African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

Consultative Meeting on

the Africa Collaborative to Advance Diagnostics to Meet the Continent's Health Agenda

24–25 September 2019

Organized by Africa Centres for Disease Control and Prevention, in partnership with:

World Health Organization

London School of Hygiene & Tropical Medicine

ASLM
African Society for Laboratory Medicine

FIND
Because diagnosis matters

Consultative Meeting on

the Africa Collaborative to Advance Diagnostics to Meet the Continent's Health

H.E. Mr Moussa Faki Mahamat
Chairperson of the African Union Commission

H. E. Mrs. Elfadil Amira Mohammed
Commissioner for Social Affairs,
African Union Commission

Dr John Nkengasong
Director, Africa Centres for Disease Control and Prevention

DAY ONE 24 SEPTEMBER 2019

8.30–9.00 am: Arrival and registration

SESSION 1

Setting the Stage
Accelerating Access and Uptake of Diagnostics in Africa: What, Why, How?

Co-Moderators

- Yankuba Kassama , Director, Medical Services, Africa Union Commission
- Amadou Alpha Sall, Institute Pasteur, Dakar

Time	Topics	Presenter
9.00–9.10 am	Welcome remarks	H.E. Mrs Elfadil Amira Mohammed, Commissioner for Social Affairs, African Union Commission
9.10–9.20 am	Introductory remarks	H.E. Dr Amir Aman, Minister of Health, Federal Democratic Republic of Ethiopia
9.20–9.40 am	Objectives of the meeting	John Nkengasong, Director, Africa CDC
9.40–10.00 am	**WHAT**: The reality of access to diagnostics in healthcare systems of Africa: gaps in HIV, TB, malaria, pneumonia, cervical cancer, and others	Wendy Stevens, University of the Witwatersrand and National Health Laboratory Service**,** South Africa
10.00–10.20 am	**WHAT:** The reality of the African diagnostics market: perspectives of a manufacturer	Isabelle Hagner, Abbott Rapid Diagnostics
10.20–10.40 am	**WHY:** Three valleys of death in access to diagnostics in Africa	Trevor Peter, Clinton Health Access Initiative

Time	Topics	Presenter
10.40–11.00 am	**HOW:** Africa Collaborative to Advance Diagnostics theory of action: advancing access to diagnostics to meet Agenda 2063, UHC and health security	Ndlovu Nqobile, African Society for Laboratory Medicine
11.00–11.10 am	Opening remarks	H.E. Mr Moussa Faki Mahamat, Chairperson, African Union Commission
11.10–11.15 am	Group photograph	
11.15–11.40 am	**TEA/COFFEE BREAK**	

SESSION 2

Accelerating Access to Diagnostics: Expediting the Evaluation and Uptake of Diagnostics in Africa

Co-Moderators

- Rosanna W. Peeling, Professor and Chair, Diagnostics Research and Director, International Diagnostics Centre, London School of Hygiene and Tropical Medicine
- Sheick Oumar Coulibaly, WHO Regional Office for Africa

Time	Topic	Presenter
11.40–11.55 am	WHO prequalification and collaborative registration process: successes and challenges in supporting access to quality diagnostics	Irena PRAT, WHO, Geneva
11.55 am–12.10 pm	Evaluating diagnostic products in African centers of excellence: the experience of US CDC	Clement Zeh, International Laboratory Branch, US CDC, Atlanta
12.10–12.25 pm	Product validation and verification, update from the Global Diagnostics Working Group	Irena PRAT, WHO, Geneva

Time	Topic	Presenter
12.25–12.45 pm	A framework for the assessment and implementation of diagnostics in outbreak situations	Mah-Sere Keita, African Society for Laboratory Medicine
12.45–1.00 pm	The glory and misery of diagnostics registration process in-country: the perspective of the manufacturers	Lalla Haidara, bioMérieux
1.00–2.00 pm	**LUNCH BREAK**	
2.00–2.10 pm	AFCAD proposed model to expedite evaluation and uptake of diagnostics in Africa	Yenew Kebede, Africa CDC
2.10–3.10 pm	**Group 1:** Africa CDC technical committee on diagnostics **Group 2:** Standard evaluation protocol on diagnostics for regular programme and disease outbreaks **Group 3:** Centres of excellence for evaluation of diagnostics in Africa: selection criteria, role of Africa CDC, processes and procedures for engagement in evaluation	All participants
3.10–3.30 pm	**COFFEE/TEA BREAK**	
3.30–4.30 pm	Reports from the breakout sessions and general discussion	

SPECIAL SESSION

HIV Viral Load Movement in Africa to Meet HIV/AIDS Control Targets by 2030

Theme: Political Commitments, Policy Framework and Partnerships

Co-moderators

- John Nkengasong, Africa CDC
- Jean de Dieu Iragena, WHO/AFRO

Time	Topic	Presenter
4.30–4.40 pm	Political and policy considerations for access to viral load	Tsigereda Kifle, Federal HIV Prevention and Control Office, Ethiopia
4.40-4.50 pm	Programmatic needs	Catherine Ngugi, National AIDS and STI Control Progamme, Kenya
4.50-5.00 pm	Commodities needs	Jason Williams, USAID, Washington
5.00-5.05 pm	Access to viral load testing: community perspectives	Solange Baptiste, International Treatment Preparedness Coalition, South Africa
5.05-5.15 pm	The role of connective diagnostics in enhancing care and treatment for viral diseases	Philip Onyebujoh, Senior Advisor, Africa CDC
5.15–5.40 pm	Roundtable discussion on viral load scale-up: experiences from countries	• Laura Takang, Cameroon • Artur Ramos, Mazambique • Yared Tedla, Ethiopia • Karidia Diallo, South Africa • Christina Mwangi, Uganda
5.40–6.10 pm	Open discussion	All
6.10–6.20 pm	Closing and way forward	• John Nkengasong, Africa CDC • Jean de Dieu Iragena, WHO AFRO

Time	Topic	Presenter
6.20–6.30 pm	Launch of the Africa Viral Load Movement	H.E. Amira Elfadil Mohammed Commissioner for Social Affairs, African Union Commission
6.30 pm	Reception at the African Union Multipurpose Hall	Organizers

DAY TWO 25 SEPTEMBER 2019

SESSION 3

Accelerating Access to Diagnostics: What it Takes to Assemble or Manufacture in Africa

Co-moderators

- Papa Salif Sow, Gilead Medical Foundation
- Amitabh Mehta, Foundation for Innovative New Diagnostics

Time	Topic	Presenter
9.00–9.15 am	Assembling all-in-one antenatal screening test kits: a solution to save mothers and children?	Pascale Ondoa, African Society for Laboratory Medicine
9.15–9.30 am	The pharmaceutical manufacturing plan for Africa: implication for the production of diagnostics on the continent	Paul Tanui, African Union Development Agency- New Partnership for Africa's Development Agency (AUDA-NEPAD)
9.30–9.45 am	Manufacturing diagnostics in Africa: the Moroccan experience	Hassan Sefrioui, Medical Biotechnology Department, Moroccan Foundation for Advanced Science, Innovation and Research

Time	Topic	Presenter
9.45–10.00 am	Manufacturing diagnostics in Africa: the Senegalese perspective	Amadou Alpha Sall, Pasteur Institute, Dakar
10.15–10.30 am	Manufacturing diagnostics in Africa: the Cote d'Ivoire perspective	Louis Kone Penali, Pasteur Institut, Abidjan
10.30–10.45 am	Production of diagnostic test kits in Africa: working with Korea manufacturer and the Korean Government	Lucy Yang, Humasis Co. Ltd.
10.45–11.00 am	**TEA BREAK**	
11.00–11.20 am	**AFCAD:** exploring the feasibility of local production of diagnostics: market intelligence	Trevor Peter, Clinton Health Access Initiative
11.20–12.30 pm	**Group 1**: What should be the diagnostics targeted for assembly or local production? Should we follow the EDL? Perspectives from healthcare **Group 2**: Different models of manufacturing/assembling for Africa: recommendations from the industry **Group 3**: Make the market work (global pricing, access, bulk procurement, product quality)	
12.30–1.00 pm	Short report from the groups and general discussion	All
1.00–2.00 pm	**LUNCH**	

SESSION 4

Accelerating Access to Diagnostics: Mechanisms for Advancing Diagnostics

Co-moderators

- John Nkengasong, Africa CDC
- Solomon Zewdu, Bill and Melinda Gates Foundation

Time	Topic	Presenter
2.00–2.20 pm	Optimizing global investment in diagnostics	Anna Laura Ross, Unitaid
2.20-2.40 pm	Driving effective local innovations in diagnostics	Amitabh Mehta, FIND
2.40-3.00 pm	The essential in-vitro diagnostics list	Adrianna Velazquez Berumen, WHO Geneva
3.00–3.30 pm	**TEA/COFFEE BREAK**	
3.30–4.30 pm	General discussion What could be the role, requirements and return on investment for the financial, industry and private sectors to support AFCAD: ▪ in accelerating the evaluation and registration of IVDs ▪ in establishing local capacity for the production or assembly of IVDs ▪ How to engage the financial sector	All participants
4.30–5.00 pm	Way forward and closing remarks	John Nkengasong, Africa CDC

Wendy Stevens, MD, MMed, FCPath, is a specialist pathologist, Head of the Department of Molecular Medicine and Haematology, University of the Witwatersrand, and Head of the National Priority Program Unit at the National Health Laboratory Service. She has been responsible for the rollout of affordable CD4, viral load, EID and HIV drug resistance programmes in South Africa and at least 60 centres in sub-Saharan Africa. More recently, her portfolio has expanded to include national molecular TB testing to 207 sites. These programmes have been extended to vulnerable populations such as the correctional services and peri-mining communities. Her success is largely due to the development of a strong research and development group, the ability to solicit and secure funding, and the support of a multi-disciplinary implementation team. Prof. Stevens has over 230 peer-reviewed publications with research priorities largely in haematological malignancies, HIV and TB for over 15 years.

Isabelle Hagner is currently HIV Director for Abbott Rapid Diagnostics. She has over 25 years of experience in pharmaceutical distribution and public health systems strengthening and works in 54 African countries. Her experience in healthcare and humanitarian programmes with a focus on patient-centric solutions in remote areas has enabled her to flourish in her passion for innovation and empowerment of under-served communities, market access of medicinal products and health systems strengthening of some of the poorest nations in Africa. Isabelle is a strategic thinker with a keen incline to seek operational improvements in all settings. She has a consultative approach to stakeholder engagement in addressing challenges with a fit-for-purpose and solution-driven approach whilst building sustainable health financing mechanisms and managing costs.

Trevor Peter PhD, MPH is Senior Director, Diagnostics and Laboratory Services at the Clinton Health Access Initiative. He has over 15 years of experience in diagnostics, infectious diseases research and global health, and has authored nearly 100 scientific articles. He has worked on strengthening laboratory services in Africa, Asia, Eastern Europe, the Caribbean and South America. Previously, he managed the Botswana-Harvard School of Public Health HIV Reference Laboratory and conducted vector-borne disease research in veterinary medicine in southern Africa. He was the Board Chair of the African Society for Laboratory Medicine from 2012 to 2016.

Nqobile Ndlovu is a public health professional and Chief Executive Officer, African Society for Laboratory Medicine. He has over 10 years of experience in managing laboratory strengthening programmes and advocating for quality standards in public health laboratories. Mr Ndlovu has led laboratory strengthening programmes in Africa and the Caribbean, and previously served as Assistant Field Coordinator for the master's in public health (FETP) training programme at the University of Zimbabwe. He holds a bachelor's degree in medical laboratory sciences and a master's degree in public health from the University of Zimbabwe.

Irena Prat is Group Lead Diagnostics Assessment at the World Health Organization. Prior to joining the WHO Essential Health Technologies Department, she served as a medical devices counsellor at the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia. She oversaw medical devices regulatory affairs and managed a variety of other programmes related to medical devices, including registration procedures, vigilance and educational programmes for stakeholders. Ms Prat joined WHO's diagnostics and laboratory technology team in March 2008, where she was involved in implementing the prequalification programme for *in-vitro* diagnostics, with emphasis on the product dossier component of the programme. Since 2014 she has led the diagnostics assessment group within the prequalification team and takes primary responsibility for the technical and managerial aspects of the programme. Ms Prat coordinates WHO's normative and guidance work in support of the prequalification of *in-vitro* diagnostics programme, supports Member States and other stakeholders in matters relating to *in-vitro* diagnostics, provides technical leadership among United Nations agencies for matters relating to *in-vitro* diagnostics and coordinates WHO's contribution to the global and regional harmonization initiatives on *in-vitro* diagnostics such as the International Medical Device Regulators Forum. Ms Prat holds a degree in laboratory biomedicine from the Faculty of Pharmacy, University of Ljubljana, Slovenia, and a postgraduate degree in management from the University of Primorska, Slovenia.

Clement Zeh, PhD, MPH, is Team Lead, HIV Viral Load and Early Infant Diagnosis at CDC Atlanta, where he is responsible for evaluating new technologies, supporting viral load and infant virologic testing scale-up, ensuring the quality of testing, and providing subject matter expertise to PEPFAR supported countries. Prior to his appointment, Dr Zeh was Associate Director, Laboratory, at CDC Ethiopia, supporting PEPFAR and the laboratory component of the Global Health Security Agenda. He was also Laboratory Advisor and acting Program Director, CDC Division of HIV/AIDS Prevention in Kisumu, Kenya. Dr Zeh has over 20 years of experience in HIV/AIDS and STIs and has served as principal investigator and co-principal investigator for several clinical trials. He established the ISO15189 accredited laboratory in Kenya designated as the national and regional reference laboratory for HIV drug resistance testing.

Mah-Séré Keita is a global health professional with more than 17 years of experience in research, patient care, project development and management. Her career has focused primarily on improving disease detection and response in low-resource settings. Ms Keita is currently Director of Programmes at the African Society for Laboratory Medicine. She had previously held leadership positions at the Catholic Relief Services Mali, American Society for Microbiology, and Association of Schools and Programs of Public Health. She holds a master's degree in public health specializing in infectious diseases epidemiology and a certificate in health finance and management from the Johns Hopkins Bloomberg School of Public Health, and a Bachelor of Science degree in pre-medicine biology from Boston College.

Lalla Haidara is Africa Public Health and Public Affairs Manager at bioMérieux. Prior to joining bioMérieux, she worked at the Global Fund, where she managed TB, HIV and malaria grants for India for more than six years. Mrs Haidara holds a master's degree in international affairs and has more than 15 years of work experience in international development in sub-Saharan Africa, Haiti and India.

Yenew Kebede, MD, MPH, MSc is Head, Division of Laboratory Systems and Networks at Africa CDC. He is a medical microbiologist and public health expert with over 16 years of clinical, teaching, laboratory, research, capacity building, programme design, and management experience. Before joining Africa CDC, he worked for more than 12 years as technical officer and later as branch chief for laboratory at US CDC Ethiopia where he provided strategic leadership for one of the most successful PEPFAR laboratory systems development programmes. Before joining the US CDC, Dr Yenew worked as assistant lecturer, lecturer and later as assistant professor at Gondar College of Medical Science, University of Gondar. He served as head of the Department of Hospital Laboratory and a member of the academic commission of the college. He has written lecture notes on microbiology, immunology and parasitology, and authored and co-authored more than 30 articles in peer-reviewed journals. He holds a medical doctorate degree from Gondar College of Medical Sciences, a master's degree in medical microbiology from Addis Ababa University, and a master's degree in public health from University of Gondar.

Catherine Ngugi is a public health specialist and Head, National AIDS and STI Control Program, Ministry of Health, Kenya. She received her training in Kenya, South Africa and New Zealand on public health and HIV programme management. She has been a principal investigator on several programmes in Kenya and Eastern Africa aimed to address key health issues, including sexually transmitted infections, newborn child and adolescent health, early infant diagnosis, mother-to-child transmission of HIV, pre-exposure prophylaxis, and post-exposure prophylaxis. These projects have led to key policy changes in Kenya and Eastern Africa. Before her appointment as head of NASCOP, Dr Ngugi held different leadership positions in the Kenya Ministry of Health. She was Technical Advisor to the Ministry of Health parastatals, Deputy Director at the National Blood Transfusion Service, and Program Manager STI and Viral Hepatitis Programme at NASCOP. Dr Ngugi has background training in innovative programme management and the design of concise and informative curriculums. She has deep knowledge of the techniques, methods, processes and guidelines for delivering public health information systems and expertise in directing and coordinating overall development and administration of public health service. Dr Ngugi is a team player and has keen interest in evaluating quality and productivity of services.

Pascale Ondoa is Director, Science and New Initiatives at African Society for Laboratory Medicine. She holds a medical degree from the University of Yaoundé, Cameroon, and a PhD in biomedical sciences (virology) from the University of Antwerp. She worked as academic researcher at the Institute of Tropical Medicine, Antwerp, from 2002 to 2009 focusing on immunology and virology studies of HIV and SIV infections of human and non-human primates, and on the development of alternative tests to monitor HIV infection. Dr Ondoa is affiliated with the Amsterdam Institute for Global Health and Development, University of Amsterdam, as an assistant professor. She worked at AIGHD from 2009 to 2016, on research and implementation of various projects on HIV drug resistance in sub-Saharan Africa, exploring ways to mitigate barriers to laboratory test uptake. Since 2016, she has been providing scientific leadership to the ASLM team, with the overall goal of advancing the laboratory profession and practice. She particularly focuses on addressing gaps in laboratory systems and networks in Africa. She leads several projects and programmes funded by PEPFAR, the Bill and Melinda Gates foundation, and the Fleming fund.

Hassan Sefrioui has over 20 years research and development experience in industrial and academic settings. Since 2010, he has been Director at the Moroccan Foundation for Advanced Science, Innovation and Research Biotechnology Center (Morocco), where he generated over US$ 2 million funding from grants and industrial clients. His team developed Morocco's first cost-effective diagnostic kits targeting prevalent diseases in Africa. Some of the MAScIR medical biotechnology centre kits were licensed to pharmaceutical companies, and some others led to the creation of MOLDIAG startup. Prof. Sefrioui was Head, Drug Discovery Programme 'Targeted Therapeutics' at Tigenix (NASDAQ) (Belgium) and led several biotechnology projects at 4AZA Biosciences (Belgium) (presently Biotie Therapeutics (NASDAQ). He holds a master's degree from the University of Liege (Belgium), a PhD in medical science from the University of Leuven (Belgium) and several postdoctoral years at the University California San Diego (USA) and University of Minnesota Twin Cities (USA). After his postdoctoral fellowships, Prof. Sefrioui held several research and development management positions in the European biotechnology industry sector. Prof. Sefrioui is co-author of 10 international patents and has around 40 publications in biotechnology. He is a board member of several international journals and has won several awards including the Competitiveness and Industry Academy Award (Morocco), the Africa Health Innovation Award (Kenya) and NIH Postdoc Fellowship (USA).

Amadou A. Sall is CEO, Institut Pasteur de Dakar, Senegal, and Director, WHO Collaborating Center for Arboviruses and Viral Hemorrhagic Fever. He has been Chairman, Global Outbreak Alert and Response Network. Dr Sall is a virologist with a PhD in public health and an expert in epidemics response and control, specifically for arboviruses and viral hemorrhagic fevers (Ebola virus disease, Zika virus, yellow fever). He is a member of several expert committees for WHO (GOARN, TDR, SAGE, STAG-IH) and OIE.

Louis Penali heads the Business Development and Partnership Bureau at the Institut Pasteur, Côte d'Ivoire and is President, National Ethics Committee of Côte d'Ivoire. He is a biologist and malariologist with postgraduate training in medical mycology at the Paul Sabatier University of Toulouse (France). He was a consultant to WHO for many years and contributed to the settlement of antimalarial drugs surveillance systems in many West and Central African countries. He was Regional Director for West and Central Africa at the Worldwide Antimalarial Resistance Network based in Dakar from 2011 to 2014. Louis Penali has authored many publications on malaria.

Amitabh Mehta is currently Senior Advisor, Strategy, at the Foundation for Innovative Diagnostics, Geneva, leading the organization's discussions for their future role in diagnostics and UHC. He is an innovative finance specialist with over 23 years of experience advising investment banks such as Deutsche Bank, development banks such as the ADB, and UN linked health and climate related organizations such as the WHO, UNIDO and UNECE. Using the best of his public sector, private sector and public-private partnership experiences globally, as the former Deputy Director and Head Asia-Pacific for GAVI Alliance, Geneva, he continues to advise the UN, WHO, corporates, pharmaceuticals, and development banks on innovative financing techniques and solutions, with a focus on sustainability, self-sufficiency, corporate partnerships, and CSR from alternative and diversified funding sources. With traditional donor overseas development assistance falling, he has been working with new donors, designing Islamic financing models, revolving funds, domestic bond platforms, including social impact bonds, and capital markets financing structures to meet these demands. His experience spans the healthcare, green finance, smart cities, infrastructure, vaccines, pharmaceuticals, financial, and funds sectors.

Paul Tanui, is a pharmacist and currently Senior Programme Officer, Technical Support for the African Medicines Regulatory Harmonisation (AMRH), a programme coordinated by the African Union Development Agency (AUDA-NEPAD). He holds postgraduate qualifications in healthcare and business management and has over 18 years of experience mainly in pharmaceutical manufacturing, regulatory affairs, medicines regulatory systems strengthening and quality assurance. Prior to his current appointment, Paul worked for the USAID-funded Strengthening Pharmaceutical Systems project at Management Sciences for Health supporting medicines regulatory activities at Namibia's Ministry of Health and Social Services and the Namibia Medicines Regulatory Council. He was also Head, Quality Control and Quality Assurance at the Universal Corporation Limited (Kenya) and held management positions at the health supply chain company, Howse & McGeorge Laborex-Eurapharma. Paul has served for three years as a board member of the Pharmacy and Poisons Board at the Kenya National Medicines Regulatory Authority.

Philip Onyebujoh is Senior Advisor for Technical Strategy and Partnerships, Office of the Director, Africa CDC. Prior to this appointment, Philip worked for WHO where he coordinated technical support for the HIV, TB and hepatitis and laboratories for WHO AFRO, covering WHO's 47 Member States in Africa. His academic background is in internal medicine, infectious diseases and clinical immunology of mycobacterial diseases. His initial research interest was in understanding the immunopathogenesis of mycobacterium tuberculosis as it applies to detection and therapeutic approaches. Philip's current interest is in exploring the potential for using next generation sequencing and bioinformatics in public health settings. He is currently setting up "The Africa **CDC Pathogen Genomics Intelligence Institute" to coordinate the use of advanced molecular detection technologies within control programme settings in Africa. He is also exploring the potential for implementing connective diagnostic platforms to advance access to test results and instrument capabilities in public health centres in Africa. Philip is a Fellow of the South Africa Academy of Sciences.**

Jason Williams is Senior Advisor for Laboratory Supply Chain System Strengthening, Office of HIV/AIDS, USAID. Jason serves as a liaison between country programmes, ministries of health, PEPFAR and other external collaborators. His primary responsibility is to provide technical leadership and advocacy to advance laboratory service delivery and laboratory supply chain support in PEPFAR countries. Jason has more than 25 years of experience in clinical, research and programmatic laboratory development and public health-based management.

Adriana Velazquez Berumen, Mexican biomedical engineer, is Senior Advisor, Medical Devices, WHO, responsible for the WHO priority medical devices and the WHO model list of essential in-vitro diagnostics. Since 2008, she has been leading the WHO global work on medical devices, including global surveys, policies, innovation, selection, procurement, donations, maintenance, and decommissioning, and in advancing the work on nomenclature of medical devices including in-vitro diagnostics. Previously she worked as director-general of a health technology national centre in the Ministry of Health, Mexico, and in public and private hospitals. Adrianna has several publications and honorary awards in biomedical and clinical engineering, medical physics and health technology assessment.

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