Reaching the Third 90: Implementing High Quality Viral Load Monitoring at Scale

MEETING REPORT

June 27-30, 2016 • Ezulwini, Swaziland
This meeting took place on June 27-30, 2016 in Ezulwini, Swaziland. It was supported in part by the U.S. President’s Emergency Plan for AIDS Relief (PEPFR) through the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under cooperative agreement number U1NHA28555, Quality Improvement Capacity for Impact Project. The content and conclusions presented here are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred, by HRSA, HHS or the U.S. Government.
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BACKGROUND

As the global community focuses on the ambitious 90:90:90 targets for HIV programming, new guidelines, technologies and resources present important opportunities to improve the impact of HIV services. Access to antiretroviral treatment (ART) has improved, and marked gains have been made, but mortality from HIV remains unacceptably high in some countries due to suboptimal coverage and quality of HIV services. Key challenges include diagnosing people living with HIV (PLWH), linking them to care and treatment, optimizing the use of ART, retaining patients in care and achieving durable viral suppression.

The 90:90:90 goals also highlight the importance of ensuring widespread access to HIV viral load (VL) monitoring, an approach needed to establish viral suppression (the “third 90”) and strongly endorsed by both the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) and the World Health Organization (WHO). The increasing availability and affordability of VL testing presents exciting opportunities for national HIV programs. The novelty of VL testing in the context of PEPFAR-supported programs also presents challenges, including the need for strategic decisions about when and how to use the new tests; how to ensure the availability of necessary laboratory infrastructure and expertise; how to train health workers on its use; how to ensure that people living with HIV (PLWH), communities and civil society understand and accept the new approach to monitoring ART; and how to ensure that VL services are consistently high quality.

Scale-up efforts need to extend beyond simple access to VL testing, and ensure that VL test results are actually used to improve patient management and outcomes. Studies from settings where VL monitoring is already available reveal that patients often remain on failing regimens for prolonged periods of time, despite access to VL services. In addition, lessons learned from CD4 testing demonstrate that though CD4 tests are routinely recommended in PEPFAR-supported programs, they are often not performed on time or at appropriate intervals due to factors from reagent stock-outs to machine breakdowns, health care worker oversight and poor record keeping. Unfortunately, even when CD4 tests are performed and results are returned to clinicians, they are not always used to guide treatment. Similarly, experience with DNA-PCR for early infant diagnosis shows that introducing a more accurate test does not necessarily result in the intended outcome unless the results are used as part of high quality clinical care. Effective VL testing is vulnerable to these same barriers.

Recognizing the need to share implementation solutions related to the rapid scale-up of VL services, ICAP at Columbia University, in collaboration with the Swaziland Ministry of Health, the International Treatment Preparedness Coalition and the African Society for Laboratory Medicine convened a three-day meeting to explore the practical challenges of introducing VL testing into national HIV programs. The meeting convened program planners, implementers, laboratorians, PLWH, key populations and civil society representatives to advance the scale-up of VL services – and ultimately improve the quality of HIV treatment – by providing the opportunity for both expert dialogue and practical south-to-south exchange.
GOALS & OBJECTIVES
The goal of the meeting was to advance the scale-up of high quality VL testing in PEPFAR-supported countries by:

- Facilitating productive discussions among program planners, front-line implementers, technical experts, clinicians, PLWH, key populations and civil society representatives;
- Discussing state-of-the-art methods for the measurement of VL, transport of specimens and transmission of results;
- Highlighting the key health systems barriers to the expansion of quality VL testing;
- Identifying approaches to utilizing VL to optimally manage patients on ART;
- Outlining and prioritizing relevant training and capacity-building needs;
- Sharing best practices and lessons learned;
- Developing a monitoring and evaluation framework relevant to the measurement of VL and its clinical utilization;
- Identifying opportunities to use quality improvement methods and tools to enhance VL services;
- Formulating a relevant priority research agenda; and
- Fostering professional relationships, partnerships and communities of practice among participants from different countries in order to promote ongoing south-to-south exchange and peer learning.

A Planning Group of global experts, diverse donors and stakeholders led meeting development, identified speakers/panelists and finalized the agenda (see page 7).

PARTICIPANTS
The meeting engaged an interdisciplinary group of participants from countries launching and/or expanding VL services as well as countries like South Africa that have had access to VL testing for some time. The meeting brought together 145 participants from 17 countries\(^1\) with expertise in five domains – program management, clinical services, laboratory services, community engagement and monitoring and evaluation – for plenary, symposia and breakout sessions. The cross-cutting issues of quality improvement, monitoring and evaluation and research were included in each domain.

PLANNED MEETING OUTCOMES
- Deeper understanding of the barriers to and facilitators of VL scale up, with a focus on practical implementation challenges, as well as key lessons learned, resources and best practices;
- New and enhanced partnerships and communities of practice focused on surmounting health systems barriers to the scale-up of high-quality VL services;

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\(^1\) Angola, Botswana, Cameroon, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Nigeria, Rwanda, South Africa, Swaziland, Tanzania, Uganda, the United States, Zambia and Zimbabwe.
• A framework for monitoring and evaluating VL services;
• A priority agenda for implementing research;
• Case studies and key lessons learned to inform further VL scale-up;
• Rapid implementation and scale-up of VL measurement and monitoring in priority countries; and
• Design and implementation of QI Collaboratives to support VL monitoring.
<table>
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<tr>
<th>Name</th>
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| Wafaa M. El-Sadr, MD, MPH, MPA                  | Director, ICAP at Columbia University  
Mathilde Krim-amfAR Professor of Global Health, Columbia University                                                                                          |
| Bereket Alemayehu, MD, MSc, MPH                 | Associate Director of Laboratory Services & Malaria, ICAP at Columbia University  
Associate Research Scientist  
Columbia University Mailman School of Public Health                                                                                      |
| Stephen Arpadi, MD, MSc                         | Professor of Epidemiology and Pediatrics, Technical Advisor, ICAP at Columbia University  
Columbia University College of Physicians & Surgeons, Columbia University Mailman School of Public Health                                                                 |
| Laura Broyles, MD                               | Branch Chief – Maternal and Child Health Branch; Division of Global HIV/AIDS  
Adjunct Assistant Professor of Medicine  
Emory University School of Medicine                                                            |
| Helen Chun, MD, MPH                             | Technical Advisor, Adult HIV Treatment  
Center for Global Health, Division of Global HIV/TB  
U.S. Centers for Disease Control and Prevention                                                                                       |
| Smiljka De Lussigny, MPharm, MPH                | Programme Manager, HIV  
UNITAID                                                                                                                                                                                                 |
| Peter Ehrenkranz, MD, MPH                        | Senior Program Officer – HIV Treatment  
Global Development  
Bill & Melinda Gates Foundation                                                                                                            |
| Dennis Ellenberger, PhD                         | Associate Chief of Science  
International Laboratory Branch  
Division of Global HIV/AIDS  
U.S. Centers for Disease Control and Prevention                                                                                      |
| Suzanne Jed, MSN, FNP-BC                         | Nurse Consultant, Data Evaluation & Quality Branch, Division of Global Programs  
Health Resources and Services Administration (HRSA)                                                                                         |
| Mark Johnson, MD, MTM&H, CTropMed               | LCDR, MC, USN  
Director of Care & Treatment  
DoD HIV/AIDS Prevention Program / Naval Health Research Center                                                                                  |
| Bacrin Killingo, MD                             | Treatment Knowledge & Research Lead, International Treatment Preparedness Coalition                                                                                           |
| Shirley Lecher, MD, MPH                         | Associate Chief for Clinical Laboratory Practice  
International Laboratory Branch, Division of Global HIV/AIDS  
U.S. Centers for Disease Control and Prevention                                                                                      |
| Spencer Lloyd, MD                               | Medical Officer  
U.S. Centers for Disease Control and Prevention                                                                                                             |
| Sharonann Lynch                                 | HIV/TB Policy Advisor, Médecins Sans Frontières (MSF) Access Campaign                                                                                                      |
| Nomthandazo Lukhele, MD, MCBC                   | National Antiretroviral Therapy Coordinator, Swaziland National AIDS Program (SNAP)  
Swaziland Ministry of Health                                                                                                                 |
| Ruben Sahabo, MD                                | Country Director, ICAP Swaziland  
Associate Research Scientist  
Population and Family Health  
Columbia University Mailman School of Public Health                                                                                       |
| Trevor Peter, PhD, MPH                          | Senior Scientific Director for Laboratory Services, Clinton Health Access Initiative (CHAI)  
Acting CEO, African Society for Laboratory Medicine                                                                                           |
| Miriam Rabkin, MD, MPH                          | Director for Health Systems Strategies, ICAP at Columbia University  
Associate Professor of Medicine and Epidemiology, Columbia University Mailman School of Public Health                                                                 |
| Heather Watts, MD                               | Senior Technical Advisor for Prevention of Mother to Child Transmission and Women’s Health, Office of the U.S. Global AIDS Coordinator and Health Diplomacy (OGAC)                                                                     |
MEETING AGENDA

Monday June 27th

Greetings & Framing Remarks
- Official Welcome Remarks:
  » Representative of Prince Tshekedi, Administrator of Hhohho Region
- Framing Remarks:
  » Professor Wafaa El-Sadr, Director, ICAP at Columbia University
  » Dr. Trevor Peter, Senior Scientific Director for Laboratory Services at the Clinton Health Access Initiative (CHAI) and acting CEO of the African Society for Laboratory Medicine
  » Dr. Bactrin Killingo, Treatment Knowledge & Research Lead, International Treatment Preparedness Coalition

Official Meeting Opening
- Dr. Caroline Ryan, Country Director, CDC Swaziland
- Ambassador Lisa J. Peterson
- Dr. Simon Zwane, Permanent Secretary, Swaziland Ministry of Health
- Hon. Minister of Health, Senator Sibongile Ndlela

Tuesday June 28th

SESSION 1: Setting the Stage
- Master of Ceremonies:
  » Professor Wafaa El-Sadr, Director, ICAP at Columbia University
- Welcome:
  » Dr. Laura Broyles, Chief, Maternal and Child Health Branch, Division of Global HIV/AIDS, U.S. Centers for Disease Control and Prevention (CDC)
- Review of Meeting Objectives:
  » Dr. Philippe Chilialde, Medical Officer, HIV/AIDS Branch, U.S. Health Resources and Services Administration (HRSA)

SESSION 2: Panel Discussion: Designing Viral Load Clinical Services, Part One
- Moderators:
  » Dr. Ruben Sahabo, Country Director, ICAP Swaziland
  » Dr. Regis Choto, Deputy National ART Coordinator, Ministry of Health & Child Care, Zimbabwe
- Framing Remarks:
  » Dr. Roger Teck, HIV Operational Advisor, Médecins Sans Frontières (MSF)
- Panelists:
  » Dr. Nomthandazo Lukhele, National ART Coordinator, Swaziland National AIDS Program
  » Dr. Frank Basiye, Technical Advisor, Lab Services, CDC Kenya
  » Dr. Charles Kiyaga, National Coordinator for Early Infant Diagnosis, Central Public Health Laboratories, Uganda Ministry of Health
  » Dr. Shirish Balachandra, Branch Chief, HIV Services, CDC Zimbabwe
• Facilitated audience discussion

**SESSION 3: Viral Load Strategies for Pregnant and Breastfeeding Women, Infants, Children & Adolescents**

• Moderator:
  » Dr. Laura Broyles, Chief, Maternal & Child Health Branch, Division of Global HIV/AIDS, CDC

• Speakers:
  » Professor Landon Myer, Head of the Division of Epidemiology & Biostatistics, School of Public Health & Family Medicine, University of Cape Town
  » Professor Stephen Arpadi, Departments of Epidemiology and Pediatrics, Columbia University Mailman School of Public Health

• Respondent:
  » Mr. Wellington Tserayi, Zimbabwe National Network of Positive Living People

**SESSION 4: Designing Viral Load Clinical Services, Part Two**

• Moderator:
  » Dr. Velephi Okello, Deputy Director of Clinical Services, Swaziland Ministry of Health

• Framing Remarks:
  » Dr. Pido Bongomin, Deputy Country Director for Programs, ICAP Swaziland

• Panelists:
  » Dr. Tendani Gaolathe, Project Director, Botswana Harvard AIDS Institute
  » Dr. Beth Harley, Clinical Medical Officer, City Health, Cape Town, South Africa
  » Dr. Florbela Bata, HIV Control Program Manager, Ministry of Health, Mozambique
  » Dr. Sipho Dlamini, Director of HIV clinic at Groote Schuur Hospital, Cape Town, South Africa

• Facilitated audience discussion

**SESSION 5: Afternoon Breakout Sessions**

**Wednesday June 29th**

**Welcome Back & Opening Remarks**

• Master of Ceremonies:
  » Dr. Ruben Sahabo, Country Director, ICAP Swaziland

**SESSION 6: Designing Viral Load Laboratory Services, Part One**

• Moderators:
  » Mrs. Tsietsi Motso’ane, Director of Laboratory Services, Ministry of Health, Lesotho
  » Dr. Shirley Lee Lecher, Associate Chief for Clinical Laboratory Practice, International Laboratory Branch, Division of Global HIV/AIDS, CDC

• Framing Remarks:
  » Dr. Trevor Peter, Senior Scientific Director for Laboratory Services at CHAI and acting CEO of the African Society for Laboratory Medicine

• Panelists:
  » Ms. Naoko Doi, Associate Director, HIV Diagnostics, CHAI
» Dr. Clement Zeh, Associate Director, Laboratory, CDC Ethiopia
» Dr. Dennis Ellenberger, Research Microbiologist, CDC Atlanta
» Ms. Sindisiwe Dlamini, Chief Laboratory Technologist, Swaziland Ministry of Health

• Facilitated audience discussion

SESSION 7: Quality Improvement & Quality Assurance for Viral Load

• Moderator:
  » Ms. Suzanne Jed, Nurse Consultant, Data Evaluation and Quality Branch, Division of Global Programs, HIV/AIDS Bureau, HRSA

• Panelists:
  » Dr. Kenneth Masamaro, Technical Advisor, Adult HIV Treatment, CDC Kenya
  » Dr. Miriam Rabkin, Director for Health Systems Strategies, ICAP at Columbia University
  » Ms. Jacquelyne Alesi, Uganda Network of Young People Living with HIV/AIDS

SESSION 8: Panel Discussion: Designing Viral Load Laboratory Services, Part Two

• Moderators:
  » Mr. Hilary Kapoteza, University Research Co. (URC), Malawi
  » Dr. Clement Ndongmo, Chief Laboratory Infrastructure and Support Branch, CDC Zambia

• Framing Remarks:
  » Dr. Bereket Alemayehu, Associate Director of Laboratory Services & Malaria, ICAP at Columbia University

• Panelists:
  » Mr. James Batuka, HIV Treatment Team Leader, USAID Kenya
  » Dr. Sergio Carmona, Pathologist, National Health Laboratory Service (NHLS), South Africa
  » Ms. Maurine Murtagh, CEO, International Diagnostics Centre, London School of Hygiene and Tropical Medicine

SESSION 9: Afternoon Breakout sessions

Thursday June 30th

Welcome Back & Opening Remarks

• Master of Ceremonies:
  » Dr. Ruben Sahabo, Country Director, ICAP Swaziland

SESSION 10: Panel Discussion: Viral Load Monitoring & Evaluation

• Moderators:
  » Dr. Tiffany Harris, Director, Strategic Information Unit, ICAP at Columbia University
  » Dr. Heather Watts, Senior Technical Advisor, Office of the U.S. Global AIDS Coordinator

• Framing Remarks:
  » Ms. Nadia Solehdin, Epidemiologist, CDC Atlanta

• Panelists:
  » Dr. Roger Teck, HIV Operational Advisor, MSF Swaziland
SESSION 11: Presentation: Community Engagement & Patient Education

- Moderator:
  » Dr. Anna Grimsrud, International AIDS Society

- Speakers:
  » Ms. Patricia Asero, Dandora Community Aids Support Association (DACASA), Kenya
  » Ms. Sanele Tendebe, MSF Swaziland

- Respondents:
  » Mr. Vusi Matsebula, Swaziland for Positive Living, Swaziland
  » Dr. Bactrin Killingo, International Treatment Preparedness Coalition

SESSION 12: Final Breakout Sessions

SESSION 13: Closing Session & Way Forward

- Moderators:
  » Dr. Carmen Perez Casas, Technical Manager, UNITAID
  » Dr. Philippe Chiliade, Medical Officer, HIV/AIDS Branch, HRSA

- Speakers:
  » Dr. Lara Vojnov, Diagnostics Advisor, HIV Treatment and Care, WHO
  » Professor Wafaa El-Sadr, Director, ICAP at Columbia University

- Closing remarks:
  » Dr. Peter Ehrenkranz, Senior Program Officer for HIV Treatment at the Bill & Melinda Gates Foundation
**Speaker Biographies**

**Bereket Alemayehu**, MD, MSc, MPH is the Associate Director of Laboratory Services and Malaria at ICAP Columbia University, as well as an Associate Research Scientist at Columbia University’s Mailman School of Public Health (MSPH). He was previously the Director of ICAP’s PMI-funded Malaria Laboratory Diagnosis & Monitoring Project in Ethiopia.

Dr. Alemayehu holds a medical degree and an MSc in Medical Microbiology from Addis Ababa University, as well as a MPH in Epidemiology from MSPH.

**Jacquelyne Alesi** is the Executive Director of the Uganda Network of Young People Living with HIV/AIDS (UNYPA). She has years of advocacy and organizing experience on behalf of the sexual and reproductive health rights of young people at the national and global levels.

Ms. Alesi has a Bachelor of Arts from Kyambogo University, and previously worked as an advocacy and psychosocial support manager at the Namugongo Fund for Special Children.

**Stephen Arpadi**, MD, MSc is Professor of Pediatrics and Epidemiology at Columbia University’s College of Physicians & Surgeons and Mailman School of Public Health. His clinical and academic interests have focused on pediatric HIV/AIDS. He has participated in the development of treatment guidelines for children infected with HIV and was a member of the WHO Technical Advisory Group on HIV and Nutrition. He is currently on the WHO-UNICEF Interagency Task Force for Child Survival and the NIH AIDS Therapeutic Trials Data Safety and Monitoring Board. Dr. Arpadi’s research interests concern growth, nutrition, bone and metabolic health, and other long-term outcomes in HIV-infected children and adolescents. He has authored over 50 peer reviewed articles and book chapters.

**Patricia Asero** is the Coordinator of DACASA Kenya. She is a staunch advocate of access to HIV medicine and serves as Vice Chair of the International Community of Women Living with HIV, Kenya Chapter. Ms. Asero is also a treatment educator, motivational speaker, community mobilizer and a member of the Technical Working Group on CSS in Kenya. She has years of experience and knowledge on HIV issues surrounding treatment, access to care and intellectual property. She holds a diploma in medical counselling and psychology.

**Shirish Balachandra**, MD is the Branch Chief for HIV Services at CDC Zimbabwe. Prior to joining CDC, Shirish served as Public Health Officer for the UN High Commissioner for Refugees in Rwanda, where he was responsible for all health and nutrition programming for approximately 75,000 refugees from eastern DRC. He also represented UNHCR on the Joint UN Task Force on AIDS and the UN Joint Task Force for Ebola Preparedness and Response.

Shirish studied molecular biology and French literature at the University of California at Berkeley, medicine at McGill University and completed post-graduate residency training at the University of Rochester.

**Not Pictured**  
**Frank Basiye** is a Technical Advisor for Laboratory Services at CDC Kenya.
**Florbela Bata**, MD is currently working as the HIV Control Program Manager for Care and Treatment in a National IST-HIV/AIDS Control Program for the Ministry of Health, Mozambique. Prior to working for the Ministry of Health, Dr. Bata worked for four years as the Clinical Director of a rural hospital, facilitating the implementation of early ART to HIV patients. She also served as Director of Health District Service for three years in Tete City, Mozambique.

Dr. Bata received her medical degree from the Eduardo Mondlane University in Mozambique in 2005.

**James Batuka** is the HIV Treatment Team Leader at USAID Kenya.

**Victor Bigira**, MBChB, MSc is a Program Manager for HIV Diagnostics, Clinton Health Access Initiative (CHAI), Uganda.

**Pido Bongomin**, MBBS is the Deputy Country Director for Programs at ICAP Swaziland. He was previously the Country Director for the Institute of Human Virology’s Uganda Program, and a medical epidemiologist with CDC Uganda.

**Laura Broyles**, MD is the Chief of Maternal and Child Health Branch in the Division of Global HIV and TB (DGHT) at CDC headquarters in Atlanta. She joined DGHT in 2010 and has focused on expanding viral load monitoring in PEPFAR ART programs in Africa with particular attention to ensuring appropriate clinical utilization of viral load results to improve patient outcomes. She is particularly interested in issues related to VL monitoring in pregnant/breastfeeding women, children, and adolescents. Dr. Broyles served as an Epidemic Intelligence Service Officer in the CDC Division of HIV/AIDS Prevention from 2001-2003 after completing residency in internal medicine. She is board-certified in infectious diseases and has been on the faculty of the Emory University Division of Infectious Diseases since 2006.
Sergio Carmona, BSc Hons, MBCh, FPath (SA) received his basic science degree and Medical degree from the University of the Witwatersrand in Johannesburg. He completed his fellowship in hematology at the Baragwanath Chris Hani Hospital in Soweto and the Charlotte Maxeke Academic Hospital in Johannesburg. He is the pathologist in-charge of one of the largest routine HIV virology laboratories in the region. He was the former pathologist at Executive Committee of the National Health Laboratory Service from 2012-2015, an over 7,000-employee organization with 268 laboratories that provides diagnostic pathology to 80% of South Africans.

Regis Choto, MBChB, MPH, MD is a public health specialist and Deputy National ART Coordinator for the Ministry of Health and Child Care, AIDS and TB Programs, Zimbabwe. Dr. Choto has been with the Ministry since 2004, when he started as a medical practitioner. Prior to working with the Ministry, he worked as the Junior and Senior Resident Medical Officer at Parirenyatwa Group of Hospitals in Harare from 2004-2006; Government Medical Officer in Chegutu District, Zimbabwe, from 2006-2007; and Director of Medical Services for Norton Town Council from 2007-2011. Dr. Choto is married with three children, and hopes to see the world free from TB and HIV within his lifetime.

Phillipe Chiliade, MD, MHA has worked in the U.S. domestic HIV field since 1990, as an attending physician, researcher and HIV clinic director, and at PEPFAR since 2006. Dr. Chiliade began his international work with FHI headquarters as lead for ART, followed by HHS/HRSA as Medical Officer of the Global HIV Program. He has represented HRSA at S/GAC as Deputy Principal, and as a member of the Care & Treatment TWG and ICPI. Dr. Chiliade received his medical degree from the Free University in Brussels, Belgium, and his fellowship in Infectious Disease from New York University.

Geoffrey Chipungu, MD is a Laboratory Advisor and Specialist Clinical Microbiologist with CDC Malawi. His current work includes laboratory capacity building in HIV testing services, strengthening laboratory management towards accreditation, early infant diagnosis and viral load monitoring. Dr. Chipungu also services as an Activity Manager on laboratory-related cooperative agreements. Prior to working with CDC Malawi, Dr. Chipungu served as Head of Pathology at the University of Malawi.

Sindiswe Dlamini, MPH is Chief Medical Technologist of the Swaziland Health Laboratory Service, overseeing 22 clinical laboratories that run at both regional and national levels. Among the clinics Ms. Dlamini oversees are four National Referral Labs that support viral load scale-up. She has also been engaged as a consultant in a nation-wide program to develop standard operating procedures for laboratories, and serves on several technical working groups supporting supply chain management as well as care and treatment of HIV and tuberculosis. Ms. Dlamini received her Master of Public Health with a focus in epidemiology and biostatistics from the University of Newcastle in Australia in 2013, and a Bachelor of Science from the University of Swaziland in 1994.
Sipho Dlamini, MBChB is a senior specialist and lecturer in the division of infectious disease and HIV medicine at the University of Cape Town and Groote Schuur Hospital, in South Africa.

Dr. Dlamini has published extensively in the area of infectious diseases. His research interests include HIV/AIDS and the use of vaccines in adults. He is also interested in neglected infectious diseases, such as hydatid disease and leprosy, which continue to pose challenges in South Africa and the continent of Africa as a whole.

Naoko Doi is Associate Director, HIV Diagnostics, Clinton Health Access Initiative.

Peter Ehrenkranz, MD, MPH is Senior Program Officer for HIV Treatment at the Bill & Melinda Gates Foundation. From 2010 to 2015, he worked in Swaziland with CDC, first as the PEPFAR Care and Treatment Lead, and later as the Country Director. Prior to that, he spent two years in Liberia with a joint appointment as the senior advisor to the National AIDS Control Program and the medical director for CHAI-Liberia. He earned an undergraduate degree in history from Yale, medical and public health degrees from Emory, and trained in internal medicine and completed the Robert Wood Johnson Clinical Scholars Program at the University of Pennsylvania.

Wafaa El-Sadr, MD, MPH, MA is the director of ICAP at Columbia University, University Professor of Epidemiology and Medicine and Mathilde Krim-amfAR Professor of Global Health at Columbia’s Mailman School of Public Health and College of Physicians and Surgeons. Through ICAP at Columbia University, the Center she established more than a decade ago, large-scale programs have been established in sub-Saharan Africa and Asia that integrate research, education, training and practice. Dr. El-Sadr’s research interests are diverse, and include research on the prevention and treatment of HIV, tuberculosis, non-communicable diseases and maternal-child health, among others. She is focused on implementation science research as a means to taking discoveries to action, ensuring that populations around the world garner the benefits of scientific discoveries. Dr. El-Sadr was named a MacArthur fellow and is a member of the National Academy of Medicine.
Dennis Ellenberger is Associate Chief of Science at CDC’s International Laboratory Branch.

Tendani Gaolathe, MD is the director of the master training program at Botswana Harvard AIDS Institute Partnership, spearheading the organization’s HIV research, treatment and education efforts. She travels the country to train health care workers and upgrade health facilities. In addition to her role at Botswana Harvard AIDS Institute Partnership, Ms. Gaolathe sits on the Botswana Ministry of Health’s National HIV/AIDS Treatment Committee and advises a number of technical working groups. Past positions in her native country include two stints at Princess Marina Hospital in Gaborone, first as a hospital specialist in internal medicine and then as interim director of the facility’s anti-retroviral drug clinic, the first of its kind in Botswana.

Anna Grimsrud, PhD is a Programme Specialist with the International AIDS Society. Dr. Grimsrud’s project focuses on supporting the implementation of differentiated models of antiretroviral therapy delivery in sub-Saharan Africa. Dr. Grimsrud holds a Master of Public Health and PhD from the University of Cape Town, and has been involved in research with IeDEA-Southern Africa Collaboration, the Desmond Tutu HIV Foundation and Médecins Sans Frontières.

Tiffany Harris, PhD, MS is an epidemiologist and public health professional with over ten years’ experience in research, surveillance, data dissemination, program evaluation and management in a range of infectious and non-infectious diseases. As the director of the Strategic Information Unit at ICAP, she oversees assessment and implementation of country- and project-specific monitoring and evaluation, surveillance and informatics activities.

Prior to joining ICAP, she worked for the New York City Department of Health and Mental Hygiene as the assistant commissioner overseeing the Bureau of Epidemiology Services.

Shona Horter, MSc works with Médecins Sans Frontières (MSF), Swaziland.
Suzanne (Suzy) Jed, MSN, FNP-BC is a Nurse Consultant within the Data, Evaluation and Quality Branch of the Global Division in the Health Resource and Services Administration’s (HRSA) HIV/AIDS Bureau. Prior to joining HRSA, she held faculty positions within the University of Washington’s School of Public Health, and the University of Colorado and University of Southern California Schools of Medicine. Ms. Jed’s experience includes management of implementation science and PEPFAR/Global Fund-funded projects, health worker training and direct patient care.

Hilary Kapoteza is a Medical Laboratory Technologist with four years’ experience working with URC’s Molecular Laboratory in Malawi. He routinely performs HIV viral load, qualitative HIV DNA and influenza tests. Prior to joining URC as a National Coordinator of Viral Load and Early Infant Diagnosis, Mr. Kapoteza successfully held positions of Laboratory Manager for Kamuzu Central Hospital and Medical Laboratory Standards Technical Adviser for the National Laboratory Information Management System at the Malawi Ministry of Health, Diagnostics Branch. Mr. Kapoteza is committed to improving the health standards of people through the provision of quality health care.

Bactrin Killingo, MD is Treatment and Knowledge Program Lead for the International Treatment Preparedness Coalition. He has been involved in community HIV treatment education and advocacy for the past ten years. As a palliative care practitioner, Dr. Killingo is involved with resource-poor communities facing insurmountable challenges with regard to access to essential HIV medicines, and mobilizes them to advocate for increased access to much needed services. In addition, he is instrumental in empowering communities with the knowledge and skills needed to assemble resources and take charge, not only of the small projects they run but also of their own health. Dr. Killingo is a graduate of medicine at Moi University School of Medicine based in his native Kenya and holds a postgraduate diploma in Palliative Medicine from the University of Cape Town in South Africa.

Charles Kiyaga, BSc, MSc, MPhil is the National Coordinator for Early Infant Diagnosis at the Central Public Health Laboratories, Uganda Ministry of Health. He has a BSc in Biomedical Laboratory Technology and a MSc in Biomedical Sciences and Management from Makerere University, as well as a BSc in Health Systems Management from the University of Manchester and a MPhil in Medical Science from the University of Cambridge.

Shirley Lee Lecher MD, MPH is Associate Chief for Clinical Laboratory Practice at the International Laboratory Branch, Division of Global HIV/AIDS, CDC.
Nomthandazo Lukhele, MD, MCBC, BS is the National ART Coordinator for the Swaziland Ministry of Health. She has played a lead role in the decentralization of integrated HIV and TB services for children and adults to primary care facilities in the Manzini region of Swaziland. In 2014, Dr. Lukhele led a pilot program that integrated non-communicable disease management into HIV care. Dr. Lukhele is passionate about her work, and believes she has a lot to offer in the fight against the HIV pandemic and other, emerging public health concerns in Swaziland. She received a Bachelor of Medicine and Surgery from Witwatersrand University in South Africa, and a Bachelor of Science from the University of Swaziland. She is currently working towards completing a Master of Public Health in Health Systems Strengthening at Witwatersrand University.

Kenneth Masamaro is a public health specialist and serves as an advisor of Care and Treatment for CDC’s Division of Global HIV/AIDS and TB Health Service Delivery Branch in Nairobi, Kenya. In his current role, Dr. Masamaro is responsible for the ideation, implementation and evaluation of HIV Care and Treatment programs for CDC’s support to the Kenyan Ministry of Health and implementing partners, with specific focus on implementation of viral load scale up in Kenya. Prior to working with CDC, Dr. Masamaro served as lead for case surveillance, implementation science and treatment programs throughout Kenya. Mr. Masamaro is a graduate of Global Health Science from Oxford University, with Thesis with Distinction and Bachelors of Medicine and Surgery from the University of Nairobi.

Vusi Matsebula supports Swaziland for Positive Living (SWAPOL).

Not Pictured

Tsietso Motso’ane is the Director of Laboratory Services, Ministry of Health, Lesotho.

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Sibongile Ndlela is the Honorable Minister of Health, Swaziland.

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**Roger Teck**, MD, MS, is the Operational Regional Adviser for HIV in Southern Africa on behalf of MSF Operational Centre Geneva (OCG). Since the late nineties he has focused more and more on developing HIV programs (Peru, Malawi, Cameroon, and Swaziland). He was Director of Operations for MSF Operational Centre Barcelona-Athens (OCBA) from 2007 till 2009. Roger did his medical training at the University of Leuven in Belgium, obtained a diploma in Tropical Medicine at the Tropical Institute of Antwerp and did a Postgraduate Master’ Degree in “Public Health in Developing Countries” at the London School of Hygiene and Tropical Medicine.
Wellington Tserayi is a member of the Regional Advocacy Team for viral load in Zimbabwe, and works with the ITPC on viral load testing, awareness and knowledge.

He is a youth representative, counsellor and National trainer in sexual and reproductive health for adolescents and youth at the Zimbabwe National Network of Positive Living People (ZNNP+). He is also a community youth coordinator for the southern district of Harare for ZNNP+, and works as a peer educator, UN volunteer and behavior change trainer. Prior to working with ZNNP+, Wellington worked with Africaid Zvandiri as a child adherence supporter, and with the Young People’s Network and Dreams Youth Network.

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Heather Watts, MD is a senior technical advisor for prevention of mother to child transmission (PMTCT) and women’s health in the Office of the U.S. Global AIDS Coordinator and Health Diplomacy (OGAC). She works on PMTCT, prevention of maternal mortality and preservation of maternal health, family planning integration, birth defect surveillance, early infant diagnosis and viral load monitoring, pediatrics, pre-exposure prophylaxis, and other issues for women and girls. Prior to her work with OGAC, Ms. Watts spent 15 years working in the Pediatric, Adolescent and Maternal AIDS Branch of the Eunice Kennedy Shriver National Institute of Child Health and Human Development of the NIH. While there, she worked on clinical trials for PMTCT, the optimization of maternal health, antiretroviral and contraceptive interactions, microbicides and on natural history studies of HIV infection in women.

Clement Zeh, PhD is Associate Director for Laboratory at CDC Ethiopia. He has over 10 years of experience in HIV/AIDS and STI research and extensive experience developing clinical laboratory services. Dr. Zeh has been at the center of advocacy for ending the neglect of public health laboratories in sub-Saharan Africa and has made substantive contributions to the establishment of the African Society for Laboratory Medicine (ASLM) Dr. Zeh has been honored with the CDC/NCHHSTP Director and US Ambassador’s awards due to his diligent service. Dr. Zeh also serves in national and international bodies including the WHO working group for HIV drug resistance, WHO working group on the development of algorithms for HIV incidence estimation, and member of Steering Committee for Africa AIDS Vaccine Partnership among others. Dr. Zeh has authored over 25 peer-reviewed articles and serves as a guest reviewer for numerous journals and an editor for the African Journal of Laboratory Medicine.
Simon Zwane, MD was appointed to be the Permanent Secretary of the Swaziland Ministry of Health in 2014. He previously served as the Director of Health Services for Swaziland.
SESSION SUMMARIES

Evening Reception & Opening Ceremony

Wafaa El-Sadr. “Honorable Minister, your Excellency, Ambassador, and dear friends and colleagues from the whole continent and the whole world, it’s thrilling to be here and to see you all today.

This evening, I’m going to give a few framing remarks that will set the stage for the several days ahead. I will very briefly go through the state of the global HIV response, then I’ll focus on viral load monitoring, and move on to scaling up of viral load services, progress and challenges, based on what you told us in the brief survey we did before this meeting, and then I will end with the goals and objectives of this workshop.

The State of the Global HIV Response

So where are we at in terms of the global HIV epidemic? As you’re well aware, it’s estimated that there are almost 37 million people living with HIV around the world, and in reality HIV has touched every continent and every country around the world. In particular the continent of Africa has been disproportionately affected by the HIV epidemic over the past several decades. We also know there’s been an amazing success, a historic response in terms of providing access to people living with HIV with access to antiretroviral therapy treatment for HIV. Over the past several years, there’s been an enormous expansion in the number of persons living with HIV on treatment – 16 million people had access to treatment by the end of 2015. And it’s important to acknowledge that the vast majority of these individuals are from sub-Saharan Africa. So, it’s a remarkable achievement for Africa as well, and that’s very important to always keep in mind.

Now what has been the value and the benefit of this remarkable scale up of treatment? As you can see in this figure, the increase in the numbers of people who are accessing treatment over the years is accompanied by a marked decrease in the number of deaths due to HIV. So, treatment has – as you all are well aware – remarkable individual benefits to the person who is getting HIV treatment; they can live long, healthy and successful lives.

We’ve also noted that over the past years, there’s been success in terms of the prevention of HIV with the decrease in the number of new HIV infections. And again, very importantly, the decrease in the number of new infections is largely because of the decrease in number of new infections in sub-Saharan Africa. So, we have good news in terms of expansion in treatment, and we have good news in terms of HIV prevention.

The other piece of good news that we have noted over the past several years is that treatment is prevention. Several studies that have shown this, as have modeling data. One big study called
‘HPTN 052’ examined HIV transmission in sero-discordant couples (couples where one person is positive and the other one is negative). And that study showed that with treatment, there was a 93 percent reduction in HIV transmission from the HIV-infected person to the HIV-uninfected person in that partnership. So the good news is not only is treatment of benefit to the individual who’s getting treated (the person who’s HIV-infected), but also treatment is of benefit to society in terms of prevention of transmission to others. And this has been noted in different populations. For example, here are data from a study in KwaZulu-Natal Province in South Africa that show the increase of ART treatment coverage over time. And in the same time and place, there was a decrease in the numbers of new infections. So living in a community where people are getting treated decreases the risk of getting HIV infected; so treatment is good for the individual, and treatment is good for the society.

And I think those two points, the individual and societal benefit of treatment, are what motivated the WHO to release its new guidelines at the end of this past year. And in these new guidelines, WHO recommends treatment for everybody, irrespective of their stage of HIV disease and CD4 cell count.

These data, and guidelines changes also motivated new and very ambitious targets that were established by UNAIDS. And these targets are the three 90s. The focus of our workshop is the third 90, but there are two other 90s. So, what is the first 90? The first 90 is that 90 percent of all people who are living with HIV should know their HIV status. The second 90 is that 90 percent of those who are HIV-infected – who have been diagnosed with HIV – will receive antiretroviral therapy. And the third 90 – the one that we’re focusing on in this workshop – is that 90 percent of those individuals who are receiving antiretroviral treatment will have virologic suppression.

So we’re focused today and the next few days on this, the third 90: how can we enable people who are on treatment to achieve the third 90, meaning to have durable viral suppression? Because through viral suppression (suppressing the virus and virus replication) we will achieve the benefit for the individual and we will decrease transmission from HIV-infected individuals to others in their community.

Viral Load Monitoring and the HIV Care Continuum
Now let’s move on to the second part of my presentation: viral load monitoring. As you all know, 90:90:90 is easier said than done. Many countries and communities are struggling with the HIV care continuum. This is the process by which people in the community receive HIV testing, and those who are identified to be HIV positive initiate antiretroviral therapy, and then they stay on treatment and are counselled and retained and provided with adherence support and other supports so that they can achieve an undetectable viral load or viral suppression. In order to achieve the benefits of treatment, one has to be able to achieve the optimal steps or to overcome all the gaps in this care continuum.

In reality, countries around the world are struggling to optimize the care continuum. In the U.S. for example, only 80 percent of people with HIV have been identified, meaning they know they are HIV positive; only 62 percent of HIV-infected individuals are linked into care; only 40 percent are
initiated on treatment; about 37 percent are retained on treatment; and only 28 percent of all the people living with HIV in the United States have achieved durable viral suppression. So in the United States, of course there’s a long way to go to optimize this continuum. And in sub-Saharan Africa, there are similar challenges. Although data are limited, it’s estimated that maybe about 50 percent of people living with HIV have been identified. And of course, as you know, until very recently viral load measurement was not available. So there are very few data on viral suppression in sub-Saharan Africa. This is one of the reasons for this workshop – to see how we can scale-up viral load monitoring to be able to measure the success of treatment.

Now there’s always a cascade in everything, and for viral load, there’s also a cascade. Viral load monitoring is more than just having a machine and getting a test. First of all, the patient needs to have a specimen drawn, that specimen needs to get tested in a laboratory – assuming you already have the equipment and the skilled staff – the result has to go back and be provided to the patient by clinicians who are aware of the meaning of the test. And then, if the patient is virally suppressed, that means that they’re doing well and should be supported to continue, and if the patient is not virally suppressed, that means that there needs to be additional action for that individual.

There are two rationales for routine viral load monitoring. The first rationale is to identify the people on antiretroviral therapy who are not virologically suppressed. And, why is this important? Because if you identify people who are not suppressed, it means you need to provide enhanced adherence support (counselling) and also offer them the option of going to second- or third-line regimens, based on availability within their country and context.

The second rationale for viral load monitoring is to identify the people who are doing well – the people who have virologic suppression. And these individuals who are doing well on treatment may be candidates for less intensive HIV services, what is now being called differentiated care. Of course for patients who do need more intensive care, they also need to receive differentiated care that’s intensive, that’s clinic-based, that’s provided by highly skilled clinicians.

Scaling up Viral Load Monitoring
So let’s move on to the third aspect of my talk, scaling up viral load services. Before this meeting, we sent you a survey which you all completed (thank you very much), and we’re going to show you your responses. We asked you: What is the single most important barrier to the scale-up of viral load services in your country? And you can see that the largest number here indicated that it was lab and procurement issues, but also funding and human resources for health, programs and systems, demand creation and health care worker training. So you can see that everybody’s identified that there are multitudes of barriers that stand in the way of scale-up of viral load services, and we’ll be
discussing some of those at this meeting and, of course, learning from each other how to overcome those barriers. These responses also illustrate that it’s not one thing alone – it’s not simply the laboratory, it’s not simply the health care workers – it is a package that needs to be optimized to be able to provide these services effectively.

Now another question was, what is the single most important facilitator of routine viral load services in your country? And you can see the responses: availability of strategic plan and guidelines, support by donors and partners, commitment and prioritization, existing laboratory platforms, patient demand and ICT and electronic medical records. Again, during this workshop, we’ll be talking about those facilitators and those barriers and trying to share experiences across the different countries that are represented here.

So here are some participant perspectives. One of you noted: “I think we are moving from the what to the how” of viral load monitoring, which is exactly what this meeting, this workshop is about. We’re going to be talking about the how: how can we optimize, how can we reach the third 90?

And then you can see another quote here, “We have good access to viral load testing, but still face challenges bringing the clinician, the patient and the test result together, and actually using the data to guide management” and that’s a very, very critical part of what we’re going to be talking about over the next few days. How can we bring all of these different stakeholders to be able to actually achieve the goal of viral load testing, and guide the management of the patient?

**Workshop Goals and Objectives**

So lastly, what is the goal and what are the objectives of this workshop? I think the goal is very clear. The goal is to reach the third 90, which is very important. Of course, all of the 90s are critical, but this workshop focuses on the third, because we are here to talk about viral load monitoring.

So what are the objectives? The first objective is to bring a diversity of stakeholders from laboratory, from clinical and programmatic services, from patients and communities, and from monitoring and evaluation experts. The second objective is to share practical lessons and tools. We are really talking about the “how”, so that’s the purpose of our days together. And the third objective is to support and advance country-specific action plans and next steps. We hope that this workshop will enable many of you in this room to be able to go back to your places of work and to take your action plans and really put them to use and to hopefully be able to implement successfully and scale up viral load monitoring within the context in which you work.

So lastly, I want to end with one observation. I think it’s important to just keep in mind that our goal is – through all of our HIV programming that all of you do and have done so successfully – is to achieve impact. And, by impact, I mean achieve an impact on the lives of people living with HIV and also achieve an impact in terms of control of the HIV epidemic. And in order to do that, there are two prerequisites. One is to expand coverage, meaning to reach as many people as possible, and that means that first 90 and the second 90: to
achieve, to reach, engage, enhance uptake and adherence and retention of all the patients there are in our services. And most importantly, of course and equally important to coverage, is to achieve all of this with high quality. So hopefully this week we’ll be talking about coverage, we’ll be talking about quality and in the end, through this work, we’ll hopefully have a major impact on the lives of people living with HIV and the communities in which they live.

I want to end by a few acknowledgements. First I want to acknowledge the Ministry of Health in the Kingdom of Swaziland for really being the key partner in planning this workshop, as well as of course for all the support over the past many, many years. And then I want to also thank the funders for this workshop: HRSA and the Bill and Melinda Gates Foundation. And then the support and guidance from PEPFAR, OGAC and USG, ASLM, ITPC, all the workshop participants, all of you who were very engaged before the meeting and will be engaged during the meeting and we thank you for this. And finally, I want to of course thank the ICAP team here in Swaziland who made this possible for us to get together here. Thank you.”

Trevor Peter. “Good evening everyone. Honorable Minister, Ambassador, other distinguished guests, on behalf of the African Society for Laboratory Medicine, I’d like to welcome you all to this week’s meeting, to this very important meeting on the scale-up of viral load testing. I’d like to start by highlighting what Wafaa so eloquently presented today: the global 90:90:90 goals. These goals were announced in 2014 by UNAIDS and they’ve really catalyzed the field, they’ve catalyzed the world in fact. And as a public health community, and as diagnosticians in particular, we recognize that, for the first time perhaps in 20 years, laboratory medicine and diagnostics now stands at the forefront of the global AIDS response. So we have within these three 90s, diagnostics being critical, actually potentially in all three of those 90s, and certainly in the third 90, diagnostics is key to achieving the goal of viral suppression.

But in terms of where we stand right now, and in terms of the scale-up of viral load, the WHO guidelines strongly recommending the use of viral load came out in 2013. We’re three years on from then, and we’ve made progress. But, I would say perhaps our progress represents an S-shaped curve and we’re still in that lag phase. And, if we project out to 2020 – which is when we expect to achieve our 90:90:90 goals – we expect over 30 million patients will need access to viral load testing, but based on current projections that are being done by WHO and other partners, we anticipate that perhaps we may reach the capacity to test 23 or 24 million patients by 2020. That represents roughly 60-65 percent of coverage, as opposed to the 90 percent coverage that we’d like to achieve. This is a gap, it’s actually absolutely disappointing when we think about what we very optimistically projected what we will achieve by 2020. And what it tells us is that those of us sitting in this room and the other public health professionals that are working on scaling-up the antiretroviral treatment response and viral load testing need to work even harder. We need to change
that curve; we need to bend that curve upwards so that we can achieve the 90 percent level of coverage that we’d like to achieve by 2020, which is a short three and a half – four years away.

Now when you look at viral load coverage country by country across Africa, and I’m looking at this really thinking on a pan-African perspective, we can see some early starters (countries that started using viral load perhaps over a decade ago) as well as countries that started using and scaling-up viral load within their public testing programs over the last few years. And these programs, you can see in terms of the numbers of patients who are receiving testing, the level of coverage, they’re much more advanced. Countries such as South Africa, Botswana, Kenya, Uganda are quite advanced in terms of their level of coverage. Other countries are at different stages. Now, this obviously represents a challenge, because the countries that need to scale-up and move forward have a long way to go, but they’re also opportunities within that. And we can look at the best practices, we can look at the lessons that we’ve learned, what works, what doesn’t work and take those lessons and use them. That’s the smartest way to approach implementation – to look at what works and take those best practices and apply them within our own programs.

So that’s looking forward at viral load. I’d like us also to remember that viral load is not the first HIV diagnostic that we’ve tried to scale-up – we as a public health community have tried to scale-up on a large scale. Do you remember CD4 testing? And while CD4 testing no longer has, I think, the level of importance that it used to have, there was a time when it was very important, and a lot of efforts went into scaling-up that test and perhaps over ten years of scale-up of CD4 testing, as well as, perhaps slightly more recently, the scale-up of early infant diagnosis. There’ve probably been at least eight to ten years of scale-up of early infant diagnosis. And both of these tests have attracted a lot of attention in the efforts of many of us.

But if you look at what we’ve achieved in terms of scale-up over the last decade of these two tests, looking historically, perhaps today at its peak, CD4 reached roughly maybe two-thirds of all patients who should have received that test. And early infant diagnosis is currently at about 50 percent. So, what this tells us is that when we look at our goal for viral load over the next four years – four to five years – we truly have to bend the curve. We truly have to do things differently. We have to learn from our successes from CD4 testing and early infant diagnosis, and apply those successes to viral load. But also to move with increased speed and increased attention to where the pitfalls are and where the gaps are that may slow us down.

Now, one other lesson that we can learn from CD4 testing history, as well as the early infant diagnosis history, is that, as a lab community, we put a lot of effort into building laboratories. We put a lot of effort into delivering tests, but sometimes we’re not very well connected to the clinical community. In fact, if you look at loss to follow-up, in other words the number or the proportion of patients or infants who receive the test after their test is done, the numbers aren’t quite as impressive – sometimes, actually quite often in the range of maybe 40 to 60 percent. So even though we’re doing the test, and we’re delivering the test, most patients are not getting the test in their hands and having that test acted upon. And this is a lesson for us, and we have to work as an integrated community – the clinical side as well as the lab side as well as the program side and Ministry
leadership and management and policy – so that we can deliver these tests in an integrated, comprehensive fashion.

Now we have, I think, ahead of us a significant challenge. This week, I think, provides a unique opportunity to come together and discuss some of these challenges, some of the historical lessons that we can learn from, as well as what we need to do differently moving forward. I think as a community, we’re probably uniquely placed to come up with new suggestions, new approaches, and renewed resolve and impetus for the coming years ahead.

So thank you everyone and we look forward to the discussions over the coming week.”

Bactrin Kilingo. “Sanibonani [SiSwati for hello], Jambo [Swahili for hello], Howdy you all (yes, we have folks from the U.S.)! So, Honorable Minister, madam Ambassador, my good friend Professor Wafa, my colleagues from civil society, members of the community of people living with HIV: I really am privileged, I think, to be invited to this forum to share a couple of things in the next three days that are seldom talked about. I’m really just going to talk about some of the things that communities and civil societies are trying to voice and some of the things that I think will be amplified in the next three days.

I think to start with, I know people have been wondering what is ITPC? We are, essentially, an organization of like-minded advocates and activists, some living with HIV and some not, across the world whose interest really is all about community activism with regard to access to optimal treatment.

We started this journey in 2003, when people weren’t accessing treatment. So at that time, we needed to push to make sure that people who are, who are in need of access to treatment actually get it. And that’s why you get to hear voices in different countries, like the Treatment Action Group, like the Treatment Action Campaign in South Africa, doing a lot of activism and advocacy, mobilizing communities to first and foremost know that they have a right to access treatment, and that when they do, this is what it is and this is what should make you start and stay, on treatment. And so ITPC has pushed that agenda over the last decade or so to ensure that the access agenda is still at the table, making sure that we mobilize communities to be aware of what they need, as far as treatment is concerned (especially quality treatment). So that we eventually then are able to provide quality of life. So that, in a nutshell, is what ITPC is.

But, talking about the third 90, it’s easy to come up with very nice, rosy, ambitious targets. And so, we embrace the three 90s, particularly the third 90. But I can tell you for free: we will never achieve it, as long as we get to hear this kind of statement coming from communities [gestures to slide projection with community quotes]. I got to visit nine countries in the last 11 weeks, and I’ll talk about why. But, some of these statements came from people in those places you call rural, those, you know, places that we are saying are hard to reach or even just in urban areas where they should be accessing treatment.

When you get to hear somebody saying we can never achieve 90 in the absence of routine viral load testing, it’s like fighting in the dark. Somebody wakes up and actually realizes that they’ve never been tested or monitored for treatment using routine viral load and actually don’t know whether their
treatment is working or not; and eventually comes out in public and says 'it’s like fighting in the dark!' and that’s something that I think we may need to think about in the course of the next three days. To ask ourselves, how can we work together to make sure that we do not fight in the dark?

And, you know, sometimes you sit and you say ‘you know they’re patients’. But up until you realize that’s a human being who needs to be in the driver’s seat in that program that you actually run, then you are fighting a losing battle. Because this is what they say [gestures to quotes again]. Somebody comes and says, ‘I don’t know why you are drawing blood, I don’t know why because you never tell me. And even when you do draw blood, I come back to get a refill and you never tell me what happened to my results. And when you do tell me, you say ‘Oh, we didn’t have some reagents’ as a by the way.’ So these are some of the things that if we think about them, helps us look back and ask, what is our plan in engaging communities to succeed, to achieve the third 90?

And this brings me to the next slide, which is the cascade, the viral load cascade according to our perspective. You notice that it’s cyclical. And this actually argues the case of the routineness of the need to do viral load testing. And it starts with – the most important part – that recipient of care.

In the nine countries that I got to visit, very few have adopted the 2015 guidelines and that’s worrying. Could we form a movement to encourage each and every one of these countries to at least put a plan; adopt the guidelines and have a three-, four-, five-year plan? I can see some of the Ministry of Health officials that I got to visit – I can see my sister there from Swaziland, I can see my sister there from Mozambique – give me deliberate efforts to hear what communities are saying, and say ‘okay here is what we need to do in terms of a plan, can you come and have a conversation with us on whether or not this makes sense to the entire country?’

But then, you sit back and you say, ‘okay, you seem to always just want to complain. Civil society, complain, complain, complain’. Well, guess what? We also are very good at identifying what the gaps are within ourselves and what the gaps are amongst, you know, members of communities of people living with HIV. And we did a survey a year and a half ago that identified that a lot of people we got to survey said, ‘how can we use a service that we don’t understand? Why are you telling me to get a viral load test and you haven’t really told me what that is?’

And so at the end of the day, ignorance really, really is powerful and can mess up any trajectory that anyone wants to achieve with regard to success. But we also do know that knowledge is important. So, when my very good friend from Malawi says that those who are knowledgeable will get treatment because they will go and ask (‘I hear there is this testing, how come I can’t get it?’), but she also is worried that these people in the village who don’t know, and who haven’t been given the
fodder or the tools to get to know why they need to have routine viral load testing. And so, for us as civil society, demand creation is extremely important.

I’ve heard folks from the lab say, ‘well we have these machines that can do 10,000 runs, but we aren’t getting enough samples, these machines are being underutilized’. Well! You can only get those machines fully utilized if you start from the beginning: the demand side of things, creating demand. And we do know that knowledgeable people will likely to routinely ask for routine viral load services.

So we as ITPC, because of this knowledge that we got from this survey, and what people are saying communities came up with a program based on our treatment education program to say, ‘how can we go to communities, provide them the knowledge around the science of HIV infection, and the science of HIV treatment, and in there the science of HIV treatment monitoring in the simplest way possible for them to then see the importance of treatment monitoring?’ And we came up with a tool; it’s called a Routine Viral Load Activist Toolkit which we have used in nine countries to tell people exactly what I’ve told you and have them then go down into their communities, use the same Toolkit in their language to mobilize people to be aware and knowledgeable on the use of routine viral load for treatment monitoring. And then, from there, drive a consciousness to say I will be going to my health care facility to have a conversation with my health care worker about appropriate treatment monitoring to make sure that my treatment is working.

Those that I’ve mentioned in the audience can bear witness because they attended some of these workshops that I got to conduct in the last 11 weeks. And so this is something that we want to replicate throughout the next many months and many years.

But what comes with knowledge, other than just owning that information that influences your own treatment? It also comes with advocacy. To come out and ask, ‘how can I contribute to positive impact, as far as accessing routine viral load is concerned?’ And, you know, seeing that people in there, in Zambia realizing that this is something that’s important; they moved, they got themselves together and they went to the Ministry, the Minister of Health. They didn’t toyi toyi (protest chant), it was a peaceful demonstration to create attention and awareness about this new thing. And by the time we got to her [the Minister of Health], you know we had a message and a petition, and what happened in about a mouth, they put in the guidelines that routine viral load needs to be ensured, and TALC [Treatment Advocacy and Literacy Campaign] was then tasked to go into the communities and create more awareness so that people are able to get this information.

So, as I conclude, I would like to encourage us to also look at, once we get to provide the services, how well will we monitor and come up with an appropriate data that tells us that country X, community Y has achieved viral suppression rate X? Right now, based on what I have seen in all
these nine countries, we are using some of the wrong data; we are talking about tests and not number of people being tested. I remember questioning people to say, when you say your viral load suppression rate is X, using viral load tests when one person can get three tests in a year, there is something fundamentally wrong there. And I think we will talk about this in the next three days, and we really are keying in and making sure that, from a data point of view, we are able to know exactly what is going on.

And, with that, I want to conclude with this message to say that because we just don’t complain and we want to be part of the action-oriented things. Ange Mavula from DRC said, ‘Once the appropriate reliable viral load testing tools are there, the onus is on the people living with HIV and associated communities to continue creating demand for the utilization of these viral load test monitoring tools and ensure they are always there for all in good working condition and working at full capacity.’ Because his colleague in Zambia was able to say that, ‘Without a viral load test, I am sure I wouldn’t be there today.’ The struggle continues. Thank you.”

Session 1: Setting the Stage

Opening remarks were provided by Professor Wafaa El-Sadr, Dr. Laura Broyles and Dr. Philippe Chilliade.
Dr. Roger Teck opened the session with a discussion of the challenges of routine VL monitoring and the lessons learned by Médecins sans Frontières (MSF). He noted the importance of VL monitoring both to identify patients with detectable VL for the purposes of enhancing their treatment, as well as to identify stable patients with undetectable VL for the purposes of referring them to less intensive differentiated care options.

In an overview of the MSF experience with routine VL monitoring, Dr. Teck stressed that VL monitoring requires much more than laboratory services. He highlighted the importance of community sensitization towards increased VL awareness; patient education and empowerment for VL demand creation; and training, sensitization and supportive supervision for health care workers and adherence counsellors. Reviewing each step of the VL cascade, Dr. Teck used data from MSF to illustrate the challenges of ensuring VL tests get taken at the correct intervals, that results are delivered to clinicians and patients, and that they are actually used to guide patient management. Successful approaches included identifying a VL focal person at each facility, flagging patient results, optimizing triage to facilitate patient flow and decentralizing access to second-line treatment towards achieving the third 90. He also noted that MSF has a viral load toolkit available at: http://samumsf.org/blog/portfolio-item/viral-load-vl-toolkit/ and that additional resources are available at: http://www.msfaccess.org/undetectable.

Dr. Nomthandazo Lukhele followed Dr. Teck’s framing remarks with a case study of Swaziland’s experience moving from targeted to routine VL testing. In Swaziland, an official VL Task Force was initially established in 2014, and revamped following the countrywide adoption of the relevant WHO Guidelines in 2015. A readiness assessment was conducted at 23 high-volume facilities, the results of which are being used to identify key barriers to routine VL roll-out and set implementation priorities. To address barriers and work towards nationwide implementation, Swaziland is optimizing lab system workflows; decentralizing lab services; adapting clinical mentoring SOPs at the national level; and integrating Test and Treat messages within existing community mobilization activities.

To provide another perspective, Mr. Frank Basiye presented Kenya’s experience using the Facility Baseline Assessment Tool, developed in 2008 in conjunction with the first VL testing in the country. The Assessment Tool is broken into three phases: (1) facilities and hubs, (2) testing labs and (3) management of results and patients. It is meant to be used on an ongoing basis, and its components evolve over time; it currently includes metrics to test facility preparedness, clinician competency, patient education, commodity management, lab infrastructure, specimen handling protocols, and results management, among others.

There are currently seven VL labs in Kenya which serve approximately 2,000 testing sites; 637,158 tests were done in 2015. Utilization of the Assessment Tool highlighted gaps and led to improvements, including improved uptake of VL services, commodity management policy
development and new policies to ensure proper maintenance of patient information, including VL test results.

Finally, Dr. Shirish Balachandra described highlights from VL implementation in two districts in Zimbabwe. A 2014 review of the VL cascade found very encouraging rates of VL uptake, and a suppression rate of 85–86%. While lack of communication between adherence counsellors and clinicians was identified as a common gap in both districts, overall adaptation of VL monitoring has gone well, as compared to CD4. Strategies for achieving similar VL uptake include equal investment in laboratory testing capacity and program implementation; simplification of documenting practices; staggering patients by month; and task shifting among health center staff.

Session 3: Viral Load Strategies for Pregnant & Breastfeeding Women, Infants, Children & Adolescents

Dr. Landon Myer opened the third session with two key messages regarding VL monitoring for pregnant and breastfeeding women, the first being that pregnant and postpartum women on antiretroviral therapy (ART) are a critical population for VL monitoring. Many clinicians observe reduced ART adherence and viral suppression during and directly after pregnancy, and the benefits of targeting this population are four-fold, including improved maternal health, reduced sexual transmission, decreased mother-to-child transmission and long-term health of children and families.

The second key message Dr. Myer presented focused on the slightly different VL monitoring strategies required for pregnant and postpartum women, with regard to urgency and timing of testing. Gestation and breastfeeding are time-limited, and involve high-risk ‘windows’ (such as delivery and early infancy) in which effective VL monitoring is critical. Testing, review and return of results and appropriate clinical action needs to be rapid. Yet, the question of when to test pregnant and postpartum women depends on multiple factors, including gestational age, duration of breastfeeding and turnaround time, among others. One approach is to test as soon as VL should be suppressed and repeat testing at intervals through the end of breastfeeding.

Dr. Stephen Arpadi then discussed the way forward to reach the third 90 for infants, children and adolescents. WHO guidance for implementing routine VL testing for infants, children and adolescents is sparse, and rates of viral suppression among this population are typically lower than adults. To address this, Dr. Arpadi recommended several strategies: Prepare health workers and systems for managing higher rates of non-suppression among younger patients; expand capacity for VL services that address the specific needs of infants, children and adolescents, adapted to local contexts; disaggregate monitoring and evaluation (M&E) and quality improvement (QI) by age along the cascade; establish the correlation, if any, between more frequent VL testing and improved viral suppression among younger people; and share best practices and lessons learned.
Mr. Wellington Tserayi provided another perspective on behalf of society. As a youth representative, peer counselor and young person living with HIV, Mr. Tserayi has an acute awareness of the specialized needs of children and young adults living with HIV. He emphasized the importance of tailored patient education materials to inform and empower patients, specifically children and adolescents, whose specialized health care needs and risks differ from those of adults. Furthermore, Mr. Tserayi spoke to education as an empowerment tool. He recommends using information to engage youth in managing their own health, rather than underestimating their ability to comprehend and digest an HIV diagnosis, its ensuing treatment and management.

**Session 4: Designing Viral Load Clinical Services, Part Two**

Dr. Pido Bongomin provided framing remarks for the second session on clinical VL service design. He discussed a phased approach to transitioning from targeted to routine VL testing, which Swaziland did by identifying priority populations: adults at risk for treatment failure, pregnant and breastfeeding women on ART, pediatric patients on ART, and adolescent patients on ART. Dr. Bongomin also described Swaziland’s approach to sample collection and transportation, highlighted important decisions about laboratory equipment and laboratory health workforce management, noted the importance of clinical standard operating procedures (SOPs) and intensive efforts to reduce test turnaround time. His conclusion was: “In summary, this can be done!”

Dr. Tendani Gaolathe continued the session with an example from Botswana, where a VL triaging system was adopted in 2002, and remains the cornerstone of HIV/AIDS care today. Implementation of VL services highlighted the need for program monitoring, and a system was developed to assess progress towards goals. Today, a decentralized lab system comprised of 38 laboratories is supported by two additional referral laboratories. Routine feedback from these laboratories is provided to an ARV Clinical Guidelines Committee as well as a Drug Forecasting and Costing Technical Working Group to determine and improve upon treatment program policies, priorities and outcomes. As a result, Botswana has a viral suppression rate of 70.2% which is well within reach of the UNAIDS target of 73%.

Dr. Beth Harley then reviewed services along the VL cascade in the context of Cape Town, South Africa where an ART program was initiated in 2004 and now serves more than 140,000 patients. Despite relatively easy access to VL tests (compared to other countries represented at the meeting), Dr. Harley noted the difficulty of bringing a test result, a clinician and a patient together to actually change clinical management. As she noted, “there is many a slip between the cup and the lip” – too often, results are not sent when indicated, or sent but not used swiftly or appropriately. She outlined simple, practical strategies such as the use of charting tools and reminders, ensuring that patients know when they should have VL testing performed, developing effective systems for filing VL results when they are returned to the clinic, and reinforcing the importance of achieving viral suppression, not just registering VL results. A final tip was not to make second line ART “too precious” as this reduces access to effective treatment.
Another service design example was presented by Dr. Florbela Bata. In Mozambique, VL monitoring was introduced in 2015, and is currently being implemented in seven of ten provinces throughout the country. To improve suppression, targeted strategies to support laboratory testing, train healthcare staff, support enhanced adherence counseling, and track patients with elevated VL test results are underway. As the scale-up of routine VL testing is expected to identify far more patients requiring 2nd line treatment, another adaptation will be decentralization of the national “second line committee” which, since 2013, has reviewed and approved all patients on 2nd line ART in the country.

To wrap up the discussion, Dr. Sipho Dlamini reviewed the experience of a tertiary hospital in Cape Town, South Africa. He explained that there are many reasons for elevated VL test results, including medication side effects, cognitive dysfunction, substance abuse and social issues. The Groot Schuur Infectious Disease Clinic employs HIV counsellors, nurses and physicians to support these high-risk patients with counselling, psychiatric and medical reviews and home visits. However, the switch to second or third line treatment (based on genotype testing and a treatment committee) is at times necessary to ensure viral suppression. Dr. Dlamini highlighted the importance of VL monitoring guidelines and documentation; a team approach; and a package of care for patients with high VL test results to ensure optimal patient care and outcomes.

**Session 6: Designing Viral Load Laboratory Services, Part One**

Ms. Naoko Doi opened session six with an overview of point of care VL testing, and considerations for where its deployment is likely to be most successful. While many countries are introducing and quickly expanding access to VL services, there is significant need to scale-up those services to meet the increasing demand. Point of care testing, although its role is still being defined, can be used to supplement more conventional testing networks in the scale-up process. Specifically, it can cut turnaround time in high-volume facilities and expand reach to geographically isolated locations.

To help countries determine optimal deployment of point of care VL testing to maximize patient impact while maintaining cost efficiency, Ms. Doi presented a Site Selection Tool developed by the Clinton Health Access Initiative (CHAI), which uses national and site-level data to measure probability of success. The Tool allows for facilities appropriate for point of care VL testing deployment to be shortlisted based on ability to meet patient volume, and clinician capacity to switch patients to second line treatment regimens.

Following this introduction, Dr. Clement Zeh presented lessons learned from the experience of early infant diagnosis (EID) VL roll-out in Ethiopia. In 2015, Ethiopia saw a 50% reduction in new HIV infection, compared to 2010; however diagnosis of HIV-exposed infants remains a challenge, and fewer than half of HIV positive babies are initiated on treatment. Key barriers include lack of community awareness and long turnaround time. To address these and other challenges, Ethiopia focused on M&E to strengthen and scale-up EID VL services.

A standardized, web-based system was developed to collect, store and report VL information from testing sites. There are currently 19 functioning labs across the country (up from seven in 2008) which utilize the system to track indicators on Ethiopia’s laboratory request form, as well as others required for reporting for MoH and PEPFAR. Results are then returned to referring facilities using
SMS printers. As the country continues to further VL scale-up, they aim to strengthen monitoring using GIS mapping; improve community engagement to increase demand for testing; and support supply chain management at national, regional and site level.

**Dr. Dennis Ellenberger** then presented a scorecard for improving efficiencies of VL testing and result utilization. The scorecard is facility-based, and aims to bridge the communication gap between laboratory and clinical staff. It is meant to be used by laboratory technicians, quality officers and managers; clinicians; policy makers; and partners.

The scorecard examines efficiency and effectiveness during pre-testing, testing and post-testing, including personnel, equipment and results documentation, among others. A final score and summary report highlight gaps and areas for improvement. The scorecard, which is being piloted in five countries, offers opportunities to identify and remediate VL testing spectrum gaps; provides a standard approach to measuring improvement; and drives optimization of workflow efficiencies for VL scale-up.

Finally, **Ms. Sindisiwe Dlamini** provided an overview of Swaziland’s experience in designing VL laboratory services. Although Swaziland’s HIV prevalence is 26%, VL testing capacity was lacking, with only three functional machines that are unable to keep up with demand. To compound the issue, frequent machine breakdowns add to backlog accumulation of untested specimens.

To strengthen systems and scale-up VL services, human resources requirements were addressed first. The workforce was increased to include phlebotomists, laboratory technologists, data clerks, health workers, couriers and drivers. At the facility level, standard operating procedures were put into place for sample collection, storage and transport, as well as results documentation and utilization. At a national level, VL specimen transport systems were improved to ensure most facilities are reached at least twice per week.

These and other activities have identified opportunities to improve the scale-up, and Swaziland will focus on targeting difficult to reach populations, such as infants and children, in the coming months.

### Session 7: Quality Improvement & Quality Assurance for Viral Load

To introduce the role of quality improvement (QI) and quality assurance (QA) for VL scale-up, **Dr. Kenneth Masamaro** presented preliminary results from a VL service quality assessment in Kenya, aimed at assessing quality of care, documentation and VL monitoring for clinical and laboratory processes. Kenya began the shift from targeted to routine VL testing in 2014. To monitor progress and assess compliance with national VL guidelines, service quality was assessed at 25 facilities across the country in 2016. Although overall coverage of routine VL testing is impressive, the swift and effective utilization of VL results continues to be a challenge. Results demonstrate delayed service delivery across the VL cascade, suboptimal documentation and, in some cases, inadequate communication between facilities and referral laboratories. Recommendations include increased collaboration with implementing partners, robust follow-up on outstanding VL results, establishment of documentation standard operating procedures and training in support of VL scale-up.

**Ms. Jacquelyne Alesi** followed with her personal story of what quality VL services look like from the patient perspective. As a person living with HIV,
Ms. Alesi talked about her experience moving through the VL cascade, from initial treatment and its failure, to her first VL test and transfer to second-line regimen, based on VL test results. She noted that it took her a year to agree to switch to second line ART, highlighting the importance of effective education and counseling, and the need to respect patient preferences.

In sharing her story, Ms. Alesi reminded the audience that VL testing and scale-up reaches far beyond laboratories and clinics, and requires input from those directly affected.

Dr. Miriam Rabkin presented the Quality Improvement Collaborative (QIC) approach, which can be leveraged to improve VL services. Using specific methodology for taking QI to scale, the QIC brings together an organized network of health facilities to work on a single focused program topic area with QI methods and tools. Participating facilities agree on a shared aim statement, data indicators and measurement process for the project period, which typically ranges from 12 to 18 months. Quarterly forums bring participants together on a quarterly basis to review data, share learning and spread successful changes, which can be scaled and spread on a larger scale.

Session 8: Designing Viral Load Laboratory Services, Part Two

Dr. Bereket Alemayehu introduced the second session dedicated to designing VL laboratory services with an overview of platform selection and deployment; specimen type (dried blood spot versus plasma); quality assurance; and supply chain management. He highlighted four operational questions for policy makers: (1) what assumptions do national programs need to make to determine the gap in testing capacity and the number of additional analyzers needed? (2) How should national programs determine which platform(s) to choose for the setting? (3) Which acquisition approach best serves national programs (purchase versus reagent rental)? (4) What should be the most important drivers of deployment strategy – distance, disease burden, administrative structures, and/or internal equity?

To provide context, Mr. James Batuka presented an experience from Kenya, where eight VL testing labs support a network of facilities with routine VL testing for all sample types. Since national scale-up efforts began in 2014, Kenya developed and implemented a single electronic system that aggregates lab data and provides reports.

Experience over the past two years has illustrated the importance of negotiating prices and terms directly with vendors; developing and utilizing a single integrated system for VL testing and supply chain management; harmonizing platforms across all testing labs; developing a central commodity security team; and continually addressing storage challenges.

Dr. Sergio Carmona continued the discussion with an overview of the use of dried blood spots for VL monitoring. While VL monitoring is widely recommended, access is limited and capacity to act promptly on VL test results is, in many cases, suboptimal. Dried blood spots provide a convenient alternative for specimen collection, and can increase access to treatment monitoring with VL testing, especially in remote areas.
Dried blood spots are easy to transport at ambient temperature, which significantly reduces transportation challenges, including cost. Additionally, they do not require centrifuge, making sample collection much easier and allowing for decentralization of collection; can be used with existing testing platforms; and can be used for drug resistance testing.

**Ms. Maurine Murtagh** provided an overarching presentation of VL testing in resource-limited settings. As she explained, VL testing is almost exclusively laboratory-based and requires sophisticated instruments with trained technicians. The cost of testing platforms, complex assays and infrastructure and transportation requirements pose additional challenges to scale-up. As a result, low access rates have created a vicious cycle in which low demand inflates the cost of VL treatment, while high prices suppress demand growth.

This cycle has led to an interest in decentralizing VL testing to move it closer to where patients receive care by simplifying testing, improving efficiency, reducing cost and increasing access. New point of care options for testing provide lower cost and systems requirements; however they do not eliminate the need to strengthen laboratory systems, human resources and/or supply chain management. Product development and distribution have also been challenging, but point of care shows significant promise in scaling-up VL services without compromising the quality of patient care.

**Session 10: Viral Load Monitoring & Evaluation**

**Ms. Nadia Solehdin** discussed considerations for M&E of VL implementation towards achieving the third 90. Planning for M&E requires collaboration, communication and coordination among people, tools and systems. Specific to VL implementation, it is important to understand and promote data use at all levels of the cascade to ensure that information is available for patient management and care.

In developing M&E systems for VL tracking, Ms. Solehdin recommended forming interdisciplinary taskforces, mapping data flow, piloting test processes and developing comprehensive training plans. At the site level, staff should also be engaged in the M&E process, and provided with training. Additionally, common data challenges can be addressed by utilizing unique identifiers and biometric technology to allow for tracking of individuals over time, and electronic medical records for easy and accurate data recall that can be linked to track VL data.

**Dr. Roger Teck** presented a 2015 evaluation of routine VL monitoring in Médecins Sans Frontières-supported HIV programs. The evaluation included diverse indicators covering three domains: (1) the VL cascade itself, including quality and impact of VL services; (2) patient and community perception and acceptance of VL monitoring; and (3) cost and cost effectiveness of VL monitoring.

Between 2012 and 2015, projects in Lesotho, Malawi, Mozambique and Zimbabwe focused on scaling-up VL services in rural settings using dried blood spot samples. An analysis of clinical and laboratory records from each facility illustrated how each step of the VL cascade was implemented according to local guidelines. Results, which demonstrated routine VL coverage between 32-91% depending on facility, were presented to program staff and used to discuss barriers and their solutions.
Dr. Victor Bigira provided another example from Uganda where a national VL dashboard is used to store and track data. Key indicators include the number of samples received, VL suppression rate and the rate of sample rejection.

Throughout his presentation, Dr. Bigira highlighted the importance of developing a central monitoring system for program performance that allows for integration of facility and patient modules to support monitoring and follow-up at the facility and patient levels.

Dr. Geoffrey Chipungu continued the discussion with a presentation of Malawi’s VL dashboard. National guidelines introduced VL monitoring in 2011, and national-level scale-up of services began in 2016. A national dashboard merges data from all laboratories throughout Malawi, and can be used for simple data analysis and reporting needs.

Two main challenges were encountered during dashboard development: lack of quality assurance and lack of internet connectivity. To address the issue of quality control, mandatory fields are incorporated in the dashboard and scripts only accept valid entries. To address the barrier of poor internet connection, a separate connection was developed for the database server.

Dr. Sergio Carmona provided a final example of VL M&E implementation from South Africa. Ministry of Health officials were engaged at the onset of national dashboard development to ensure its alignment with treatment guidelines. Laboratory functions were reviewed by an advisory team, informed by an extensive literature review and used in a pilot dashboard tested with 16 VL laboratories. Following minor modifications, the dashboard has been rolled-out nationally and is monitored on a monthly basis.

The dashboard allows for real-time monitoring from the facility-level up, and can generate heat maps to illustrate problematic locations with regards to each indicator. Access to data and regular monitoring has led to an increase in VL testing and optimized remote quality monitoring tools at laboratories across South Africa.

Session 11: Community Engagement & Patient Education
Ms. Patricia Asero, third from right, shared personal experiences – as a person living with HIV – across the HIV and VL cascades. Throughout her moving story, Ms. Asero highlighted the critical importance of messaging and communication, and the need to engage people living with HIV in HIV programming. Enhanced adherence counseling, in particular, helped inform and support Ms. Asero; however, she was quick to note that “counseling is very vital, but when it is done correctly.”

Following an important training co-sponsored by the International Treatment Preparedness Coalition and the Network of African People Living with HIV, Ms. Asero became involved as a treatment activist. She now uses her experience and education to inform and support individuals and communities struggling with HIV/AIDS.

In closing, Ms. Asero provided three key recommendations, “you need to train health care providers, the people who do the real work. Give them that opportunity. Also give money to do treatment education for people living with HIV and our communities. The third area is the messaging. If there is a standard message, then the nurse who is blaming a person living with HIV, will not do that because they’ll have a different message. When you are doing all of this in different countries, work with us. Don’t leave us behind in the third 90, and don’t leave us behind when you are talking of routine viral load.”

To further explore the patient perspective, Ms. Sanele Tendebe presented findings from a qualitative study aimed at understanding how HIV-positive patients interpret and understand their VL test results. In an effort to examine possible negative consequences of receiving undetectable VL test results, semi-structured interviews were conducted with 22 patients in Swaziland in 2013. Analysis of interview transcripts demonstrated that VL monitoring can have a positive impact. Participants reported that access to VL test results enhanced their understanding of HIV and its treatment, increased support for ART adherence and motivated self-protection with regard to sexual practices. However, care must be taken for health care workers to avoid assumed non-adherence, and provide additional support to avoid undermining patient hope in treatment.

Dr. Bactrin Killingo continued this message with a presentation of the International Treatment Preparedness Coalition’s Activist Toolkit used to support and train community activists to advocate effectively on access to treatment for people living with HIV.

In addition to highlighting this useful tool, Dr. Killingo’s key messages circled around the importance of treating patients as partners who deserve respect. In order to affect change and engage communities in the scale-up of VL services, it is essential to change negative health care worker attitudes, support treatment education to accelerate demand creation and provide timely, friendly and appropriate communication of VL test results to affect health outcomes.

Session 12: Final Breakout Sessions

For the final breakout session, participants were asked to meet in country teams to develop a post-meeting action plan. They were asked to discuss lessons learned, next steps and action points to present back to the plenary. The following is a summary of their responses:

Angola recognized the long way ahead, and identified the most important learnings as the need to quantify current need and capacity, and anticipate supply needs. The team was also interested in learning about programming and training needs along the entire VL cascade, and creative ways to
address and manage M&E. In the coming months, the team from Angola will conduct a quantification exercise with stakeholders to establish an M&E process; design workflows specific to each site; and conduct intensive training, mentoring and supportive supervision along the cascade.

**Ethiopia** identified patient engagement, the use of dried blood spots to enhance access to VL testing and the need for a comprehensive M&E system as key meeting takeaways. Upon return to Ethiopia, they planned to increase awareness for routine VL testing among clinicians and patients alike; improve turnaround time by implementing a quality management system; strengthen M&E systems by emphasizing the clinical-laboratory interface; and ensure adequate supply availability for rapid VL scale-up.

**Kenya** found the need to involve the recipient of care in VL monitoring scale-up to be a key message. They were also interested to learn about integration of disparate data reporting systems and hear experiences from countries at different levels of implementing VL monitoring. In the future, Kenya will work to reduce time between test result receipt and intervention; improve data reporting systems to allow for longitudinal patient tracking; improve quality and monitoring of adherence counselling and complete laboratory accreditation towards improving the quality of VL tests.

**Lesotho** learned the importance of engaging people living with HIV in care and treatment services, including VL monitoring, and establishing adherence clubs to improve treatment and retention. Representatives also identified the use of dried blood spots for rapid VL test scale-up as a key learning. Their priority actions include linking unique patient ART identifiers within the existing data dashboard to improve turnaround time and track patients for follow-up; engaging people living with HIV as major partners; and implementing a dried blood spot-based VL test to increase coverage among difficult to reach areas.

**Malawi** acknowledged four main learnings, including the importance of engaging people living with HIV in patient engagement and decision-making; applications for QI along the VL cascade; M&E of performance at hub laboratories; and prioritization of high-risk patients for VL testing, including children and pregnant women. Upon return to Malawi, they will focus on involving people living with HIV to strengthen patient education and increase demand for VL services; support QI team roll-out; adopt M&E tools to monitor VL samples; and reduce the backlog of VL tests for children.

**Mozambique** found the importance of appointing a VL focal person interesting, and enjoyed learning about considerations for developing decentralized laboratory services for VL testing, including the pros and cons of implementing point of care testing. In the future, they hope to improve VL demand by increasing patient involvement; develop a well-defined package of care for patients with VL test results greater than 1,000 copies/mL; develop a well-defined package of care for stable patients; implement a robust M&E system and dashboard applicable across their system of care.

**Swaziland** identified community sensitization and empowerment of recipients of care as key lessons learned, in addition to methods for ensuring facilities convey VL test results to patients, and approaches to M&E. Following the meeting, representatives from Swaziland planned to begin developing a VL register, involve people living with HIV in the development of new patient education materials and improve lab capacity by forming direct partnerships with equipment manufacturers.

**Tanzania** was most interested in learning about the need for partnership between service providers and recipients to reach the third 90, the importance of collaboration among multidisciplinary teams; and methods for applying the VL cascade approach to identify system barriers and develop
innovative solutions. In the coming months, they will work to revise the VL testing algorithm to include pregnant and lactating women and children; validate and agree upon implementation protocol for dried blood spots; and include people living with HIV in the National Viral Load Technical Working Group.

Uganda learned the importance of conducting quality assessment to review program gaps and improve services; the need for a site-level VL focal person; the role of point of care testing; and various methods for strengthening clinical, lab and M&E interface to provide coordinated VL services across the cascade. As follow-up to this meeting, representatives from Uganda plan to initiate planning meetings with key stakeholders to discuss methods for improving overall VL services; adopt an M&E tool that allows for longitudinal patient tracking; review a point of care test implementation plan; and form a VL sub-committee to provide technical guidance for VL testing implementation.

Zambia learned that a multidisciplinary approach is necessary to successfully achieve the third 90. They were also interested to learn about pros and cons of equipment rental versus purchase, and different methods for demand creation and patient education. Following the meeting, they plan to set up a national VL technical working group to spearhead and monitor VL service roll-out; adapt and disseminate 2015 WHO guidelines on when to start ART and pre-exposure prophylaxis for HIV; and facilitate a national stakeholder meeting to share lessons learned from this meeting.

Zimbabwe was most interested to learn that reaching the third 90 can be done successfully. They also found the critical nature of coordination across disciplines interesting, and were interested in recent M&E innovations and the value of leveraging competition among VL equipment suppliers. Their priority actions include accelerating demand creation activities; maximizing performance and productivity among existing testing equipment; and forming a VL Task Force with concrete deliverables and a timeline linked with the national VL scale-up plan.

Session 13: Closing Session & Way Forward

Rejoice Nkambule. “Welcome to the final session of the meeting. Indeed, there has been great work happening in the last three days, and it has been a great honor to listen to the country presentations. I am Rejoice Nkambule, Deputy Director of Public Health in the Kingdom of Swaziland, and my co-moderator is Dr. Philippe Chiliade, and I am just going to hand over to him to make a few remarks.”

Philippe Chiliade. “Thank you, and good afternoon. The few words I want to say are related to what I said the first day of the workshop: I said that the value and the quality of this meeting will depend on you, it will be your meeting and you will create this meeting. And, I have to say I was really stunned by what you have accomplished. A big applause to you! From the presentations we’ve seen that are very relevant to our programs, to the comments made, and most importantly the exchange of information and lessons learned, I’ve witnessed that there has been immediate progress and impact. Again, thank you very much. I would also like to remind us of what Professor El-Sadr said in the beginning. The impact of the third 90 is a combination of two things: it’s a combination of coverage and quality, and quality is not just the technical quality of the overall system that we discussed, but also quality as it is perceived by clients of those services. So please keep in mind, not just to scale but also focus on quality. Thank you.”

Dr. Lara Vojnov presented an overview of HIV drug resistance and its likely effects on the scale-up of VL services. Although the WHO 2015 guidelines (recommending that all HIV-infected individuals initiate ART as soon after diagnosis as possible) will undoubtedly lead to a decrease in
HIV incidence, they will also paradoxically lead to an increase in HIV drug resistance among those infected, despite prevention and treatment interventions, including routine VL monitoring to diagnose and confirm treatment failure.

To combat the influx of HIV drug resistance, the WHO/HIVResNet laboratory strategy functions to support HIV drug resistance surveillance by providing accurate and timely genotyping results. The approach is supported by multiple networks of regional, national and specialized laboratories in Africa and across the globe. Early warning indicators are monitored to gauge factors associated with virologic failure and emergence of HIV drug resistance at treatment facilities.

Because of its intimate link with viral suppression, drug resistance can impact our ability to achieve the third 90; efforts to measure and respond to drug resistance are therefore critical to achieve sustained population-level VL suppression and ultimately achieve the goal of eliminating HIV by 2030.

Wafaa El-Sadr. “Good afternoon everyone, and thank you all for being here until the very last session. We’re thrilled to have you all with us at this meeting. I’ve called this presentation The Way Forward, and I’d like to start by revisiting our meeting goals. It seems like a long time ago, but it was only Monday evening when we opened this meeting, and had the pleasure of having with us the Minister of Health of the Kingdom of Swaziland as well as other senior leadership from the Ministry of Health. And, we’re honored today to have here today two such senior leaders with us in this closing session.

Our goal was to bring together a variety of stakeholders, as you recall, from fields that are somewhat ‘silied’. This includes laboratorians, clinicians and program staff, patients and community members, and also monitoring and evaluation experts. The second goal was to share practical lessons and tools. And the third one was to support and strengthen country-specific action plans and next steps. And hopefully – I hope you agree – we have achieved at least some of our goals in the last several days.

So who attended the meeting? About 160 people came to this meeting from many countries, and they included clinicians, providers, persons living with HIV and civil society members, as well as program managers, policy makers, laboratorians, implementing partners, M&E experts, researchers and also funders. So we’ve had quite a diverse group of individuals here, and I think that has brought a real richness to the conversations and to the exchange that occurred over the past several days.

What we have realized is that we have underestimated the complexity of the viral load cascade. This figure is from one of the presenters, and highlights the complexity involved in achieving our goal, in terms of scaling-up of routing viral load monitoring. We see the steps from demand generation, to educating the recipients of care, to educating clinicians on the importance of viral load measurement, as well as, of course, to all of the different steps that need to occur in terms of specimen transport and within-laboratory work, to the return of the viral load results to providers, and
very importantly the action on such results in a conversation between the clinicians, counselors and the recipient of the care.

There are several gaps that were identified during our conversations. The first is demand generation and this became very obvious very early on during this meeting. We need to work hard at generating demand for viral load measurement among the recipients of care: patients, clients, communities, people living with HIV. We have a long way to go in order to achieve this, and without achieving this, we’re not going to succeed. I think also there needs to be demand generation from the clinician side, to get the clinicians to buy into the importance of viral load measurement and monitoring, and be keen and attuned to receiving the results, and then to work very hard at transmitting these results in an appropriately sensitive way to their patients, as we have heard from several countries today. And lastly, of course, demand generation involves, engaging peer educators who are very fundamental to the success of all HIV programs.

We identified many additional gaps, and I won’t go through them all, but I think it was nice to break them into the pre-laboratory, within-laboratory, and post-laboratory domains. The pre-laboratory arena involves identifying which patients need viral load tests, providing education and counseling as to why the test needs to be done, obtaining high quality specimens and getting them to the lab on time. Within-lab issues include human resources, which machines to utilize, how to maximize the available platforms that are there within laboratories, and how to provide high-quality laboratory results. And finally the post-laboratory component includes, of course, return of results to the facilities from where they were obtained, and the all-important ‘meeting’ of the results, the clinician, and the patient that leads to action.

Another area or gap that was highlighted is the laboratory-clinical interface, and it was very encouraging to hear the conversations, and to see individuals who have spent their lives working within the laboratory system, and then others who are in the clinical system, to sit together and really try to appreciate each other’s perspectives. And two areas stood out in terms of critical importance: the flow of information and the need for action on the information, within the clinical context.

Another gap that was identified was monitoring and evaluation, and the need for process measures to really measure every step of these multiple cascades – there are many, many cascades within the viral load cascade. We discussed the importance of these process measures to be able to assess those steps, as well as the outcome measures of interest. We also noted the importance of having some standardized indicators that we can utilize across all the different countries where this work is being done.

Last, but not least, was the identification of the importance of quality and quality improvement. Certainly, monitoring and evaluation can help identify the gaps, but it’s only through quality improvement processes that one can address those gaps. So, there’s a very tight relationship between M&E and quality improvement.

Ultimately, I think what we want to do is to have empowered recipients of care. This is a beautiful photograph, and the word ‘empower’ is what will stay with me from this whole conference. This is a person who has received his viral load measurement, and that’s really, ultimately, what we want; what it’s all about and what we should all be focusing on is empowering our patients with this information, and empowering them to lead healthy lives.
We also recognize that having scaled-up viral load monitoring is more than just the machines. Machines are just one small bit of the puzzle. Again within that cascade that exists within the laboratories – before the lab and after the lab and within the lab.

And I think many of us will be haunted by the point made by Trevor Peter, who showed us that almost half of CD4 results and half of the positive EID results that have been performed to date have never been delivered to the patients themselves, which is a really troubling message. I think this is something we need to keep in mind and keep with us: it’s our responsibility as a community that the findings from these very important results have to go back to the people who need them. And, I hope that we’ll do better with viral load measurements, and we need to, of course, do much better with EID and giving back the results to the mothers and to the families.

I think another important message came from Roger Teck, when he presented the findings from different cascades that MSF conducted in a variety of programs in different countries. For example, he showed us that only between 22 to 43 percent of those who had viral load above the limit were re-suppressed, and it’s unclear what proportion of them had received the recommended enhanced adherence counseling. And depending on the program, only 10 to 38 percent of the individuals had actually been switched to second-line therapy. So this, again, tells us the importance of maintaining the cascade and closing the loop in order to achieve optimal health outcomes. And then we heard from Beth Harley, a frontline clinician, about the challenges of developing systems to ensure that viral load results not only get sent, but actually get used. Even in South Africa, where access to viral load testing is easier than in some of the other countries represented here, she noted the struggle to actually bring the test result, the clinician, and the patient together and to act on the information. One of her tips was that program and laboratory staff need to work together in systematic ways, to look at the results and act on them. A second tip: to ensure that the last viral load is always brought forward and recorded on the “top sheet” of the clinical notes, so it’s not buried in the chart or register. For patients with elevated viral load, she strongly recommended that the date of the next viral load test be highlighted prominently in the chart, rather than simply noting that enhanced adherence counseling is needed. And her last tip was also very important: don’t make second-line therapy too precious, meaning, don’t deny access to patients who need a change in therapy because of this fear of using second-line ART when it’s appropriate to switch the patients.

That was a quick summary of what we’ve learned this week. This conference was entitled Reaching the Third 90. I am advocating that the next one will be called Achieving the Third 90 Together because one of the key messages of the week is that we have to work together, across silos, to be able to achieve this goal. Thank you very much for your attention.

**Peter Ehrenkranz.** “I’m happy to say that there’s no more slides. Thanks for the kind introduction, and thank you to everybody for staying awake and attentive to the end of this really exciting conference. I think everyone here would agree that we’ve had quite a productive few days. I’m not going to attempt to repeat or summarize anything that Wafaa has already covered, and I also promise not to go on too long. My role is to thank the really important folks and organizations who’ve helped get us here, and to highlight how we as the co-conveners and funders hope to work with all of you to ensure that the momentum that we’ve built here can actually be sustained.

So first, thank yous. I want to acknowledge the Kingdom of Swaziland, in particular, the Ministry of Health for hosting us here in this very beautiful country. As many of you know, I had the pleasure to
live here for about five years and it is really nice to be home. I would like to thank Miriam Rabkin, Wafaa El-Sadr, Lauren Walker, Ruben Sahabo and really the whole ICAP Team in their numerous blue bibs – for the many hours that they put into the organization of this workshop, and for ensuring that despite our really packed agenda, there was time outside of the formal agenda for discussion and interaction among all of us. I would also like to thank my former PEPFAR colleagues, particularly Suzy Jed and Philippe Chilade from HRSA, for being the initiators of this really important idea; and then being willing to share some of the organization with us so that it could be co-funded by myself and my colleagues at the Gates Foundation. I’d further like to thank Trevor Peter from ASLM and Bactrin Killingo from ITPC for working with us as part of the organizing committee and as co-conveners of this session. Lastly and very importantly, I’d like to thank each of you who travelled from near and far, and who clearly heeded the request to participate actively in this meeting and really make it your own. Can I hear some applause, maybe, for yourselves? It really has been a pleasure to hear from you and learn from you, as you challenge each other and encourage each other to improve your outputs. Most important, I want to acknowledge – as many of you have already done – the gift of humility that I felt that our colleagues from civil society gave to us by their active participation in this meeting. To paraphrase Jacqueline [Alesi], ‘we must remember that there are individuals behind all of our statistics, each of them with his and her own face, story, challenges and dreams.’ I also really liked what Patricia [Asero] had to say, that 95 percent of reaching that third 90 is about empowering the person who is taking those medications.

So, viral load is a tool. It’s a tool that has the possibility of helping these partners, these patients, these clients, helping them improve their health. But, as we’ve heard very clearly, one size does not fit all, and it’s up to us – those of us who are the health care providers in the room – to develop the systems to improve access to viral load and to ensure the quality of results. And as we do so, we face the challenge that my colleague from WHO noted, of finding that balance between a public health approach and an individual, truly client-centered care approach.

So that leads us to the question, how are we going to do that? This morning, a small group of us met at breakfast to discuss how we can maintain this energy, this momentum and these relationships that have been kindled in these last three days. In the near-term, ICAP has promised to produce a report that’s going to describe the key challenges and country-specific responses that we highlighted in our various discussions on clinical services, laboratory services, monitoring and evaluation, community engagement and patient education, and the many interfaces between them all.

Our goal that we came up with out of our discussion was to try to come up with a checklist, for lack of a better word, a checklist and then some mini case studies. The idea is that as you continue your conversations in your home countries, that the checklist should help ensure you’re thinking through your system comprehensively – that, as we’ve clearly heard, is much more complicated than what can be presented in one slide – that you remember all those little bits, and you can say, ‘Oh right! We should remember about X.’ Then, next to it, we’ll see some mini case studies – if there’s a country that did a good job with whatever that X was (with procuring equipment as our friends from Kenya did, with recognizing the importance of using expert clients for counseling as I know some other countries have done). So, that’s the idea and we may find some gaps. There may be a spot in the
checklist where there is no good case study, and I think that that’s going to be a very important place for us all to recognize and work together to try to fill.

The idea is to show that we’ve begun to turn the corner – I think Wafaa said in the beginning – from the what to the how, and to really complement some of the excellent tools that have already introduced (we’ll make sure we give this information to you). But there are tools from ASLM, from MSF, from ITPC and a really, I thought, quite nice tool from CHAI about how we can start to think about how to properly place equipment in our different countries. I know that all of those organizations will be very willing to assist anyone who raises their hand and says, ‘we don’t quite understand how to use this, can you come help us?’ they’d be happy to sort that out with you.

So in the longer-term, I’ve heard many of you say that we should try to find ways to exchange ideas and collaborate, whether virtually or in-person, in the future. And we want to make sure we include not only the countries that are present here, there are many who are not – there are many on the continent and there are also countries outside of this continent who probably would be interested in what we’ve had to say. So, to that end, I’m happy to inform you that the Bill & Melinda Gates Foundation will be giving a series of grants to organizations with just this purpose in mind. One of the grants is going to go to ICAP to establish a learning network of countries seeking to improve access to and quality of HIV care. Another is going to go to ASLM to establish a community of practice for countries who are building their laboratory systems, as all of you are. And its purpose is going to be to pick up this momentum around viral load, this opportunity to scale-up viral load, and drive complementary changes within the whole laboratory system. So we’re not just scaling-up viral load, but as we’re thinking about sample transportation, it’s remembering that there’s lots of other diseases that need sample transportation for their key tests as well, and all the other aspects of a laboratory system. The third grant is going to go to WHO to determine best practices around unique identifiers, which is a theme that we’ve really heard over and over and over again, about how this is a barrier that every country is facing, and there is almost no country that I know of besides India that is at near universal coverage with unique identifiers. And I know Swaziland is on its way, but not quite as far as India.

All of these grants are still in their planning processes, ICAP’s is the furthest forward, but I expect that you’re going to be hearing from all of them soon. And at the very least, they’re going to include some form of webinars, teleconferences, site visits, journal clubs, face-to-face meetings all hopefully led by those of you in this room and your colleagues. We at the Foundation, and among all of the conveners and co-conveners and funders, we’re really committed to making sure that this energy moves forward, to bringing you back together in person and also in these various virtual ways so that these action plans that you’ve created today can continue to have some life and you can hold each other accountable. So, as you can see, this meeting is really only the beginning.

Speaking on behalf of all the co-conveners, I know we all look forward to working with you and the communities of people living with HIV in the coming months and years to reach that third 90 and hopefully a little beyond.”
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