Summary report on the

WHO-EM/LAB/393/E

Second intercountry meeting of the directors of public health laboratories in the Eastern Mediterranean Region

Muscat, Oman 31 October–3 November 2016



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1. Introduction

The intercountry meeting of the directors of public health laboratories in the Eastern Mediterranean Region was held in Muscat, Oman from 31 October to 3 November 2016. The meeting was attended by 48 participants, including representatives from 19 countries of the Region, temporary advisers, partner organizations and WHO staff. The objectives of the meeting were to:

- review progress and challenges in the implementation of the WHO regional Strategic Framework for Strengthening Health Laboratory Services (2016–2020) at regional and country level;
- review the current status of antimicrobial resistance surveillance in the Region with a view to early implementation of the WHO Global Antimicrobial Resistance Surveillance System (GLASS);
- discuss and agree on the way forward for development of the WHO
 Eastern Mediterranean Regional Emerging Dangerous Pathogen
 Laboratory Network (EMR-EDPLN); and
- identify mechanisms and tools for monitoring and evaluation of the implementation of the regional strategic framework for strengthening health laboratory services (2016–2020).

2. Summary of discussions

Session 1: overview: global and regional strategic guidance for health laboratory services

Participants were updated on the WHO work at global and regional (Eastern Mediterranean and Europe) levels to strengthen health laboratory services, particularly in the context of health emergencies.

The meeting noted with satisfaction that the strategic framework for strengthening health laboratory services (2016–2020) had been endorsed by the Sixty-third Session of the Regional Committee for the Eastern Mediterranean. Upon presentation and discussion of the current status of the implementation of the strategic framework from regional and country perspectives, the meeting concluded that baseline conditions of health laboratory services vary widely from country to country. Most countries have a solid foundation for successful implementation of the strategic framework. Countries should prioritize implementation based on their context and circumstances, with particular emphasis on quality management, biorisk management, and integrated, coordinated laboratory networks. Experience-sharing and communication among countries and at the regional level will help expedite the implementation of the framework and achieve better results.

Session 2: quality management systems and biorisk management

Session two was dedicated to discussion of selected priority issues in laboratory quality and biosafety. Oman gave a presentation on the experience of operating an external quality assessment programmes over a period of 12 years at both national and regional levels. The regional external quality assessment programme, co-funded by WHO, was established in 2005, and currently covers 35 laboratories in 20 countries of the Region. It includes bacteriology, serology and parasitology/mycology panels which are dispatched twice a year (in May and October). The programme is jointly administered by the Central Public Health Laboratory of Oman and the Reference Health Laboratory of the Islamic Republic of Iran; the latter prepares panels for parasitology/mycology and serology of HIV, hepatitis, B surface antigen (HBsAg) and hepatitis C virus (HCV) and evaluates their results. Panel composition, grading scores and trends in performance of participating

laboratories were discussed. The persisting problems faced by the programme included difficulties in preserving the viability of pathogens, no acknowledgment of specimen receipt and delay in result reporting by participating laboratories, delays due to customs procedures, and communication problems. To further improve service quality and obtain wider coverage, the programme is planning to train new staff, replace wet simulated samples with lyophilized samples, improve results analysis through dedicated software, and establish a website for online result reporting and feedback. The Central Public Health Laboratory of Oman also plans to apply for international accreditation ISO/IEC 17043 for proficiency testing scheme providers.

Oman further presented the locally developed health information system "Al-Shifa". The system is a good example of a sustainable solution for a national, comprehensive and fully integrated health information system.

The Islamic Republic of Iran presented its experience of the development of a national accreditation scheme for clinical laboratories. The scheme was established in 2007, when the Iranian National Laboratory Standard was officially endorsed and published by the Ministry of Health as a set of minimum quality requirements mandatory for all clinical laboratories. This was followed by the development of a strategic plan for the implementation of the standards that included setting up a governance and coordination structure and tools, human and institutional capacity building, and filed implementation activities. The country now has a pool of more than 400 assessors. A nationwide external quality assurance programme was established, in which laboratories have to participate at least three times a year. Currently the accreditation scheme is administered by the reference health laboratory; however, a guideline document titled Requirements for accreditation bodies was published in 2010, and organizations that are able to fulfil these requirements will be authorized to act as accreditation bodies.

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Tunisia presented its experience of establishing a biorisk management training programme through collaboration between the Ministry of Health and WHO. The programme started in 2010, when 12 local staff were trained as trainers in the WHO biorisk management advanced trainer programme. Since then, through a series of 25 training sessions, the programme has trained 389 technicians from both human and animal health sectors.

At the end of the session, WHO updated the meeting on the paradigm shift in laboratory quality and biosafety from reliance on a set of predefined solutions to a management-system approach. WHO assists countries in implementing this shift by facilitating the development of national regulatory frameworks and coordination mechanisms for quality and biosafety, providing resources and tools for and performing large-scale capacity-building activities both at the regional and national levels, and establishing monitoring and evaluation mechanisms for the performance of both individual laboratories and laboratory systems.

Participants then discussed the varying roles of central public health laboratories in different country contexts. It was stated that while some countries (such as Lebanon or Pakistan) do not have a formal central public health laboratory, others (such as Somalia) may have several central public health laboratories for each zone. The mechanisms for institutionalizing training courses, in particular those on infectious substances shipping, were also discussed.

Session 3: speeding up the implementation of the regional strategic framework: approaches and tools

Session 3 opened with two presentations reporting experiences with WHO's stepwise approach to laboratory quality management system implementation in Cambodia and Fiji. Both programmes demonstrated

visible improvement within a relatively short time (about two years). In Cambodia, the importance of mentors and a need to take into account cultural challenges in the working environment were emphasized. In Fiji, factors for success included strong and visible commitment by the Ministry of Health, the presence of quality champions at all tiers of the laboratory network, evidence-based planning and realistic budgets, the involvement of technical staff as equal partners, transparency in implementation, constant communication, and information sharing.

In small working groups, participants then discussed challenges and obstacles that could interfere with the implementation of the regional Strategic Framework, and recommended solutions that could be used to overcome these obstacles and speed up the implementation. Working groups' presentations revealed a wide variety of challenges faced by different countries, once again emphasizing the need for customized implementation plans adapted to specific country contexts and circumstances. Some common challenges included the lack of a coherent and comprehensive national regulatory framework for laboratory services, shortages in laboratory workforce and limited technical expertise for framework implementation, insufficient information about laboratory capacities and resources available in countries, and poor communication and coordination between agencies and across different sectors. Specifically in relation to biosafety, biosecurity and waste management, the working groups noted a lack of awareness and support from higher authorities, shortages in expertise and tools, and difficulties in converting newly learned knowledge and skills into systematic practical implementation. In terms of building laboratory networks and coordination, the working group noted difficulties related to coordinating and sharing resources and assets across sectors, the lack of coordination among the networks of different sectors/ministries, disease programmes or specializations (clinical

versus public health), poor network governance or a lack thereof, and non-existent or fragmented laboratory information systems.

The working groups emphasized the importance of streamlining the oversight and governance of laboratory services, with thorough representation from all concerned sectors, clearly defined roles and responsibilities, and communication cross-sector mechanisms. Components of national regulatory frameworks for laboratory services, such as national policy, strategic plans, quality standards or laboratoryrelated legislation should be developed with the involvement of all essential sectors, and have a shared ownership. An important step towards quality-assured and safe services would be the establishment of a management structure for quality and biosafety, such as networks of quality managers and biosafety officers at the peripheral (individual labs), provincial/regional (where appropriate), and national levels. All working groups stressed the continuous need for training and capacity building in various areas of laboratory system operations, and placed particular emphasis on the need to train and nurture laboratory managers at various levels to ensure they were equipped with the knowledge and skills necessary to run modern laboratories, laboratory networks and bigger laboratory services successfully. A pressing need for monitoring and evaluation mechanisms, with national and regional pools of trained staff able to perform laboratory assessments and other performance evaluation tasks as well as train others, was also stressed.

The working groups reflected on how to ensure laboratory services were given increased priority by government decision-makers, and on ways to improve and diversify funding streams and thus achieve sustainability of services. A suggestion was made to develop a business model for laboratory services to facilitate the ability of laboratory managers to engage in sophisticated financial discussions with national authorities, donors and development partners and to clearly articulate not only the

strategies any given laboratory or laboratory service would need to succeed, but also what this success would mean.

To ensure the availability of adequate numbers of trained and qualified staff with a well-balanced mixture of skills, participants suggested reviewing or developing workforce plans in the context of national laboratory policies (where they exist); developing effective human resource planning and management models specifically for laboratory services; introducing competency assessment programmes and mechanisms for compulsory registration or licensing of laboratory staff with regular license renewal; developing unified training curricula for pre- and in-service education; and adopting cascade training models.

Building effective regional and national laboratory networks will require the mapping of existing capacities, infrastructures and ongoing programmes, the willingness and readiness of selected countries to participate in a regional referral network or host one or more regional reference laboratories, and the establishment of regional laboratory database and networking tools (such as an online platform for information sharing).

WHO should play a multifaceted role in the process of implementing the strategic framework. In particular, the working groups suggested that WHO build capacity and provide guidance, tools and technical expertise, especially for advanced tasks or tasks not typically performed by most laboratory managers (such as policy or legislation development). It was also suggested that WHO should advocate for laboratory system strengthening, facilitate cross-sector communication, share best practices and success stories among countries, help with resource mobilization, and facilitate twinning with advanced laboratories and academic and research institutions. Countries with

laboratories that are potentially able to play a regional role will look at WHO for support in building their regional capacities.

Session 4: early implementation of the WHO Global Antimicrobial Resistance Surveillance System (GLASS)

Participants were updated on the alarmingly high resistance rates to commonly used antibiotics for a number of bacterial pathogens in the Region. GLASS was been launched by WHO as part of the implementation of the global action plan on antimicrobial resistance, and the data generated will help to inform national, regional and global decision-making, strategies, and advocacy, which demands multisectoral collaboration from clinicians, laboratory professionals, and epidemiologists in each country.

The role of laboratories in antimicrobial resistance surveillance was discussed. Laboratories play an essential role at various levels of antimicrobial resistance surveillance. At individual patient level, laboratory results guide prescription decisions and treatment monitoring. At the institutional level, they inform clinical practice guidelines, infection prevention and control, and antimicrobial stewardship programmes. At national level, they allow the emergence and prevalence of resistant strains to be evaluated, and provide evidence for policy decisions. Finally, at the global level (that is, through GLASS), the results of laboratory investigations help track global trends and the evolution and spread of resistant strains, and inform global policy decisions and coordination., The high-quality performance of laboratories is therefore crucial to ensure the reliability of data fed into the patient management and surveillance systems. Four country capacity review missions for the implementation of antimicrobial resistance surveillance were conducted by the WHO Regional Office for the Eastern Mediterranean between November 2015 and June 2016. The

missions identified a number of challenges common to all countries visited. In particular, different, and mostly outdated, editions of CLSI standards were used for the interpretation of antibacterial susceptibility results – even in different facilities in the same country, which raises questions about their accuracy and comparability. Antibacterial susceptibility results were almost exclusively submitted to requesting clinicians only; they were only sometimes submitted to infection prevention and control committees, and were never used for antimicrobial resistance surveillance. No formalized networks existed for the verification of unusual or new resistance patterns, genotyping, or investigation of atypical samples, and there was little or no interaction between human and animal health laboratories. To establish an effective and sustainable antimicrobial resistance surveillance system, countries would need to urgently take a number of actions, including strengthening quality management systems and biosafety, ensuring consistent provision and use of quality control strains, ensuring evidence-based, workload-sensitive budgeting, enhancing reporting, analysis and use of antibacterial susceptibility data, establishing networks for the verification of unusual or new resistance patterns, genotyping, or investigation of atypical samples, and taking into consideration the importance of the role of private laboratories, and strengthening cross-sectoral collaboration.

Several countries reported on progress and challenges in establishing their antimicrobial resistance surveillance systems. In Pakistan, antibiotics are freely available without prescription, leading to a 51% self-medication rate, and 70% of patients are prescribed antibiotics by their doctors. The country established a multisectoral antimicrobial resistance containment steering committee and developed a draft national policy for the containment of antimicrobial resistance. The policy will be implemented through the national strategic plan and provincial operational plans. A pressing need to involve all stakeholders

concerned (including health, agriculture and environment sectors) was emphasized.

In the Islamic Republic of Iran, antimicrobial resistance rates in common bacterial pathogens vary from 2.7% in *Shigella* up to 54% in *Klebsiella pneumoniae* and *Escherichia coli*. The country is working towards establishing a multisectoral integrated plan for the national antimicrobial resistance surveillance system using the One Health approach. To that effect, a national stakeholder committee is being created and will include representative from ministries of health and agriculture, the Health Insurance Organization, the Iranian Medical Council, the Infectious Disease Network Steering Committee, and the Iranian National Standards Organization. The activities of the national reference laboratory in the antimicrobial resistance surveillance of the human health sector were highlighted, including their role in operating external quality assessment schemes and the epidemiological tracking of resistant bacteria.

Sudan had recently gone through joint external evaluation that revealed that there was a limited or no capacity regarding antimicrobial resistance-related indicators. To rectify the situation, the country plans to develop a national antimicrobial resistance plan in line with the Global Action Plan on Antimicrobial Resistance, implement antimicrobial resistance surveillance systems in the human and animal health sectors, implement a national infection prevention and control plan (including an infection prevention and control curriculum and training and for undergraduate and postgraduate studies), and develop antimicrobial resistance awareness programmes for stakeholders.

Oman reported increasing rates of antimicrobial resistance, particularly carbapenem-resistant Enterobacteriaceae, multidrug-resistant *Acinetobacter*, salmonella, pneumococcus and methicillin-

resistant *Staphylococcus aureus*. In terms of antimicrobial resistance surveillance, the country faces challenges related to a lack of standardized antibiotic susceptibility testing, a lack of standardized reporting, and a lack of reporting of laboratory results to epidemiologists. The government endorsed an antimicrobial resistance surveillance programme in May 2016, and a very successful national antimicrobial resistance awareness campaign was conducted from 9 to 12 May 2016. Plans are in place to finalize enrolment and begin uploading data in GLASS by December 2016.

Qatar presented the incidence and distribution of pathogens isolated from health care facilities during the period from 2009 to 2015, and gave additional details on the three most prevailing pathogens (*E.coli*, salmonella and *Pseudomonas*).

The discussion that followed re-emphasized the importance of strong laboratory systems as a part of national health systems. It stressed the importance of resolution WHA 68.7, in which the World Health Assembly adopted the Global Action Plan on Antimicrobial Resistance and urged Member States to implement the actions proposed in the Global Action Plan as well as to have in place national action plans on antimicrobial resistance by May 2017. Participants agreed that the resolution should be used for advocacy purposes to mobilize the countries, and also that World Antibiotic Awareness Week, scheduled for the second week of November 2016, could be used for the same purpose. The meeting concluded that the three top priorities for country action on antimicrobial resistance are the national action plans on antimicrobial resistance, advocacy and awareness-raising at all levels and with all stakeholders, and national antimicrobial resistance surveillance.

Session 5: the Eastern Mediterranean Regional Emerging Dangerous Pathogen Laboratory Network (EMR-EDPLN)

The session started with an overview of the global Emerging and Dangerous Pathogen Laboratory Network and the Global Outbreak Alert and Response Network. The Emerging and Dangerous Pathogen Laboratory Network is a global network of high security (BSL-4 and selected BSL-3) diagnostic laboratories from both human and animal health sectors, able and willing to collaborate and share their knowledge, biological materials and experimental research results in a real time framework to detect, diagnose and control novel disease threats. It currently has 23 members globally. The role of the Emerging and Dangerous Pathogen Laboratory Network during the Ebola outbreak of 2014-2016 was presented in great detail. The meeting concluded that even though modern technologies can help detect, manage and contain the cross-border spread of emerging zoonotic diseases more effectively, high-level government commitment and international collaboration remain the fundamental principles of disease control.

The meeting further discussed the goals and implementation strategies of the Eastern Mediterranean Regional Emerging and Dangerous Pathogen Laboratory Network. The goal of the regional network is to establish a network of reference laboratories at BSL-3 or BSL-4 levels to carry out surveillance, detection and response duties regarding emerging and dangerous pathogens, and also serve as national, subregional and/or regional reference laboratories for the confirmation of cases in and capacity building of other countries of the Region. the regional network is being implemented through the following four phases: 1) identification of candidate laboratories; 2) assessment of candidate laboratories for their readiness to be upgraded to start functioning as reference laboratories; 3) building capacity of the staff of

candidate laboratories; and 4) enrolling candidate laboratories in the regional and global external quality assurance schemes. In order to identify candidate laboratories, the Regional Office has conducted an assessment of the epidemiological situation in the Region vis-à-vis viral haemorrhagic fevers and other emerging and dangerous pathogens, and the mapping and review of current laboratory capacities for emerging and dangerous pathogen diagnosis. The next step will be to assess the infrastructure, equipment, practices and staff competence of candidate laboratories to determine how ready they are for upgrade to reference laboratory status. Follow-up visits will be conducted within a year after the assessments to evaluate progress, identify additional needs and mentor staff. A regional forum will be created for collaboration and information- and experience-sharing purposes. The meeting concluded that a collaborative approach through all three levels of WHO, and actively engaging Member States, donors, and local and international would development partners be the key to the successful implementation of the regional network.

Participants were updated on the outcomes of the assessment of the epidemiological situation in the Region aimed at identifying hotspots of viral haemorrhagic fevers and other emerging and dangerous pathogens in order to inform the establishment of the regional Network. The assessment included viral haemorrhagic fevers caused by arenaviruses, bunyaviruses, filoviruses and flaviviruses, as well as emerging and dangerous pathogens with the potential to cause public health including emergencies of international concern, influenza A(H1N1)pdm09, respiratory severe acute syndrome, cholera, pneumonic plague, Middle East respiratory syndrome coronavirus, chikungunya, leptospirosis and Rickettsia species. A literature search was performed in the PubMed®, ProMED-Mail® and GIDEON® databases. Reported data included disease burden (reported cases and deaths), human prevalence (general population, high-risk groups),

vectors, and reservoirs. A scoring method was developed that allowed for the division of the 22 countries of the Region into four groups according to level of threat ("very high", "high", "medium", and "low" affected countries). The analysis period was restricted to 1995–2015. For viral haemorrhagic fevers, "very high" affected countries were Afghanistan, Egypt, Islamic Republic of Iran, Saudi Arabia and Sudan. "High" affected countries were Djibouti, Morocco, Oman, Pakistan, Tunisia and Yemen. "Medium" affected countries were Iraq, Somalia and United Arab Emirates. "Low" affected countries were Bahrain, Jordan, Lebanon, Libya, Palestine, Qatar and Syrian Arab Republic. As countries join the regional network, this regional assessment will help to highlight which countries should become part of the network as a matter of priority, and will also help to address specific country needs related to outbreak investigations, surveillance and research.

The results of the laboratory mapping exercise for regional network purposes were then presented and discussed. The objective of the mapping was to establish a regional database of health laboratories in countries of the Region to help develop, maintain and deploy capacities for adequate, effective and integrated response in emergency situations. The data were collected through external on-site assessments, telephone interviews and filling out the health laboratory mapping tool (selfadministered/ assisted). The data were further reviewed, collated, validated and analysed to identify regional network candidate laboratories. The health laboratory mapping tool was developed specifically for the purpose of this exercise. Data were collected for 45 laboratories from 16 countries, and the self-assessments of some laboratories were validated though on-site external assessments. During the identification of candidate laboratories, the results of their participation in the regional and global external quality assurance programmes (wherever available) were also taken into account. The meeting concluded that the data obtained would be helpful not only in

the establishment of the regional network but also for other purposes such as identifying partner laboratories for educational or research projects, and prioritizing donor and development partner support.

Updates on epidemiology, outbreak preparedness and response to viral haemorrhagic fevers and emerging and dangerous pathogens at the national level were presented by Afghanistan, Islamic Republic of Iran, Morocco, Oman, Pakistan, Palestine and Sudan. The meeting noted some common challenges faced by the countries, including sample transportation and custom clearance issues, the shortage of reagents for diagnostic examination of many viral haemorrhagic fevers and emerging and dangerous pathogens, limited access to specific areas of many countries due to the security situation in these countries, and the shortage of qualified laboratory workforce. Participants emphasized that a very serious issue that needed to be addressed immediately was the inadequate coordination among the various sectors of the government and among the various stakeholders involved, which was leading to overlap, duplications and wastage of resources in some areas, and neglected needs in others. The meeting also stressed the critical importance of strengthening quality management systems and biosafety and biosecurity at the laboratories that were or would be performing reference functions.

The Victorian Infectious Disease Reference Laboratory (VIDRL, Melbourne, Australia) presented latest updates on emerging viral infections, including Ebola, Zika, Chikungunya and MERS-CoV. Testing strategies, algorithms and methods used by VIDRL were discussed. Participants were taken on a virtual tour of a Biosafety Level 4 (BSL-4) laboratory.

At the end of the session, partners' updates on their regional laboratory strengthening programmes were presented by the national reference laboratory (Melbourne, Australia) and the Merieux Foundation.

Session 6: monitoring and evaluating progress in implementation of the regional strategic framework

At the beginning of the session, participants discussed the importance of monitoring and evaluating the implementation of the regional strategic framework at both regional and country level. Continuous and consistent monitoring and evaluation provides consolidated information to measure progress, allows for comparisons between countries and for lessons learnt to be shared, and also identifies gaps and offers paths for continual improvement. In addition, it offers an opportunity to learn from experience and incorporate this experience into policy and practice, contributes to transparency and accountability, and provides a basis for resource mobilization. Participants were introduced to the conceptual model for the monitoring and evaluation of laboratory system strengthening, based on the WHO health systems framework, also known as the building blocks model.

Through small working group deliberations, participants identified a set of suggested indicators to be measured at the regional and national level. It was agreed that indicators should meet several broad criteria to facilitate their measurement and follow up. The criteria discussed and agreed upon were as follows.

• Indicators should be selected from the International Health Regulations (2005) (IHR (2005)) monitoring framework wherever possible, and supplemented by additional indicators for areas requiring specific consideration.

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- Indicators should be realistic and applicable to all countries of the Region.
- The number of indicators should be manageable (no more than 10—12) and, wherever possible, they should utilize routinely collected data or data that already exist, to reduce the burden of data collection.

Based on these criteria, a monitoring and evaluation framework was developed for the implementation of the regional strategic framework. The meeting agreed to report the results of the monitoring and evaluation activities annually through a survey to be conducted by the Regional Office.

3. Recommendations

- 1. In pursuance of resolution EM/RC63/R.5 of the Regional Committee for the Eastern Mediterranean, Member States should work in close coordination with WHO and other development partners to implement the regional strategic framework for strengthening health laboratory services 2016–2020 in an expeditious manner, and strengthen the capacities of countries of the Region for the implementation of the International Health Regulations (2005) and the global action plan on antimicrobial resistance.
 - a. WHO should provide Member States with technical support, guidance and tools as well as facilitate communication and coordination at the national and regional level to speed up the implementation of the Strategic Framework.
 - b. Progress with the implementation of the regional Strategic Framework for Strengthening Health Laboratory Services 2016–2020 should be continuously monitored, evaluated and

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- documented using the agreed indicators and the mechanism developed during the meeting.
- c. WHO, in collaboration with Member States and partners, should set up a regional forum as a listserv or in other appropriate form to establish a communication and information-sharing channel, and facilitate the implementation of the regional Strategic Framework for Strengthening Health Laboratory Services 2016–2020 and other critically important public health initiatives.
- Member States should ensure that all health laboratories in their jurisdictions participate in national, regional and/or international external quality assessment schemes that cover tests of critical importance for public health and clinical management depending on country context.
- 3. National, regional and/or international mentors who understand the national context and circumstances and are assigned nationally should provide local quality champions with consistent supportive supervision to facilitate the sustained implementation of laboratory quality management systems and biorisk management systems at targeted laboratory facilities. WHO and other development partners may assist in identifying and preparing the mentors.
- 4. WHO should collect more information on laboratory capacities in the Region that can be mobilized in public health emergencies of international concern and other humanitarian emergencies. Laboratory mapping using available and appropriate standardized tools can be employed for this purpose.
- 5. The Eastern Mediterranean Regional Emerging Dangerous Pathogens Laboratory Network (EMR-EDPLN) should be established through close collaboration between Member States, development partners and WHO to provide self-sufficient capacity for early and accurate detection, confirmation and response to

- novel, emerging and re-emerging infections of public health importance. This network should serve as a resource for all countries of the Region and at the global level for training, logistics and research and development.
- 6. In coordination with the national antimicrobial resistance focal points for human health in their respective countries, designated national reference laboratories should initiate early implementation of the national antimicrobial resistance surveillance system and enrolment in the WHO Global Antimicrobial Resistance Surveillance System (GLASS).

