT

Laboratories provide a large range of testing – from the site of patient care to addressing environmental issues – all of which require accurate and reliable results for disease prevention and management. Until now, external financing to strengthen laboratory services in low- and middle-income countries, including those of the World Health Organization (WHO) European Region has mainly benefited vertical programmes aimed at specific diseases. Insufficient national coordination and oversight of such initiatives has led to fragmentation, duplication and uneven quality within laboratory services.

In response, Better Labs for Better Health, an initiative of the WHO Regional Office for Europe, has taken an intersectoral approach by assisting countries with the creation of national laboratory working groups (NLWGs), which have developed national laboratory policies and strategic plans. This article reports an analysis of four national policies and identifies a few strengths of the current systems, such as laboratories of better quality because of the support from vertical programmes, political commitment and motivated staff. It also reveals well-known core cross-cutting challenges such as human

resources, infrastructure development and quality management systems. Three new challenges are identified: accessibility of services, sustainable financing of laboratory activities and ethics. All challenges need an intersectoral approach to find solutions at the country level, such as in education, clinical waste management, health system strengthening and collaboration with the private sector. The NLWGs form intersectoral platforms through which common weaknesses and capacity building can be addressed throughout national laboratory systems.

**Keywords:** NATIONAL LABORATORY POLICY, LABORATORY SYSTEMS, INTERSECTORAL APPROACH, EUROPE

## BACKGROUND

Most external financing for health in low- and middle-income countries is directed through vertical funds that target specific diseases, such as tuberculosis, or programmes, such as reproductive health. Although beneficial, these vertical initiatives have been criticized for not incorporating long-term planning and for leading to duplication of efforts, lack of

coordination and waste of resources, especially if many donors are involved (1). Overall, the channelling of aid for health through vertical programmes has been to the detriment of horizontal, sector-wide health system strengthening.

The effects of vertical versus horizontal approaches to external assistance are exemplified by current challenges to laboratory systems in low- and middle-

income countries. Laboratories are an essential and fundamental component of all health systems. Whether at the site of patient care or for addressing environmental issues, laboratories are responsible for providing a wide range of accurate and reliable test results. In low- and middle-income countries, significant differences exist in the quality of tests depending on the programme that supports the laboratory. For example, there may be a range of constraints in performing biochemistry and haemoglobin tests in laboratories that do not benefit from the logistic and practical support provided through vertical programmes (2). By targeting specific diseases, vertical initiatives have led to the development of specialist laboratories, for example in HIV or influenza, which have resulted in fragmentation and duplication within the regular clinical laboratory systems. In addition, many laboratories supported by international vertical programmes have developed higher levels of quality than non-supported laboratories, resulting in an uneven distribution of services.

In 2008, the Maputo Declaration on strengthening of laboratory systems recognized the following as areas requiring strengthening in resource-limited settings: leadership and advocacy, human resources, career-path structures, retention of staff, national laboratory policies, strategic planning, physical infrastructure, supply-chain management and quality management systems (3). In the same year, the essential role of laboratory quality management systems was also emphasized by a global consensus of the World Health Organization (WHO) and technical partners (4).

## LOCAL CONTEXT

In 2012, in line with the Health 2020 European policy for health and well-being (5), the WHO Regional Office for Europe initiated the Better Labs for Better Health (BLBH) initiative, a sustainable, horizontal, sector-wide approach providing development assistance to strengthen national ownership and help build nationally managed systems, while still allowing for continuing donor engagement. For each country, the first step towards BLBH is the development of a national laboratory policy by a formally recognized national laboratory working group (NLWG). These policies are based on broad consensus and lead to the development of national strategic plans (6). Through

these national policies and strategic plans, BLBH uses an intersectoral approach to strengthen the core elements of laboratory systems identified by the NLWGs.

## APPROACH

We analysed the first four policies developed under BLBH project, which were from four countries of eastern Europe and central Asia: Kyrgyzstan, Republic of Moldova, Tajikistan and Uzbekistan. We compared the national challenges described in these policies with previously identified challenges to laboratory systems in resource-poor countries (3, 7). The purpose of this analysis was (i) to reveal the core cross-cutting elements that affect laboratory systems, regardless of the disease, specificity and level of the laboratory; and (ii) to highlight areas requiring intersectoral solutions.

## OBSERVATIONS

### COMPOSITION OF NLWGS

The NLWGs of the four countries include national experts who know the national system well and can determine what is needed; these experts represent facilities and services including public health laboratories, clinical diagnostics, chemical, radionuclear, food safety, toxicology, veterinary services, teaching universities and colleges and laboratory accreditation agencies, as well as the ministries of health. Table 1 shows the sectors, organizations and institutes that were represented in the four countries' NLWGs when the main topics in their respective policies were defined. In the future, these NLWGs can be expanded to include other relevant sectors as the process of laboratory system improvement develops.

### SCOPE OF POLICIES

Overall, the four policies addressed the needs of laboratories testing for the purposes of disease diagnosis, screening, prevention, medical treatment decisions, surveillance and public health. The policies covered both clinical and public health laboratory systems as well as veterinary, food safety, water, environment, chemical, toxicology, radionuclear and other laboratories. All four policies reflected the One Health concept, which recognizes that the health of humans is related to the health of animals and the environment. In addition, the policies should make considerable contributions to implementation of the

**TABLE 1. INTERSECTORAL COMPOSITION OF THE NLWGS OF THE FOUR COUNTRIES<sup>A</sup>**

INSTITUTION OR ORGANIZATION	NUMBER OF MEMBERS			
	Country 1	Country 2	Country 3	Country 4
Ministry of health	N/A	2	1	9
Ministry of health: human resources	1	N/A	N/A	1
Ministry of health: drugs and medical equipment unit	1	N/A	N/A	1
Ministry of health: medical university	1	1	N/A	3
Ministry of health: public health laboratories	13	12	6	5
Ministry of health: clinical laboratory	2	1	6	3
Ministry of health: tuberculosis laboratory	1	1	1	3
Ministry of health: HIV laboratory	N/A	1	1	2
Ministry of health: blood centre	N/A	N/A	N/A	1
Ministry of health: hospitals, health care	1	4	2	1
Ministry of agriculture	N/A	1	N/A	1
Ministry of agriculture: veterinary laboratory	N/A	N/A	N/A	1
Ministry of agriculture: food safety laboratory	N/A	1	N/A	1
Ministry of environment	N/A	1	N/A	N/A
Ministry of economy: metrology centre	N/A	1	N/A	N/A
National laboratory accreditation body	N/A	1	N/A	N/A
Postgraduate university	N/A	N/A	N/A	2
Academy of sciences: nuclear and radiation safety laboratory	N/A	1	1	1
Academy of sciences: chemistry laboratory	N/A	N/A	1	1
Private laboratories	N/A	1	1	1
International agencies/projects/ organizations	N/A	2	N/A	11

N/A: not applicable.

<sup>a</sup> Countries are numbered randomly.

International Health Regulations (2005) (8) in the area of strengthening laboratory capacity. Relevant policy topics included ensuring strong laboratory biorisk management, laboratory quality, functional specimen transport and information systems in order to identify and communicate important public health events, including public health emergencies of international concern. Many of these aspects of laboratory capacity were lacking in countries affected by the outbreak of Ebola virus disease in west Africa (9) and some were addressed to improve capability for Middle East respiratory syndrome coronavirus infection testing (10).

Within all four countries, there has been considerable training and quality assurance implementation in HIV, tuberculosis and malaria laboratories as a result of specific disease funding programmes. Similar work has been implemented in influenza laboratories through the WHO European Regional network (11) with support from the Global Influenza Surveillance and Response System and, more recently, through the Pandemic Influenza Preparedness Framework (12). The policies of all four countries noted that future laboratory strategies should build on the improved performance of these laboratories.

## POLICY CHALLENGES

When developing the national laboratory policies, NLWGs identified challenges in the national laboratory systems. As shown in Table 2, when the challenges were grouped by topic, there was considerable commonality not only between the four countries but also with the difficulties facing laboratory systems previously identified by others (3, 7). In addition to the topics in Table 2, the NLWGs identified problems with: inadequate communication within the laboratory system and with customers and workloads that were insufficient to maintain staff skills. However, the NLWGs also identified the following common strengths: laboratories of better quality because of the support from vertical programs, political commitment and motivated staff.

With only a few exceptions (Table 2), the policies of all four countries identified the classic core cross-cutting elements of laboratory health systems to be strengthened. These were: human resources management; infrastructure development and rationalization, including tiered national laboratory system networks; supply-chain management and maintenance of laboratory equipment; specimen

TABLE 2: CHALLENGES FACED BY LABORATORY SYSTEMS IDENTIFIED BY NLWGS<sup>A</sup>

Country 1	Country 2	Country 3	Country 4	PREVIOUSLY IDENTIFIED AND NEW <sup>B</sup> CHALLENGES (3, 7)
Yes	Yes	Yes	Yes	Governance/regulatory policy
Yes	Yes	Yes	Yes	Specimen referral systems
Yes	No	No	No	Accessibility of services <sup>b</sup>
Yes	Yes	No	No	Leadership, commitment and coordination
Yes	Yes	Yes	Yes	Laboratory information system
Yes	Yes	Yes	Yes	A framework for training, retraining and career development of laboratory workers
Yes	Yes	Yes	Yes	Finance <sup>b</sup>
Yes	Yes	No	Yes	Infrastructure development
Yes	Yes	Yes	Yes	Biosafety and waste management
Yes	Yes	Yes	Yes	Supply-chain management of laboratory supplies and maintenance of laboratory equipment
Yes	Yes	Yes	Yes	Quality management systems
No	No	Yes	No	Ethics <sup>b</sup>

<sup>a</sup> Countries are numbered randomly.

<sup>b</sup> New challenges identified in the current analysis.

referral systems within integrated quality management systems; laboratory information systems; biosafety and waste management; and governance with leadership, commitment and a coordination structure to address regulatory issues (3, 7).

In addition, our analysis revealed three new challenges: accessibility of services, finance and ethics (Table 2). Two NLWGs identified a need for customers to be aware of available laboratory services and to be able to access to these services without discrimination. While one part of this challenge is linked to advocacy for greater laboratory capacities, the other aspect relates to the Health 2020 ethos (5) in terms of providing accessible, affordable and equitable services. With regard to financing, all NLWGs emphasized the need for sufficient and sustainable funding mechanisms in place for the laboratories,

with decreased reliance on donor funds. For the four countries, this will entail new cost analyses; integration of laboratory testing in the health insurance systems; and discussions with private laboratories. One NLWG noted the challenge of ensuring awareness and respect of ethical standards throughout the laboratory system.

## LESSONS LEARNED

### NEED FOR INTERSECTORAL APPROACHES

Analysis of the four national policies highlights the need for reform not only within the laboratory systems but also in other sectors. Leadership and coordination are needed at ministry level, with coordination not only of donor funding but also between the different ministries involved in laboratory activities such as agriculture, environment and health. Only then can there be a reform and rationalization of the laboratory system to fit the needs and resources of the country.

Laboratories must be fully integrated within health systems and solutions identified on how to make services accessible and available to the population. Health is the responsibility of the public rather than the private sector in these countries, and the public sector cannot ensure sufficient laboratory funding, particularly since support from the GAVI Alliance and the Global Fund to Fight AIDS, Tuberculosis and Malaria is being phased out. To ensure sustainability, financial reform is needed, with a reassessment of how laboratories should be funded and a review of the costs of laboratory activities. Specialist advice should be sought on the potential for establishing new public–private partnerships for laboratory services' financing.

Work with universities, training colleges and other institutions, as well as with the public and private laboratory managers, is needed to revise laboratory-worker curricula such that they are aligned with current needs. Quality and biosafety management and the use of modern equipment and new techniques should be integrated in the basic training curricula, which should also cover ethics and collaboration and communication with different stakeholders. Partnership with the ministry of education and the quality assurance agency will be required to ensure accreditation of the revised curricula. Each country also needs a comprehensive human resources plan

to address the number and types of laboratory workers to be trained, performance management, motivation, career pathways, retention policies and continuing education policies.

In addition to leadership, financing and human resources, the countries need to strengthen clinical waste management systems and establish national reference centres to ensure regular equipment maintenance and accuracy. Together with laboratory quality management systems, work with national accreditation bodies is needed to allow certification and accreditation of the laboratories as the quality improves. In addition, specialists in legislation should be co-opted to determine laboratory regulation and monitoring.

All these activities for laboratory system improvement clearly need an intersectoral approach. This is why the BLBH initiative has focused on establishing intersectoral NLWGs, as these collaborations constitute the critical platforms for further development of the laboratory systems.

## PROGRESS TO DATE

The NLWGs have been formally established and recognized by the ministries of health in all four countries. This has allowed people from different sectors to work together to identify the strengths and weaknesses focus on how to make changes in their laboratory systems. This intersectoral approach is working well and is expected to result in significant changes as people gain a deeper understanding of problems in sectors other than their own and continue work collaboratively to achieve reform.

It has been recognized, when analysing strengths of the actual laboratory systems during the policy development process, that what has been achieved by vertical programmes will be useful and must be fully harnessed to help other laboratory sectors improve. The BLBH initiative will therefore use national experts who were trained through vertical programmes to mentor other laboratories in quality management systems implementation. Where insufficient experts are available, new mentors from the region will be trained.

BLBH has conducted training curricula reviews in four countries and workshops to identify the gaps, develop competencies and propose recommendations

for the training improvements. Recommendations included: improved practical training of students by strengthening collaboration between educational institutions and public and private laboratories; improved examination methods of practical skills; development of training for laboratory managers; and review curricula based on the developed competencies.

BLBH will continue focusing on in-country capacity building for improving the national coordination of laboratory services and the quality of the services provided. This will allow countries to start tackling common weaknesses and building capacities in an intersectoral manner throughout their laboratory networks.

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