

WHO-EM/LAB/382/E

Report on the

Consultative meeting to develop a strategic public health laboratory plan

Amman, Jordan
9–11 December 2013



World Health
Organization

Regional Office for the Eastern Mediterranean

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1. INTRODUCTION

Effective and efficient laboratory capacity is a cornerstone of any country's capacity to prevent accidental or deliberate use of pathogens, investigate any biological event and apply evidence-based control of disease. The world is faced with growing threat of outbreaks of known, emerging or unknown diseases such as poliomyelitis (polio), meningitis, measles, influenza (H1N1, H5N1 and H7N9) and Middle East Respiratory Syndrome coronavirus (MERS-CoV). In addition, accidental or deliberate release of dangerous pathogens, such as anthrax, from unsafe or unsecured laboratories has occurred. Under the 2005 edition of the International Health Regulations (IHR 2005), countries are required to develop the capacity to detect, investigate and report to the international community through the World Health Organization (WHO), potential public health emergencies of international concern. Central to this response is a credible, accessible and sustainable laboratory service capable of early detection and characterization of epidemic and pandemic-prone pathogens, safely containing and handling dangerous pathogens and producing high quality results in a timely manner.

However, the oversight of health laboratories is often fragmented within national health systems. Ineffective donor coordination, lack of robust national laboratory policies and diversity of funding sources have contributed to the development of uncoordinated public health laboratory services in many countries. While many disease-specific programmes have been very effective in developing their laboratory component, this has frequently been independent, and to the detriment, of the broader national laboratory system.

Accordingly, a consultation was held in Amman, Jordan from 9 to 11 December 2013 in order to develop an outline of a strategic plan for use by public health laboratories in the countries of the WHO Eastern Mediterranean Region to develop sustainable strategies to improve laboratories in a cross-cutting manner for better preparedness for, surveillance of and response to, epidemic-prone diseases and other potential public health emergencies of international concern. Strategies for improving safe blood transfusion (blood safety) were included in the same discussion.

The objectives of the meeting were to:

- define a vision for health laboratories for better preparedness for, surveillance of and response to, epidemic-prone diseases in the Region for 2014–2018;
- define a vision and identify priority areas for strengthening national blood systems, achieving self-sufficiency and preventing transfusion-transmissible infections.

Expected outcomes of the meeting included a vision of a linked system of health laboratories across the Region responsive to patient and public health needs and an outline (with potential priority areas/goals) of a public health laboratory strategic plan to guide WHO and countries in strengthening laboratory services.

The meeting was opened by a video address from Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean. Dr Alwan emphasized the cross-cutting importance of laboratory services which touch on all five regional priority areas endorsed by the WHO

Regional Committee for the Eastern Mediterranean in 2012. In addition, laboratory services are a key core capacity to be strengthened under IHR (2005). The Regional Director also highlighted the area of blood transfusion and its links with laboratory services. He expressed his hope that the meeting would develop a clear vision and strategy for public health laboratories, looking at how to address the existing gaps and constraints, and taking into account that different countries in the Region may have common priorities but different needs for technical support. Dr Alwan expressed his support for the strategy, and promised to ensure that this area would remain a priority for the Regional Office over the coming years.

Dr Jaouad Mahjour, Director, Department of Communicable Diseases Prevention and Control, Regional Office for the Eastern Mediterranean, emphasized that the work of the meeting was the beginning of a longer process and shared his hope that the group would serve as the basis for an effective network in strengthening laboratory services over the coming months and years. The meeting selected Dr Akhtam Haddadin and Dr Robert Martin to serve as Co-Chairs.

In discussion, participants agreed that an emphasis on prioritization, with a focus on doing that which is possible, was important in such a diverse Region. It was considered important to promote integration among and between laboratories, epidemiological units and programmes, in order to best use laboratory information to support and drive public health programmes. The need for integration across different functions – surveillance, diagnosis and treatment – was also highlighted and it was suggested that it might be helpful to think of links in the context of functions rather than laboratories. It was suggested that the strategy should be flexible enough to be presented to ministries of health with guidance appropriate to the different economic contexts found within the Region.

2. TECHNICAL PRESENTATIONS

2.1 WHO global and regional public health laboratory strengthening strategies

Laboratory services serve a number of different purposes such as surveillance, diagnosis and preparedness, performing a large number of essential public health functions. Additionally, laboratory services are cross-cutting in supporting the five priorities in WHO's Twelfth General Programme of Work 2014–2019, and therefore multiple WHO strategies and work plans in some way address laboratory services or their clinical and/or public health functions. These include specific communicable disease control and blood safety programmes, the Global Influenza Surveillance and Response System (GISRS), the Global Foodborne Infections Network (GFN) and WHO's Department of Global Capacities Alert and Response (GCR). Two examples of such cross-cutting strategies are the WHO Laboratory Biorisk Management Strategic Framework for Action 2012–2016 and the draft health laboratory strengthening strategy 2013–2017. Regional work in this area includes a WHO Regional Office for Africa strategy guided by Regional Committee for Africa resolution AFR/RC58/R2 and working paper AFR/RC59/WP/3; the 2010 Asia Pacific Strategy for Emerging Diseases; and the Asia Pacific Strategy for Strengthening Health

Laboratory Services (2010–2015). There is therefore no single WHO global strategy in this area, but rather multiple relevant documents.

In discussion, addressing the gaps in existing strategies was focused on. These include: (1) distinguishing between patient care and public health surveillance; (2) the role of contingency plans for health care crises within the country; (3) poor recognition of patient-centred services, such as how tests will be linked to, for instance, a counselling service; (4) the quality of laboratory service delivery (which is often unintegrated) and reporting on adverse events; and (5) the role of laboratory accreditation and International Organization for Standardization (ISO) standards, which provide an existing forum for harmonization.

2.2 Public health laboratory situation analysis

Public health laboratory facilities and diagnostic capacities are unevenly distributed across the Eastern Mediterranean Region. Most countries have bacterial diagnostic capacities that require updating of equipment and techniques, while only a few countries have some limited capacity for viral infection diagnostics. Some countries have no central public health laboratory capacities and depend on teaching hospital laboratories or WHO collaborating centres for these functions. Furthermore, infectious substance shipping is a problem due to long delays, embargoes and lack of available contracts. Laboratory networks exist in the Region for vertical programmes including polio, measles and rubella, global invasive bacterial vaccine preventable diseases (IB-VPD), influenza, tuberculosis (TB), malaria, HIV and blood safety.

Facility challenges include issues around human resources, facilities, equipment, reagents and supplies, and shipping systems. System challenges include questions of ownership and advocacy, resulting in inadequate support from higher authorities (for example, no allocation of funding to laboratories as part of a health budget) and implementation gaps. These gaps include lack of position description and poorly-identified roles and authority for quality and biorisk managers, a lack of designated laboratory funds for laboratory quality management systems and insufficient biorisk management activities, national external quality assessment programmes and national continuous training programmes.

Key issues identified in discussion included finding resources, promoting leadership, empowering laboratory directors and negotiating sustainable budgets. Alongside advocacy, it was noted that responsibility needs to be assigned throughout the system up to senior leadership level in order to ensure sustainable long-term commitment to laboratories. As an example, it was noted that quality management systems in the Region are not working as well as they should due in part to a lack of resources and support for training and implementation.

It was felt that promoting achievements and providing evidence of how a strong laboratory can benefit medical services should be done, and that highlighting success stories could help motivate change. There was agreement that the strategy should promote a broad base rather than a vertical approach. It was felt that partner funding for specific activities in

countries should rather support the existing strategic plan for the Region rather than simply meeting donor needs.

It was suggested that WHO could provide guidance to countries on public health laboratory involvement in external quality assurance programmes, similar to the inspection and certification of national polio laboratories every year, and the possibility was raised of expanding similar activities to ensure that external quality assurance is extended to all testing.

2.3 Vision, action-oriented guidance and priority areas

The group discussed the vision for the strategy and agreed upon the following:

“In the Eastern Mediterranean Region, health laboratory services are comprehensive, sustainable and able to report safe, accurate, timely and reliable test results for use in clinical and public health settings.”

Considerations for the development of strategic plans include identifying the current status of the system, the stakeholders, the challenges/barriers and the steps required to carry out the plan. The plan’s goals should be a broad statement of intent, its objectives should be what will be done towards that intent, and the activities specified should refer to who will do what and when. This should be further broken up into tasks and subtasks, and adopting a SMART approach (i.e. ensuring that the objectives and activities are specific, measurable, achievable, relevant and time-bound) is recommended.

A number of suggestions were made about the way forward. These included grouping topics in order to limit the number of goals (ideally between three and five) and the importance of indicators, including for regional offices, was noted. There was discussion over the consistent use of terminology, and it was agreed that the categories used should include strategic goals, objectives, activities and expected outcomes.

It was emphasized that the guidance on strategic planning will be used by countries as a basis for their own strategic plans, and that the strategy should provide guidance in this respect. While the IHR (2005) are a common denominator, there is flexibility in country priorities. In this light, it was suggested to develop broad statements that can be adapted by countries who will determine what activities and tasks they need to undertake to move towards these goals. The overarching goal might, for instance, be to meet the health priorities of individual countries.

2.4 Challenges and priority needs in blood safety

While blood transfusion is a multiple-step process, only some of these steps take place within the laboratory system. There have been a number of blood system reforms in many countries, driven by a response to the risk of HIV transmission through the blood supply. Challenges include: inefficient blood supply structures (infrastructure and human resources); increasing needs, blood shortages (with rates lowest in developing countries), inequitable

access, fragmentation, high prevalence of HIV and hepatitis, and high losses through collection from unsuitable donors or poor storage and transportation; weak quality systems; risk of transfusion-transmitted infections due to lack of standards for donor selection and varying blood screening coverage between and within countries; inappropriate use of blood products due to inadequate training and lack of hospital infusion committees; and unsafe transfusion practices.

One core area of WHO's work in this area is the global and regional analysis of data for the Eastern Mediterranean Region. Validated quality data collection is often problematic, though some countries have moved towards a more nationally-coordinated system due to HIV or hepatitis concerns and the World Bank has identified blood safety as a priority for several years. Other key issues include the need for organization and management of collection and testing processes, good quality system processes, separate institutions and investment in donor selection and education.

Promoting participation in external quality assurance (EQA) schemes is recommended as an important part of improving laboratory performance. National strategic plans have proved very useful in countries such as South Sudan, as this provides sustainable long-term systems development rather than ad hoc support. Collaboration with laboratory strengthening is essential. Additionally, where donor funding exists, this can also be a strong driver for change at the national level as well as in international advocacy.

Essentially, the strategies being discussed for laboratory strengthening are not very different from those being followed by blood transfusion experts. Many of the hurdles faced in blood safety and laboratory capacity are similar, and the strategies adopted by the WHO programme on Blood Transfusion Safety are useful across the board. There are, however, two different perspectives in play: one addresses generating a product for test in a laboratory and the other addresses the use of the product in a clinical setting. In attempting to unify blood safety and laboratory capacity in a single document, it is important to ensure that both perspectives are addressed. Conversely, there will be some redundancy if the two are addressed in separate documents. However, given that several elements of blood safety are not within the remit of health laboratories, a separate regional strategic plan for blood safety will be needed.

2.5 Global impact of the emergence and spread of vector-borne diseases and the importance of international networks

The European Network for Diagnostics of "Imported" Viral Diseases (ENIVD) is a European Commission-funded network to exchange information and diagnostic capacities with respect to viral threats. ENIVD members meet regularly with representatives from the European Commission and WHO to exchange and gather information for the improvement of collaboration and diagnostics in "imported" viral diseases in Europe, because sharing duties and strengthening collaboration will help to enhance the emergency preparedness in all participating countries.

Key network tasks include: (1) building a network of European laboratories working on diagnostics of “imported” and rare viral infections; (2) identifying those viral infections more likely to be imported, co-ordinating the objectives and identifying laboratories capable and willing to perform the rapid diagnostics (< 24 hours) of an acute case suspected to be viral haemorrhagic fever; (3) working out recommendations for standardization and quality control in laboratories involved in the diagnostics of such diseases; (4) identifying and operating standard assays according to defined quality control criteria; (5) optimizing limited resources by exchanging reagents, methodologies and expertise; (6) encouraging regular contact within the network through meetings and exchange of laboratory personnel; (7) opening the network for members of other European laboratories; and (8) organizing and coordinating international activities with the surveillance network group and other national organisations such as Centers for Disease Control and Prevention (CDC), or international organizations such as the European Centre for Disease Prevention and Control (ECDC) or WHO. ENIVD provides advice and support to the ECDC in questions related to laboratory diagnostics, and has recently widened its core competencies to include activities in the area of network secretariat and information management, epidemic intelligence, support and training, and preparedness.

In discussion, the issue of the acquisition of quality reagents and how these could be validated for rarely-occurring diseases was raised. It was felt that in an emergency, laboratories must take what they can get, but that expert laboratories should always be involved. It was noted that there are many challenges in dealing with the unknown, and that the accreditation structure is one way to address this. Involved laboratories will have their processes accredited, documented and reviewed so that they are not “starting from scratch” in an emergency situation.

2.6 Monitoring and evaluation

The WHO uses a results-based management framework as a systematic way to monitor performance. A results chain that includes inputs, activities, outputs, outcomes and impact, links WHO’s work to the health and development changes to which it contributes, both in countries and globally. In this way, WHO’s outputs are directly linked to the health outcomes and impacts that WHO aims to achieve.

WHO uses indicators that are SMART and that focus on process, output and outcomes. Relevant indicators for health laboratories include those identified under alert and response capacities for the WHO General Programme of Work 2014–19 and the Programme budget 2014–15. Other relevant indicators include the laboratory indicators on the IHR (2005) core capacity questionnaire, those used for the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) at national and regional levels, those used in the Asia Pacific Strategy for Emerging Diseases (2010), and those used in the WHO Laboratory Assessment Tool. A key challenge is the alignment of the different indicators associated with these various processes.

In discussion, it was noted that the work that had been done to align these various indicators had been fairly limited so far, with the possible exception of disease-specific programmes. It was pointed out that a more elaborate tool that allows examination of the causes of problems is very useful in gap analysis, whereas most existing tools tend to be more like checklists and cannot point to why something is absent or not functioning. It was suggested that some difficulties come from losing sight of functionality, and that ideally indicators should specifically address what one would like the system to achieve. It was also observed that process indicators are important (as opposed to immediate output), and that it is necessary to reflect this when looking at milestones. It was suggested that countries should look to evidence of progress, as well as public health impact.

3. Country presentations

3.1 Egypt

In Egypt, the public health laboratory system has three levels: rural, district and general hospital/governorate. The central public health laboratory is the national reference laboratory and supervises governorate laboratories. It has both technical and administrative departments, offering preventive and diagnostic laboratory services, and coordinates the quality assurance programme for most laboratories in general and district hospitals. It also supervises the work of governorate central laboratories and general, fever and chest hospital laboratories, as well as providing technical support and training for staff, and addressing standardization of laboratory methodology and approving licenses.

Key challenges that have been identified include a lack of planned continuing education programmes, poor capacity to maintain equipment, limited financial resources for supplies and maintenance, a need for the laboratory network to be harmonized and integrated, and that although the central public health laboratory, as a reference laboratory, should supervise all Ministry of Health and Population laboratories, this is not being done in practice. Legislation and regulation in support of laboratory services needs to be revised and updated, private medical laboratories should be gradually covered by a legally-obligatory quality management or quality assurance programme and the EQA programme should be extended to cover all medical laboratories. It is also recommended that national quality assurance programmes be extended to cover all laboratories in Egypt, implementation of internal quality control in laboratories occurs at all levels and a public health laboratory network is established. Additionally, there should be continuing training and education for all staff categories and training courses to improve computer skills in the main laboratories at the different levels in governorates.

3.2 Jordan

Jordan has over 800 laboratories, 290 of which are managed by the Ministry of Health. The vision of the laboratory directorate is to ensure and sustain medical clinical and public health laboratories with competent staff and good quality equipment, instruments and diagnostic materials that can contribute to the provision of good quality health care. There is

a public health laboratory plan for surveillance and response, and diagnostic capacity within the various laboratories. The strengths of the health laboratory system in Jordan include a highly educated and experienced central public health laboratory staff producing trustworthy laboratory results. Central public health laboratory staff has gained much experience in surveillance, particularly through the influenza-like illness (ILI) and severe acute respiratory illness (SARI) surveillance projects. In addition, there are well-equipped laboratories and experienced teams that monitor and evaluate the implementation of quality assurance (QA) and biorisk management in all Ministry of Health laboratories using well-designed checklists. Furthermore, excellent cooperation and communication exists between central public health laboratory leaders and the relevant international organizations, and full cooperation and coordination takes place with the communicable disease directorate.

However, challenges remain including a lack of appreciation of the value of laboratories by health policy-makers, coupled with inadequate access by the laboratory leadership to key decision-makers and an absence of laboratory leadership at the governorate level. There is also a lack of inter-ministerial cooperation and coordination, and weak involvement of other sectors in public health issues. Insufficient awareness on the core elements of the pre-analytical phase (the selection, collection, preservation and transportation of specimens) is another issue. High staff turnover and a lack of resources to introduce new technologies and to sustain the availability of kits and materials remain challenges. Given this situation, the recognition of the role of laboratories in the health care system by top national authorities and policy-makers, accompanied by a commitment to provide the needed human and financial resources, are the key to successfully establishing, maintaining and improving the quality of the public health laboratory system in the country.

3.3 Oman

Within Oman, there are laboratories run by the Ministry of Health, by governmental sister institutions such as hospitals and polyclinics, and by other government ministries (non-clinical), as well as private laboratories within hospitals, polyclinics and clinics. The central public health laboratory is the main reference laboratory in Oman, focusing mainly on infectious diseases. It serves the Region and neighbouring countries for the Regional External Quality Assessment Scheme (REQAS), measles/rubella, TB and polio.

Within the system, there are gaps in the area of analytical capabilities, human resources, legislation and infrastructure. Priority needs include: legislation; a laboratory information management system (LIMS); training and capacity-building; development of quality management manuals; EQA and accreditation; purpose-built infrastructure; human resource development; and financial investment in laboratories.

3.4 Discussion

The role of leadership, governance, coordination and collaboration, and the need to identify stakeholders and target audiences, were all discussed. There was a sense that lack of organization is a problem within the Region, and that with better organization more can be

accomplished between countries and internationally. While there is a desire not to place too much emphasis on single disease laboratories, there is much to be learnt from the way in which these programmes have tackled the problems of capacity and equipment, as well as sample transportation, quality assurance schemes and cooperation between countries and laboratories. It was also noted that the importance of twinning should be reflected in the strategy, given the wide spectrum of capabilities within the Region. Given the differing financial resources available in countries of the Region, the strategy should be a flexible document which can be used according to country needs. Other key issues identified include gaps in reporting and follow-up systems, the role of LIMS, common problems such as lack of basic machines, supplies being provided without training, poor distribution of resources and gaps in the description of minimal standards. The importance of adopting a stepwise approach in addressing these gaps was stressed.

4. WORKING GROUPS

There was group discussion of the strategic goals for the public health laboratories strengthening strategy. Three working groups were assigned to review the development of strategic goals, objectives and activities across the following eight priority areas:

1. developing and strengthening leadership structure
2. human resources/ laboratory workforce
3. laboratory services (public health and diagnostic capacity)
4. biorisk management
5. quality management system development
6. networking (in-country and among countries) and coordination
7. the role of partners
8. funding (mapping opportunities and optimizing to meet regional and country needs).

One group suggested combining these into the following five strategic goals: (1) to strengthen the organizational structure of national laboratory systems and empower leadership; (2) to establish sustainable, sufficient and competent human resources for laboratory service delivery; (3) to ensure a safe, secure laboratory environment; (4) to implement quality management system practices in all health laboratories; and (5) to promote effective networking of laboratories with public health responsibilities both in-country and among countries.

The outcomes of these discussions, including the strategic goals, objectives and activities proposed by the three separate groups, can be found in Annex 3. These will be used as a basis for development of the strategy. The discussions on each goal are summarized below.

Strategic goal 1: Developing and strengthening leadership structure

There was agreement that this is a key goal, with substantial discussion about the best structure that might promote this. While one group proposed a structure within the ministry

of health, other groups were not as clear about this, some feeling that laboratory structure should not be linked to ministry of health bureaucracy. A question was raised as to whether a CDC model, with an external laboratory under ministry of health control, might be better, as some countries are moving towards this. Another possibility raised was that of an inter-ministerial council which would bring together the role of an advisory committee and a focal point for laboratories in all sectors contributing to public health functions.

There was discussion on promoting visibility through national advisory committees. However, there was also a strong sense that having a focal point within the ministry capable of advocacy and communications is critical, and that the strengthening of leadership and management requires a responsible person to ensure that plans and policies are brought about. This would help move towards a concept of the laboratory as a genuine partner in health delivery. While committees are important, they lack a budget or line authority to manage, and are ineffective without a focal point and assigned responsibility. Furthermore, such committees have often been found to be unsuccessful because they are often made up of clinicians who lack understanding about public health laboratories. In this regard, it was pointed out that while Oman has a national committee for laboratories, the functioning is poor and lines of reporting are unclear. It was recommended that multiple options might appear in the strategy for flexibility, as national laboratory systems are in different stages of maturity throughout the Region.

Similarly, there were some differences of opinion on the links between focused programme support and broader laboratory advocacy. Some participants felt that individuals within the programmes that the laboratory supports could best act as advocates; others felt that, as a sole strategy, this was inadequate. There was some discussion of comparative systems, such as the American CDC and National Institutes of Health (NIH), which encompass many stand-alone laboratories, the highly-centralized French system, and the system in Pakistan where these functions are devolved to provinces.

Another key issue raised was the inability of some countries to buy quality reagents, and the fact that it is important to look at changes in national procurement structures which would address this.

Strategic goal 2: Human resources/laboratory workforce

It was felt that the laboratory workforce needs continual training. The issue of addressing training within outsourced activities, such as cleaning staff, was raised. The example was given that while specimen handling is crucial, it is more often an issue of quality assurance processes than technical training, so root cause analysis needs to be applied in defining the appropriateness of a training intervention. Further discussion pointed out that the document will be too high-level to provide detail about which staff are to be trained, and also that all staff (not just laboratory but clinical, administrative and programme) matter with respect to ensuring good quality testing and patient care. This highlights the need for cross-training among staff.

A distinction was drawn between an emphasis on the (pre-service) education system and matters of job satisfaction and motivation for current staff. Career development and the “professionalization” of laboratory work were viewed as a key issue. It was noted that the sense of making a contribution to community health is an important component of staff morale and retention. The importance of communication as a tool to educate clinicians and public health professionals was also emphasized.

Strategic goal 3: Laboratory services public health and diagnostic capacity

It was pointed out that it will be necessary to have communication for disease control at the animal-health interface, in order to adequately address zoonotic diseases. It was suggested that specimen transport and data management across both ministry networks and national borders poses serious issues for many countries, and that laboratories should play a more central role in the strategy.

Strategic goal 4: Biorisk management

It was noted that strategies have been developed on referral structures for moving infectious disease specimens, and that it is important to bring this together with specimen transport in addressing safety and biosecurity. It was suggested that the need for awareness by all staff working in laboratories, including cleaners, and clear risk assessment, requires an official with this responsibility; ideally, a microbiologist (though it was suggested that the strategy cannot specify the discipline). Comments on responsibility noted that while this always rests with the laboratory director for biorisk, in practice some activities will be delegated.

Strategic goal 5: Quality management system development

Quality assurance is at the heart of the issue, in that the laboratory provides information for action and with mistakes or failure, the credibility of the laboratory system is at stake. The goal of accreditation must be incorporated into the strategic plan, even though cost remains a concern. The strategic plan should include a message that a functional system for quality assurance assures that a test is performed correctly the first time and is therefore a cost-efficient approach since it reduces repeat testing and potential misalignment of health programme resources.

Leadership (goal 1) is required to ensure that a quality management system is a key component of the accreditation process. A whole-government approach regarding accreditation of laboratories will help ensure that there will be a greater chance of acceptance. It was noted that the accreditation system can be stepwise; this is an approach that many laboratories have implemented. Ideally, the national strategy would ensure consistency and sustainability of laboratory quality. An accreditation body within the Region, as for other vertical programmes, would be useful.

Strategic goal 6: Networking (in-country and among countries) and coordination

Participants stressed the need for greater clarity as to whether this goal and related activities refer to an LIMS or to sharing information across a network. It was agreed to ensure access to testing capacity in resource-constrained countries and strengthening of public health capacities. In this regard, national/regional/global reference capacities should be mapped and fully utilized through networking.

Strategic goal 7/8 (merged): Role of partners and funding (mapping opportunities and optimizing to meet regional and country needs)

It was noted that partners and donors/funders must be involved early in the process of laboratory strategic planning. Donor engagement is necessary to ensure the appropriate understanding of unique laboratory needs and the considerations that impact the outcomes of proposed initiatives and activities that rely on laboratory input. Too often delayed involvement leads to unforeseen costs and missed opportunities to leverage across programmes and networks. It was suggested that this goal be incorporated into the first strategic goal.

Discussion outcomes: Strategic goals, objectives and activities

The outcomes of these discussions, including the goals, objectives and activities proposed by the three separate groups, can be found in Annex 3.

5. ROADMAP FOR OPERATIONALIZATION OF THE STRATEGIC PLAN

The anticipated milestone dates for operationalization of the strategic plan on public health laboratories and on blood safety are set out below in Table 1 and were accepted by the meeting.

Table 1. Roadmap for operationalization of the strategic plan

Strategic plan on public health laboratories		Strategic plan on blood safety	
Action	Dates	Action	Dates
Develop draft plan	15 January 2014	Develop concept note	January 2014
Feedback	15 February 2014	Expert consultation meeting	March 2104
Collection and collation to finalize draft	March 2014	Collection and collation of comments to finalize draft	May 2014
Finalize document during an intercountry meeting	May 2014	Present final draft during intercountry meeting	June 2014
Final approval of plan	May 2014	Final approval of plan	July 2014
Preparation of paper for the Regional Committee	June 2014	Preparation of paper for the Regional Committee	June 2014
Adoption by the Regional Committee	October 2014	Adoption by the Regional Committee	October 2014
Implementation phase	Begins end 2014	Implementation phase	Begins end 2014

In discussion, it was noted that it will be important to have references to blood safety and to clinical laboratories in the introduction. While the scope of the strategy will be laboratories with public health functions, there should be no guidance contrary to clinical or public health laboratories or to blood transfusion. It was understood that a similar strategy will be developed for blood safety. Links and obligations under the IHR (2005) should form part of the discussion.

6. RECOMMENDATIONS

To WHO

1. WHO should finalize the strategic public health laboratory plan for review and adoption by the Sixty-seventh Regional Committee for the Eastern Mediterranean for implementation in Member States.
2. Strategic plan activities should be prioritized to achieve the goals.
3. WHO should publish and disseminate the framework plan and support countries in the implementation of the document entitled “Stepwise implementation of health laboratories quality management system in the Eastern Mediterranean Region: essential criteria and implementation strategy”.
4. WHO should provide advocacy and technical support to countries for implementing national strategic policies and plans according to national priorities.
5. Given that several important systemic elements of a national blood system are not part of the health laboratory, it is recommended to develop a specific regional strategic plan for blood safety and self-sufficiency.
6. In settings where part or all functions of a national blood system are implemented by health laboratories, the policies, principles, systems and practices applicable to health laboratories should also be applicable to blood transfusion laboratories.

Annex 1**PROGRAMME****Monday, 9 December 2013**

08:30–09:00	Registration	
09:00–09:50	Opening session: Address by Dr Ala Alwan (via video conference), WHO Regional Director for the Eastern Mediterranean Introductions of participants and selection of Chair Objectives of the Meeting and adoption of the Programme	
09:50 – 10:10	WHO global and regional public health laboratory strengthening strategies	<i>Dr S. Cognat</i>
10:10 – 10:30	Public health laboratory situation analysis in the Eastern Mediterranean Region	<i>Dr H. Asghar</i>
11:00–11:40	Country presentation on status of public health laboratory networks: – Egypt – Jordan – Oman	<i>Dr M. Rakha Dr A. Haddadin Dr S. AL-Busaidy</i>
11:40 – 12:30	Vision for public health laboratory in the Eastern Mediterranean Region	<i>Dr H. Asghar</i>
12:30 – 13:00	Action oriented guidance-strategic planning for success	<i>Dr R. Martin,</i>
14:00–14:20	Possible strategic goals	<i>Dr H. Asghar</i>
14:20 – 17:00	Setting strategic goals for action	<i>Chair</i>
17:00 – 17:30	Summary of the day	<i>Rapporteur</i>

Tuesday, 10 December 2013

08:30 – 09:00	Introduction to Group Work	<i>Dr H. Asghar</i>
09:00 – 17:00	Strategic goals	<i>Group discussion</i>
17:00 – 17:30	Summary of the day	<i>Rapporteur</i>

Wednesday, 11 December 2013

08:30 – 09:15	Other priority areas: Blood safety	<i>Group discussion</i>
09:15 – 10:30	Plenary Session: Group presentations on outline of strategic plan.	<i>Rapporteur</i>
11:00 – 13:00	Plenary Session: Group presentations on outline of strategic plan.	<i>Rapporteur</i>
14:00 – 14:20	The global impact of the emergence and spread of vector-borne diseases and the importance of international networks.	<i>Dr M. Niedrig</i>
14:20 – 14:40	Monitoring and evaluation at process, output and outcome level	<i>Dr S. Cognat</i>
14:40 – 15:00	Draft roadmap for operationalization of the strategic plan	<i>Group discussion</i>
15:30 – 16:30	Conclusion and provisional recommendations	<i>Dr H. Asghar</i>
16:30	Closing session	

Annex 2

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Annex 3

OUTPUTS FROM WORKING GROUPS

Strategic goals, objectives and activities for a regional public health laboratory plan		
Goal	Objectives	Activities/outcomes
<i>Strategic goal 1: Developing and strengthening leadership structure</i>		
Group 1 To strengthen the organizational structure of national laboratory systems and empower leadership	<p>Establish a focal point at the ministerial level for national laboratory services</p> <p>Analyse the current environment for laboratory service delivery</p> <p>Develop a national health laboratory strategic plan</p> <p>Strengthen leadership and management</p> <p>(former goal 7/8) Establish and sustain adequate funding for laboratory services</p> <p>(former goal 7) Strengthen partnerships for technical and financial assistance</p>	<p>Engage WHO in advocacy to support establishment of the focal point</p> <p>Establish a national laboratory authority/advisory body</p> <p>Assess/map the current infrastructure of the laboratory system</p> <p>Determine the current legislative and regulatory framework for laboratories</p> <p>Establish licensing mechanisms</p> <p>Identify stakeholders</p> <p>Develop a planning committee</p> <p>Identify appropriate roles and responsibilities for leadership</p> <p>Identify specific needs in leadership (gap analysis)</p> <p>Identify available resources/programmes</p> <p>Ensure laboratory services form part of the national health budget</p> <p>Develop a business case model for laboratory funding</p> <p>Identify potential partnerships and stakeholders</p> <p>Engage laboratory directors from planning through implementation (total process)</p> <p>Develop MoUs or equivalent involving the laboratory to assure mutual understanding and stability</p> <p>Identify twinning partners</p>
Group 2 Developing and strengthening leadership structure	<p>Establish an independent intersectoral organizational committee which oversees laboratory services to ensure appropriate access, diagnostic capacity and quality, and reports to ministry of health</p>	<p>Define membership and terms of reference (ministry of health, other ministries, professional associations, public health professionals, laboratory scientists, etc.).</p> <p>Develop/update and enforce laws, regulations on:</p> <ul style="list-style-type: none"> • Diagnostic capacity, including reference laboratories for priority diseases, diseases notification mechanisms • Quality human resources <p>Expected outcome: Clear mechanisms to ensure quality</p>
Group 3 Developing and strengthening leadership structure	<p>To persuade high-level executive/administrators of the importance of laboratories and providing support in policy and resources</p>	<p>Establishment of national laboratory committee in the country (chaired by Minister)</p> <p>WHO appraise successful countries (in meetings/by formal letter)</p> <p>Outcome:</p> <ul style="list-style-type: none"> • National committees • National policy establishment • Formal appraisal letter from WHO • Inclusion on Ministerial agenda of laboratory issues

Strategic goal 2: Human resources/laboratory workforce

Group 1 To establish sustainable, sufficient and competent human resources for laboratory service delivery	Establish human resources policies for sufficient competent staff to manage laboratory services Develop a system for staff recruitment for laboratory services Develop a system for education Develop a system for training and competence Develop a system for retention of staff in laboratory services	Review existing best practices and procedures in human resource management Draft human resources policy for laboratory staff Establish standardized position descriptions Assess existing capacity against needs Carry out needs assessment via workforce mapping Prepare a staff recruitment plan Assess existing capacity against needs Evaluate existing educational programmes and courses in laboratory sciences, technology and medicine Identify stakeholders, e.g. Ministry of Education, universities, international institutions Assess existing capacity against needs Identify category of staff to be trained Carry out competency assessment Promote career development/structure Link training with incentive mechanisms
Group 2 Human resources/laboratory workforce	Train an appropriate laboratory workforce as well as clinicians and public health professionals on the rational use of laboratory services Require minimal qualifications for laboratory scientists for laboratory registration or licensing including for private laboratories Ensure continuing education for all professionals including private laboratories	Review/improve/define education curricula and qualifications standards Identify training needs through continuing review process Explore reward/motivation/incentive and compensation mechanisms and continuing education to ensure staff retention Elevating the position of laboratory staff to their proper place in the public health/health care system Outcome: staff motivation and retention
Group 3 Human resources/ laboratory workforce	Enhance the importance and competency of laboratory personnel Capacity-building for laboratory personnel	Impart training on technical and quality parameters in the higher education system (university level) for the relevant degree courses Adjust laboratory licensing system to incorporate capacity-building and training Enhance the role of laboratory directors to build competent laboratory personnel through annual performance evaluation and training plans, especially for new work Promote and support local recruitment

Strategic goal 3: Laboratory services public health and diagnostic capacity

Group 2 Laboratory services: public health and diagnostic capacity	Ensure that diagnostic capacity meets national needs, especially public health needs	Define structure of national laboratory services with clear roles and responsibilities, with an emphasis on public health functions (e.g. clear policy for designation of national reference laboratories) Establish clear networking, referral and reporting mechanisms through a tiered system with a particular emphasis on the importance of a regulated and functional/modernized/systematized specimen transportation system Ensure maintenance and updating of facilities and equipment Improve supply chain
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Group 3 Laboratory services	<p>Ensure reliable test results of laboratories for both public and private</p> <p>Ensure effective control of disease originating from animals</p> <p>Strengthen technical aspects of the procurement system</p> <p>Share information regarding laboratory results among countries</p>	<p>Motivate laboratory accreditation</p> <p>Incorporate corrective actions and training for EQA outliers</p> <p>Coordinate, cooperate and communicate with other ministries regarding zoonoses</p> <p>Inclusion of technical requirements and evaluation of scientific supplies (procurement)</p>
<i>Strategic goal 4: Biorisk management</i>		
Group 1 To ensure a safe, secure laboratory environment (This group operated under the assumption that an Office of Health and Safety exists or will be established and that reference documents such as Laboratory biorisk management: strategic framework for action 2012–2016 (WHO/HSE/2012.3) will be utilized.	<p>Ensure a safe working environment</p> <p>Ensure a secure facility</p>	<p>Develop national policies and procedures/guidelines, with a safety officer at an institutional level</p> <p>Establish a laboratory safety officer position description</p> <p>Develop risk-based national policies on biosecurity</p> <p>Establish a biorisk manager position description</p>
Group 2 Biorisk management	<p>To prevent accidental or deliberate release of infectious agents</p> <p>To protect laboratory workers and community</p>	<p>Define, recognize and value biorisk management duties in job descriptions</p> <p>Conduct risk assessment at each facility level</p> <p>Update/establish regulations</p> <p>Ensure adequate physical infrastructure is in place and maintained</p> <p>Ensure pre-service and in-service training</p>
Group 3 Biorisk management	To implement biorisk management the country with a proper strategic plan	<p>Awareness created at all personnel levels</p> <p>Assigned responsibility (terms of reference) to biorisk management officer</p> <p>Structure of appropriate equipment and facilities, and for seeking support, in place</p> <p>Establishment of procedures</p> <p>Training of personnel in biorisk management</p> <p>Establishment of system and procedure for transferring of microorganisms at different levels</p>
<i>Strategic goal 5: Quality management system development</i>		
Group 1 To implement quality management system practices in all health laboratories	<p>Ensure national organizational infrastructure for establishing and implementing standards and guidelines</p> <p>Ensure processes for reviewing laboratory function are in place</p> <p>Develop national accreditation standards</p>	<p>Develop national laboratory and testing standards and guidelines</p> <p>Establish and implement national accreditation/certification or equivalent processes</p> <p>Carry out initial review of elements of Stepwise implementation of health laboratories quality management</p>

		systems in the Eastern Mediterranean Region: essential criteria and implementation strategy, against local conditions
	Establishment of quality assurance office/officer	Create position description for quality assurance officer Determine appropriate staffing
	Implement quality management system practices	Provide quality management system training and competency assessment Ongoing monitoring and evaluation of implementation
	Improve procurement/equipment maintenance processes	Establish an effective process that utilizes quality specification for the purchase of supplies and equipment Establish a process for maintenance contracts Identify ownership and responsibility for equipment and its maintenance Review with WHO the establishment of regional capacity for equipment maintenance and repair
	Improve supply chain management	Establish a process for acquisition of validated reagents Assure proper importation and storage and adequate distribution of materials
Group 2 Quality management system development	None agreed	Implement the recommendations of the 2012 regional workshop on strengthening health laboratory quality systems (establishment of national quality committee and focal points, development of national standards according to WHO guidelines, organization of training activities) Implement quality assurance measures, including quality manuals and proficiency-testing programmes as a priority WHO pre-qualification of diagnostic kits/regulation of diagnostics “Envisage accreditation to internationally recognized standards as ultimate goal” (no agreement on this statement) Expected outcomes: <ul style="list-style-type: none"> • Evaluation of laboratory performance • Reliable and timely laboratory results
Group 3 Quality management system development	To implement quality management system/national standard/international standards at all levels of laboratories	Establishment of national standards and their implementation, and encouragement towards international standards Management support in policy and resources sought for Personnel assigned with responsibility for the quality system Training of quality system or standards concept prior to implementation Use of stepwise implementation Accreditation sought for For measurement purposes, the indicators will involve looking at internal audit, involvement of management and feedback from stakeholders
<i>Strategic goal 6: Networking (in-country and among countries) and coordination</i>		
Group 1	Assist resource-limited countries to establish or strengthen their national public health laboratory networks	Develop policy, procedures and testing algorithms Develop guidelines and training materials on specimen collection and transport Use LIMS within and across laboratories and surveillance systems

	Support regional and global networks	<p>Identify regional and global reference capacities</p> <p>Develop streamlined regulatory process for material transfer</p> <p>Organize regular meetings</p> <p>Facilitate training activities</p> <p>Promote technology transfer</p> <p>Facilitate access to reagents or protocols</p> <p>Support specimen-sharing across networks, through pre-agreed MoUs</p>
Group 2 Networking (in-country and among countries) and coordination	Ensure access to testing capacity when local or domestic capacity is not available, especially for disease or events of public health concern	<p>Map testing capacity and quality at national and regional level</p> <p>Establish national and regional referral systems</p> <p>Explore establishment of a regional network for diseases not covered by existing networks</p> <p>Expected outcome: Reliable and timely results</p>
Group 3 Networking (in-country and among countries) and coordination	<p>Strengthen existing networks to be fully functional</p> <p>Establish new network wherever necessary</p>	<p>Fully functioning level of networking regarding surveillance systems and other activities:</p> <ul style="list-style-type: none"> • Reporting of results • Confirmation of results • Sharing of information • Training of personnel • Networking for EQA • Monitoring of networked laboratories <p>Networking with other stakeholders in both governmental and private organizations</p> <p>Making use of successful networks for other activities</p> <p>Consider role of information technology within the network for efficient cooperation</p> <p>(Include twinning)</p>
<i>Strategic goal 7: Role of partners</i>		
Group 2 Role of technical partners	Partners facilitate the work of the public health laboratories	<p>Identify needs</p> <p>Map existing partners at national, regional and global level:</p> <ul style="list-style-type: none"> • Training/academic institutions, professional associations • Partners for transportation of specimens (courier companies) • Referral networks • Commercial in vitro diagnostic testing • Providers of proficiency testing <p>Identify additional partners to fill gaps</p> <p>Ensure coordination of partners by Ministry of Health/WHO, information-sharing and trust among them</p> <p>Expected outcome: Functional laboratories and networks</p>
Group 3 (7 and 8 combined)	<p>To match the requirements of Member States and donors in the assistance project</p> <p>To provide WHO with a more effective mechanism to align Member State needs and donor objectives</p>	<p>Countries prepare pre-defined projects and regularly update them</p> <p>WHO establishes a procedure to ensure assistance meets not only donor objectives but also country needs</p> <p>WHO establishes a guided estimated duration for project proposals and informs donors in order to have good and clear outcomes from projects</p>

Countries communicate with donors in order to create suitable projects for countries

WHO provides the priority area that needs assistance of the region and countries

Strategic goal 8: Funding (mapping opportunities and optimizing to meet regional and country needs)

Group 2

Public health laboratory activities are funded in a sustainable manner

Ministry of Health to allocate funds for networking and emergencies as part of the national disease surveillance system

Ensure technology improvement and access to appropriate technologies

Prioritize country/laboratory needs, make a calculation of the costs, implement successfully and communicate success before expanding

Expected outcome: Recognition that the laboratory plays an integral role in public health



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