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REGIONAL STRATEGY ON DIAGNOSTIC AND LABORATORY SERVICES AND SYSTEMS, 2023–2032 FOR THE WHO AFRICAN REGION

Report of the Secretariat

EXECUTIVE SUMMARY

1. The availability and accessibility of diagnostic and laboratory services are crucial for patient care, disease prevention and research. However, 47% of the global population lacks access to diagnostics, with low and middle-income countries in the WHO African Region particularly affected. The situation is even more acute in primary care settings. Disparities between rural and urban populations, as well as socioeconomic disadvantages faced by vulnerable groups, exacerbate the problem.

2. Improving availability and access to diagnostic services is essential for achieving universal health coverage and the health-related Sustainable Development Goals. In the Region, a number of key issues contribute to the current state of diagnostics, including weak diagnostic systems, inadequate leadership and governance, infrastructure and equipment deficiencies, lack of national standards, and insufficient funding. The COVID-19 pandemic further exposed these weaknesses and emphasized the urgent need for stronger and coordinated laboratory services, medical imaging, rapid diagnostics, and genome sequencing.

3. This regional strategy has been developed to increase the availability and accessibility of quality-assured diagnostic and laboratory services in the WHO African Region. The strategy aims to enhance a coordinated approach towards expanding diagnostic services to all levels of the health system, establish leadership and governance mechanisms, promote quality-assured services, and provide guidance for improvement. Member States are encouraged to strengthen governance structures, ensure accessible and quality services, and prioritize availability at the primary health care level.

4. The priority interventions of the strategy aim to integrate diagnosis into essential health services, strengthen leadership and governance, develop comprehensive national diagnostic lists, improve health technology management, and promote education and training.

5. Strengthening diagnostic systems will improve health care provision, disease control, and outbreak response, thereby contributing to universal health coverage and the Sustainable Development Goals.

6. The Regional Committee is invited to consider and adopt this strategy.

CONTENTS

Paragraphs

INTRODUCTION

1. The term “health diagnostic services” or diagnostic services encompasses a range of services used for diagnosing/detecting disease states or conditions, screening, monitoring, predicting, staging or surveillance of diseases or health conditions. Health diagnostic services include: (i) laboratory diagnostic services (covering clinical medicine, pathology, public health functions such as outbreak detection); (ii) diagnostic imaging (X-ray, magnetic resonance imaging, ultrasound); and (iii) quality control of health products such as medicines. Health diagnostic services are essential to patient care; disease prevention, surveillance and control; health event and outbreak detection and management; and research.

2. Early diagnosis increases the chances of a positive outcome, helping to improve the lives of patients and saving costs of further treatment. It plays a vital role in the prevention and control of noncommunicable diseases, including diabetes and cardiovascular diseases. Regular screenings and diagnostic tests allow for early intervention, lifestyle modifications, and appropriate management.[1]

3. According to recent estimates, 47% of the global population has little to no access to diagnostics.[2] Only 30% of health facilities in Africa have the necessary equipment and reagents to perform basic diagnostic tests[3] due to lack of national prioritization, underfunding and inadequate resources. The peripheral level is the most deprived, with poor, rural, and marginalized communities particularly affected. In the WHO African Region where most countries are classified as low- and middle-income, clinical laboratory[4] and imaging services[5] are inadequate, with poor and inequitable access. Access to diagnostic services remains a huge challenge in developing countries. Disparities in access between rural and urban populations are clear, and reduced access may be experienced by women and other vulnerable groups due to economic or social disadvantages.[6]

4. There is need to provide care across the continuum which involves promotive, preventive, diagnostic, curative and palliative interventions. Diagnostics need to be presented as stand-alone sets of interventions, but they are not, and are usually included under curative interventions.

5. Improving availability and access to diagnostic services is important to achieve universal health coverage and the health-related Sustainable Development Goals in the WHO African Region.

SITUATION ANALYSIS AND JUSTIFICATION

Situation analysis

6. Despite the scarcity of data and status on the availability of and access to diagnostic services in the WHO African Region, these services are recognized to be weak and not adapted for people-

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1 American Diabetes Association. Standards of Medical Care in Diabetes – 2022. Diabetes Care. 2022;45(Suppl 1):S1-S246.

2 Kenneth A Fleming et al. The Lancet Commission on diagnostics: transforming access to diagnostics. The Lancet, Volume 398, Issue 10315, 2021, Page 1997–2050. https://doi.org/10.1016/S0140-6736(21)00673-5

3 The State of Diagnostics in Africa by the African Society for Laboratory Medicine

4 Michael L Wilson, Kenneth A Fleming, Modupe A Kuti, Lai Meng Looi, Nestor Lago, Kun Ru. Access to pathology and laboratory medicine services: a crucial gap. The Lancet, Volume 391, Issue 10133, 2018. http://dx.doi.org/10.1016/S0140-6736(18)30458-6

5 Guy Frija, Ivana Blažić, Donald P. Frush, Monika Hierath, Michael Kawooya, Lluis Donoso-Bach, et al. How to improve access to medical imaging in low- and middle-income countries ? eClinicalMedicine, Volume 38, 2021, 101034. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8318869/pdf/main.pdf

6 WHO, Increasing Access to Diagnostics Through Technology Transfer and Local Production. 2011, https://www.who.int/publications/i/item/9789241502375

centred health care, disease control and health security. Among 10 low- and middle-income countries, including seven African countries, the median availability of diagnostics was 19·1% in basic primary care facilities, 49·2% in advanced primary care facilities, and 68·4% in hospitals.[5] The COVID-19 pandemic clearly highlighted the weaknesses of diagnostic systems, the unpreparedness of regional diagnostic services for epidemics, inequities in systems distribution and supply of diagnostics, and the importance and need for better laboratory services, medical imaging, rapid diagnostics, and genome sequencing as a diagnostic/surveillance tool.[7]

7. That situation led to the adoption by the Seventy-sixth World Health Assembly of a resolution on "Strengthening diagnostics capacity".[8]

8. Recognizing the weakness of laboratory services and systems in the WHO African Region and the need to strengthen them, key milestones in the process have included the adoption of the Maputo Declaration (2008) on Strengthening of laboratory systems, and resolution AFR/RC58/R2 (2008) on Strengthening public health laboratories in the WHO African Region. In 2014 the WHO/AFRO Guidance for establishing a national health laboratory system[9] was published and disseminated to Member States. The stepwise laboratory improvement process towards accreditation (SLIPTA),[10] which supports countries to achieve international standards (ISO 15189), was also established in 2011.

9. Similarly, diagnostic imaging services are inaccessible, receive little attention and investment and are therefore one of the least developed areas of health care systems in the WHO African Region.[11]

10. The challenges faced in the provision of diagnostic services in the Region include inadequate leadership and governance, the absence of essential infrastructure, basic equipment and supplies, skilled workforce, problems of supply chain management, equipment maintenance, lack of national standards for testing, inadequate quality management systems and biosafety measures.[12]

11. Governance and leadership, which are essential to the organization, functioning and development of any sector, are also relatively weak in the Region in respect of health diagnostic services. With respect to governance, and in line with the Maputo Declaration, 26 countries[13] (55%) in the Region have established directorates or a unit for laboratory services within their ministry of

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7 Tessema GA, Kinfu Y, Dachew BA, et al. The COVID-19 pandemic and healthcare systems in Africa: a scoping review of preparedness, impact and response. *BMJ Global Health* 2021;6:e007179. doi:10.1136/ bmjgh-2021-007179. https://gh.bmj.com/content/bmjgh/6/12/e007179.full.pdf

8 World Health Organization. EB152/CONF./10, 152nd session Agenda item 5, 1 February 2023. Strengthening diagnostics Capacity. https://apps.who.int/gb/ebwha/pdf_files/EB152/B152(6)-en.pdf

9 World Health Organization. Guidance for Establishing a National Health Laboratory System. 2014 https://www.afro.who.int/sites/default/files/2017-06/afro-guidance-lab-systems-final_dec2014.pdf

10 WHO. WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the African Region (SLIPTA), 2015. https://www.afro.who.int/sites/default/files/2017-06/guide-for-the-slipta-in-the-african-region071115.pdf

11 Maru, D.SR., Schwarz, R., Andrews, J. et al. Turning a blind eye: The mobilization of radiology services in resource-poor regions https://doi.org/10.1186/1744-8603-6-18

12 John N Nkengasong, Katy Yao, Philip Onyebujoh. Laboratory medicine in low-income and middle-income countries: progress and challenges. The Lancet, Volume 391, Issue 10133, 2018, Pages 1873-1875. http://dx.doi.org/10.1016/S0140-6736(18)30308-8

13 Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cabo Verde, Central African Republic, Chad, Congo, Democratic Republic of the Congo, Guinea, Kenya, Liberia, Malawi, Mozambique, Namibia, Niger, Nigeria, Senegal, Sierra Leone, South Africa, South Sudan, United Republic of Tanzania, Uganda, Zambia and Zimbabwe

health; 27 countries[14] (57%) have a laboratory policy; and 30 countries[15] (64%) have a strategic plan. Benin, in addition, has a directorate that covers imaging and diagnostics.

12. The regulatory landscape for in vitro diagnostics (IVDs) is weak in the Region, opening the way for supplies of non-assured quality.[16] Most national regulatory bodies are not equipped to process IVDs and do not have national standards nor lists of essential diagnostic devices.[17] Only four countries the Region; Ghana, Nigeria, United Republic of Tanzania and South Africa have national regulatory authorities rated at Maturity Level 3 of the WHO Global Benchmarking Tool.[18]

13. In addition to being inadequate, with poor and inequitable access and lack of quality management systems and biosafety measures, both clinical laboratory and imaging services also suffer from lack of regular, stable and sustainable funding.[19] The uncertainty of funding and the selective nature of donor funding often negatively impact leadership priorities and pose significant challenges for implementation of strategic plans.

14. This situation is detrimental to the effective contribution of health diagnostic services to primary health care and the achievement of universal health coverage, for which they must be available and geographically and financially accessible.

Justification

15. Adequate and appropriate health diagnostic services are imperative for ensuring quality, comprehensive, and integrated primary health care and health services for everyone, everywhere, and contributing to improve health security and sustainable primary health care in the pursuit of the SDGs as stipulated in the resolution on strengthening diagnostics capacity.

16. The current situation of diagnostic services in the Region can be generally characterized as suboptimal, unavailable, inaccessible and of poor quality, which collectively exacerbate morbidity and mortality in the Region.

17. The resolution[20] adopted by African Member States clearly highlights the importance of improving the availability and access of diagnostic services in the Region to address gaps in primary health care, health security and to strengthen the core capacities required under the International Health Regulations.

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[14] Benin, Botswana, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of the Congo, Guinea, Kenya, Madagascar, Malawi, Mali, Liberia, Malawi, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, South Sudan, United Republic of Tanzania, Uganda, Zambia and Zimbabwe

[15] Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Democratic Republic of the Congo, Eswatini, Gambia, Guinea, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mozambique, Namibia, Niger, Nigeria, Senegal, Sierra Leone, South Africa, South Sudan, United Republic of Tanzania, Uganda, Zambia and Zimbabwe

[16] Ruth McNerney , Rosanna W. Peeling, Regulatory In Vitro Diagnostics Landscape in Africa: Update on Regional Activities, *Clinical Infectious Diseases*, Volume 61, Issue suppl_3, October 2015, Pages S135–S140. https://academic.oup.com/cid/article/61/suppl_3/S135/355754

[17] WHO. WHO launches List of Priority Medical Devices for management of cardiovascular diseases and diabetes. https://www.who.int/news/item/30-06-2021-who-launches-list-of-priority-medical-devices-for-management-of-cardiovascular-diseases-and-diabetes

[18] WHO, List of transitional WLAs (in alphabetical order), 2022, https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/rev-list-of-transitional-wlas.pdf?sfvrsn=1f6c2140_7&download=true

[19] Michael L Wilson, Kenneth A Fleming, Modupe A Kuti, Lai Meng Looi, Nestor Lago, Kun Ru. Access to pathology and laboratory medicine services: a crucial gap. The Lancet, Volume 391, Issue 10133, 2018. http://dx.doi.org/10.1016/S0140-6736(18)30458-6

[20] World Health Organization. EB152/CONF./10, 152nd session Agenda item 5, 1 February 2023. Strengthening diagnostics Capacity. https://apps.who.int/gb/ebwha/pdf_files/EB152/B152(6)-en.pdf

THE REGIONAL STRATEGY

Aim, objectives, and targets

Aim

18. The aim of this strategy is to increase the availability and accessibility of quality-assured diagnostic and laboratory services in the WHO African Region in line with universal health coverage indicators and targets.

Objectives

19. In all countries of the WHO African Region:

(a) to support countries in strengthening diagnostic and laboratory services at all levels of the health system to ensure better access, availability and accessibility of these services;

(b) to support countries in establishing leadership and governance mechanisms for diagnostic and laboratory services;

(c) to promote the establishment of mechanisms for the provision of quality-assured diagnostic and laboratory services;

(d) to provide guidance on improving diagnostic and laboratory services and systems.

Targets

20. Targets by 2032

(a) At least 80% of Member States have a functional governance structure for diagnostic and laboratory services.

(b) At least 80% of Member States have accessible diagnostic and laboratory services, including imaging, that meet appropriate quality and safety management standards. These services should be supported by regulated supplies procurement, a health technology management structure, and standards that cover 80% of the population.

(c) At least 80% of Member States ensure the availability, accessibility and affordability of diagnostic and laboratory services at the primary health care level in all health districts.

Guiding principles

21. **Country ownership and leadership:** Member States will demonstrate ownership and leadership by implementing strategies to improve diagnostic and laboratory services and systems. Improving diagnostic and laboratory services and systems is first and foremost the responsibility of governments. This strategy calls for Member States to show political commitment and accountability at all levels through decision-making, adapting regulations and structures, and ensuring efficient functioning.

22. **Health system approach with a focus on primary health care**: The strategy will prioritize the strengthening of district health systems, with a specific focus on revitalizing primary care. The implementation of this strategy will focus on improving health system facilities with special attention to the delivery of primary health care at community level with strong technical support from the national level to make the services available and accessible to all.

23. **Collaboration and partnership**: Effective collaboration with all structures within ministries of health and across government sectors as well as established public-private partnerships to improve access to quality diagnostic services and ensure harmonization and pooling of resources.

Regulation, health technology management including procurement and maintenance of equipment, and national networks can be assured in collaboration with existing structures and services. There should be alignment and effective partnerships for efficient programming and implementation. Regional coordination with subregional entities and Africa CDC will help reduce duplication and provide for efficient use of scarce resources.

24. **Domestic financing**: For long-term sustainability, the funding of diagnostic and laboratory services should be from domestic resources. Therefore, mobilization of adequate domestic financial resources should be assured by governments, with consideration of public-private partnerships and innovative funding mechanisms.

25. **Gender, equity and human rights**: Effective implementation of this strategy requires the active participation of the entire community and the prioritization of equity and gender mainstreaming. Due consideration will be given to equity, which is a goal and principle, and gender mainstreaming. Emphasis will be laid on ensuring the safety and security of affected populations, with particular attention to safeguarding the welfare of affected and most vulnerable populations especially women, girls, children, and persons with disabilities.

26. **Innovation and digitization**: The adoption of new diagnostic tools and laboratory services will be prioritized through the integration of innovations such as digital tools, telediagnosis, new technologies and self-testing to enhance efficiency, accuracy, and accessibility.

27. **Enabling environment** for the promotion of diagnostic services: There is need to ensure consideration of important aspects that contribute to the effectiveness of diagnostic services. They include quality management systems and accreditation; national networks with systems for transportation of samples; supply chain management and local production of supplies; technology and knowledge transfer and sharing within the Region and incorporating the use of artificial intelligence and digital health while ensuring affordability, service delivery and user adaptation, and standardization.

Priority interventions

28. **Ensuring diagnosis is included in the essential health services package** in all regional policies, plans and products and ensuring integration of diagnostic and laboratory services as part of the national health strategy and plan.

29. **Strengthening leadership and governance of diagnostic and laboratory systems:** Departments or units should be created or reinforced at the ministry of health to ensure coordination of all diagnostics and integration of the public and private sectors for better coordination, specifically on imaging services and point-of-care tests. Advocacy and awareness raising should be promoted for the development and expansion of laboratory services for improved availability and accessibility to all populations.

30. **Developing and updating policies and plans for all health diagnostic services including medical imaging services and health products quality control laboratories** by creating an enabling environment for better coordination of the sector.

31. **Establishing and updating comprehensive national diagnostic lists** to ensure that quality diagnostics items are sourced, facilitating pooled procurement, and enabling harmonization of technologies and methods at national and subnational levels.

32. **Improving health technology management** for optimal acquisition, utilization and maintenance of health technologies to ensure reliable, consistent and accurate patient results.

33. **Promoting education and training for sustainable workforce development:** The availability of a suitable, trained workforce is vital, therefore a continuous learning mechanism should be encouraged and implemented in collaboration with academic and professional associations.

Roles and responsibilities

34. **Member States should:**

(a) commit political will and leadership and promote the strategy, including by enacting legislation and establishing regulatory frameworks where needed;

(b) mobilize domestic and external resources and ensure sustainable financing to support the implementation of the strategy as an integral part of the national health plan;

(c) review and adapt the existing structures, systems, policies and strategic plans for quality diagnostic and laboratory services networks and systems at national and subnational levels;

(d) expand laboratory and imaging services to subnational levels and ensure minimal laboratory tests at first-level and remote health facilities utilizing existing and new technologies;

(e) commit resources and develop an appropriate and adequately skilled health workforce to operationalize essential diagnostic services at all levels of the health system;

(f) invest and ensure logistics and maintenance of equipment by trained technical personnel;

(g) engage private sector laboratories and their networks in all aspects relating to diagnostic and laboratory services;

(h) establish a monitoring and evaluation mechanism to collect and capture data annually on the existing diagnostic and laboratory services using and adapting the existing tools in line with the information management system structure.

35. **WHO and partners should:**

(a) disseminate policy guidance, technical guidelines, and review resolutions and recommendations to support implementation of the strategy;

(b) provide support to Member States to develop evidence-based policies and operational plans that are regularly monitored and evaluated;

(c) support Member States with technical advice on equipment maintenance training opportunities for improving health diagnostic services;

(d) promote synergy and alignment with IHR core capacity building and primary health care implementation with and between partners;

(e) promote collaboration between key regional and international partners for concurrence on initiatives to achieve maximal impact.

RESOURCE IMPLICATIONS

36. Implementation of this strategy will require additional funding and commitment from national and international stakeholders. The existing level of funding for diagnostic and laboratory services varies from country to country but is generally insufficient. Additionally, there is need to ensure the availability of skilled human resources at all levels.

37. Recognition of ongoing costs for diagnostic and laboratory services such as equipment maintenance should be considered in national budgets.

38. Increased capacity for resource mobilization and more efficient partnership for the improvement of diagnostic and laboratory services will require strategic planning, policies and guidelines.

MONITORING AND EVALUATION

39. Monitoring and evaluation of strategy implementation by Member States should be tracked annually using a menu of indicators to monitor progress across the three primary health care components (policy level, operational level and by people and communities) according to the operational framework that aligns with ongoing universal health coverage and SDG monitoring efforts[21] and IHR core capacity reporting.[22]

40. A progress report on the implementation of this strategy should be presented to the WHO Regional Committee every two years.

CONCLUSION

41. Equitable access to accurate, reliable diagnostic testing is limited in the Region, leading to frequent misdiagnosis of diseases and conditions. Strengthening heath diagnostic systems and expanding them to all levels of the health system will enhance availability and accessibility to populations as required for successful implementation of primary health care to achieve universal health coverage.

42. Implementation of this strategy will support the building of resilient diagnostic and laboratory systems and support health care provision, prevention and control of communicable and noncommunicable diseases, as well as activities to prevent and respond to outbreaks.

43. The Regional Committee is invited to consider and adopt this regional strategy.

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[21] WHO. Operational Framework for Primary Health Care. Transforming vision into action. https://www.who.int/publications/i/item/9789240017832

[22] https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/states-parties-self-assessment-annual-reporting