

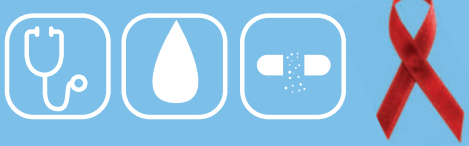
BOTSWANA
HARVARD AIDS INSTITUTE

PARTNERSHIP

FOR HIV RESEARCH AND EDUCATION



ANNUAL REPORT 2020





BOTSWANA HARVARD AIDS INSTITUTE PARTNERSHIP

———— 2020 ————

ANNUAL **REPORT**



Botswana Harvard AIDS Institute Partnership
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2020 - Annual Report

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1. STRATEGIC FOUNDATIONS



VISION

To Be a World-Renowned Public Health Institute.



MISSION

To Fight HIV/AIDS and Emerging Public Health Challenges Through Innovative Research, Education, and Capacity Building That Impacts Policy and Practice.



CORE VALUES

- **BENEFICENCE**

All activities done at BHP shall be of relevance and benefit to those affected by HIV /AIDS and/or other public health challenges. The knowledge generated through our research shall be availed to advise public health policy and shall be shared with the general public and scientific community for the benefit of mankind. We shall be guided by the principle of “Do Not Harm” in our Research and related activities.

- **INNOVATION**

BHP staff is committed to finding solutions to the evolving HIV /AIDS pandemic and other public health challenges. We shall endeavor to be continuously innovative and resourceful in our quest to understand and address public health challenges.

- **COLLABORATION**

BHP recognizes that the fight against HIV /AIDS and other public health challenges will not be won by one individual or one institution. We commit and emphasize the importance of teamwork and collaborative research in our activities.

- **EXCELLENCE**

To achieve our vision of being a “world renowned public health institute” we at BHP commit to quality driven research and training programmes and processes. We will be second to none in our drive to attain quality in our research and training.

- **BOTHO**

An encompassing Setswana word that means amongst other, integrity, respect, honesty, and compassion. We are committed to adhering to moral and ethical principles treating all our customers, including research participants, with respect, dignity and compassion. All information about studies will be handled with utmost confidentiality

2. BHP AT A GLANCE

ESTABLISHMENT

Botswana Harvard AIDS Institute Partnership (BHP) is a Not-for-Profit, limited liability organization, established through a partnership between the Government of Botswana, represented by the Ministry of Health and Wellness (MoHW), and Harvard University (HU), represented by the Harvard T.H. Chan School of Public Health (HSPH). It was established in 1996 and registered as a limited liability company in 2009.

BUSINESS

Knowledge generation and dissemination, Advocacy, Health Policy Transformation and Systems Strengthening through Research, Education and Capacity Building.

CONTACT DETAILS

Registered Office: Botswana Harvard HIV Reference Laboratory Plot 1836 (Princess Marina Hospital premises) North Ring Road, Gaborone, Botswana

MAILING ADDRESS

Private Bag B0320, Gaborone, Botswana
Tel: (+267) 3902671
Fax: (+267) 3901284
Web: www.bhp.org.bw

Company Auditors: Price Waterhouse Coopers
Company Secretaries: DPS Consulting
Company Attorneys: Armstrong's Attorneys, Notaries & Conveyancers
Main Bankers: Standard Chartered Bank & Stanbic Bank



3. GOVERNANCE

a. Board of Members



Prof. Michelle Williams
Angelopoulos Professor in Public Health and International Development, Dean Harvard T.H. Chan School of Public Health.



Prof. Eric Rubin
Irene Heinz Given Professor of Immunology and Infectious Diseases and former Chair, Department of Immunology and Infectious Diseases, Harvard TH Chan School of Public Health.



Prof. Mark Elliot
Mark Schwartz Professor of Chinese and Inner Asian History, and Vice Provost for International Affairs, Harvard University



Prof. Michael Hughes
Professor of Biostatistics, Director, Center for Biostatistics in AIDS Research Harvard TH Chan School of Public Health.



Dr Madisa Mine
Consultant Virologist Ministry of Health & Wellness (MOHW)



Prof. Sheila Tlou
Co-Chair of the Global HIV Prevention, Former Minister of Health and Wellness Botswana.

b. Board of Directors



Chair: Prof. Roger Shapiro
Associated Professor, Department of Immunology and Infectious Diseases, Harvard T.H. Chan School of Public Health.



Ms Katie Hope
Chief Financial & Administrative Officer, Harvard T.H. Chan School of Public Health.



Dr Malaki Tshipayagae
Ex-Director Health Services, Ministry of Health and Wellness (MoHW).



Dr. George Matlho (Deceased)
General Manager, Botswana Vaccine Institute



Mr Modise Modise
Economist & Former Permanent Secretary of Development, Office of the President



Dr Shahin Lockman
Associate Professor in the Department of Immunology and Infectious Diseases, Department of Immunology and Infectious Diseases at HSPH.



Dr. Joseph Makhema
Chief Executive Officer BHP



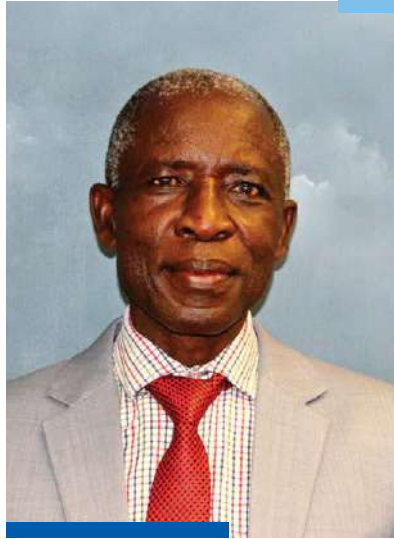
Ms. Ria Madison
Chief Operations Officer BHP - Ex Officio Member, non-voting Director

c. Executive Management



Joseph Moeketsi Makhema
MB.ChB, FRCP (UK)

Dr. Makhema is a Practicing Internal Medicine Physician and is the CEO of the Botswana Harvard AIDS Institute Partnership (BHP). He Provides strategic leadership, manages and supervises all initiatives of the BHP. He oversees grant funded research and training awards sponsored by NIH, Wellcome Trust, EDCTP, and various PI initiated research projects. He is the Co- PI of the BHP/HSPH Clinical Trials Unit, providing oversight and clinical mentorship for all CTU trials. He is Site PI for HPTN and the newly established COVID-19 Prevention Trials Network. He advises on the selection of the BHP clinical research portfolio. He has published and been involved in over 100 publications. He is interested in community HIV prevention initiatives, translational policy issues, and health systems strengthening.



Mompoti Oganne Mmalane
MD, FRCS-Ed, MSc – Ortho

Dr Mmalane obtained his MD Degree from the University of Tuebingen then trained in surgery and became a Fellow of the Royal College of Surgeons of Edinburgh. In 2002 he obtained a M.Sc. degree in Orthopaedics from the University College London. He has worked for 22 years in the public health sector before joining BHP as Co- Director in 2009. He is a co-investigator in several BHP studies. He has co-authored over 40 papers. Dr Mmalane's strength is in partnerships creation and management, community engagement, systems thinking, and strategic management and leads BHP's strategic planning activities. His main interest is in community-based research.



Ria Madison

Ms Ria Madison is Chief Operations Officer of BHP, providing overall oversight for Administration, Finance, Grants, Human Resources, IT and DMC. She is responsible for the oversight of all donor/grant funds, compliance of spending per donor requirements and meeting statutory and compliance audits. She also oversees the implementation and development of operating policies and strategic planning for Administration. Ms. Madison has been with BHP since its inception. She studied Accounts and Business Studies, Grants Management and Human Resource Management.

d. Senior Management



Sikhulile Moyo
MSc, MPH, PhD

Dr. Moyo is BHP's Laboratory Director and a Research associate with HSPH. He is a former Harvard T.H Chan School of Public Health McGoldrick Fellow Biostatistics, and has completed 2 Post-Doctoral Fellowships supported by NIH Fogarty International Center (Global Health Fellow, Harvard HBNU) and Wellcome Trust funded DELTAS SANthe program (Post-Doc Scientific Fellowship, BHP). His interests include characterization of early HIV-1 Infection, estimating HIV incidence, evolutionary bioinformatics, phylogenetics and molecular epidemiology. He has made a number of significant recent advances in the analysis of HIV recency of infection by incorporating HIV diversity refine cross-sectional incidence estimation and over 140 peer reviewed publications. He has worked on various projects including: evaluation of point-of-care viral load and CD4 devices, early infant treatment, community-based prevention studies, Hepatitis, CMV and HPV genotyping, HIV-1 drug resistance. In 2016, Sikhulile was nominated co-vice Chair of the ACTG/IMPAACT Laboratory Technologist Committee. He participates in various international and local HIV technical working groups. Dr Moyo is a member of the Botswana's Presidential COVID-19 Task Force Team as a co-Chief Scientist. He is an Investigator & Site-Principal Investigator for some NIH funded projects and is a supervisor/mentor for many fellows/researchers at BHP.



Cornelius Gaetsaloe

Mr. Cornelius Gaetsaloe is Director of Finance and Grants. He is responsible for BHP's strategic financial management, grant administration and sustainability planning, the implementation of BHP policies and procedures through the administrative stewardship of BHP's portfolio of grants and research projects. Cornelius is also responsible for risk management and compliance and has more than 12 years experience working in senior strategic positions in non-profit organizations.



Gaerolwe R. Masheto
MD, PGDip FamMed

Dr. Gaerolwe Masheto started working at Botswana Harvard AIDS Institute (BHP) Clinical Trial Unit (CTU) in 2011 as a Study Physician and has worked with a team which has successfully conducted International maternal, paediatric, adolescents AIDS clinical trials (IMPAACT), AIDS clinical trials (ACTG) and HIV prevention trial network (HPTN) clinical trials. Currently Dr. Masheto is the CTU Coordinator, IMPAACT Network Project Leader/Principal Investigator (PI) and Molepolole Clinical Research Site Leader. Dr. Masheto is also a Co-Investigator for ACTG and HPTN studies. Dr Masheto graduated from Ross University School of Medicine in 2007 and Stellenbosch University in 2012 with Post Graduate Diploma in Family Medicine. He is enrolled to Masters (MSc) in Clinical Epidemiology at the London University's London School of Hygiene and Tropical Medicine. Dr. Masheto's interests are in Public health, Infectious Disease Epidemiology and Management with a focus on design, modelling, implementation, monitoring and evaluation of HIV/AIDS and TB prevention, care/support, treatment programs, and PMTCT interventions. He is also interested in research for HIV Cure and he is a fellow for International AIDS Society (IAS) 2018 Academy-for-Cure Research.



Ayotunde Omoz-Oarhe
MBBS, MPH

Dr Omoz-Oarhe is ACTG principal investigator and Gaborone clinical research site leader. He has worked with BHP Clinical Trials Unit (CTU) for many years now where he has served in various capacities and gained a wealth of research experience. He has been at the forefront in the conduct and oversight of numerous NIAID sponsored protocols covering a wide variety of public health issues including Tuberculosis and women's health. He has also served in various ACTG committees and is currently a serving member of the ACTG Performance Evaluation Committee (PEC).



Coulson Kgathi
BSc

Mr. Coulson Thabo Kgathi is a Software Engineering & Data Management Centre Manager at Botswana Harvard Partnership. His team builds data collection systems and laboratory systems for the research lab. He holds a BSc Computer Science and is currently doing his MSc in Computer Science. He has been part of the team that developed robust systems that collect data across the country in multiple communities with poor connectivity, with a system designed for functioning offline and capable of transmitting data when there is low bandwidth. This system enforces research protocols to ensure quality data, data security and easy data sharing.



Dineo Tumagole
BAcc

Mrs. Dineo Tumagole is the Finance and Grants Manager at the BHP. Her role is to ensure effective management of BHP's funds through monitoring of Grant Budgets and compliance with sponsor regulations. She keeps tab of the internal control environment to ensure smooth Statutory and Yellow Book Audits. Dineo is a self driven individual whose over 10 years of experience in the financial accounting and grants management environment has enabled her to build a robust Finance, Grants and Procurement Team and drive change. She has been working for the partnership since July 2012.



Thuso Mokane
BSc

Mr.Thuso Mokane is a Bachelor of Science in Computer Science graduate from the University of Botswana who is passionate about Linux. He began his career in IT in 2012 as an Associate Software Engineer at DCDM Consulting and joined BHP in 2014 as a Systems Administrator, where he gained a lot of experience working on IT Systems based on open-source technologies. Throughout his career, he has gathered certifications in Linux System Administration, and is internationally recognised as an ISC2 System Security Certified Practitioner. Thuso Mokane is now the IT Infrastructure & Security Manager and utilises his skills in both systems administration and cyber security to ensure the availability of information systems and security of data.



Tlhopho Kgotla

Mrs. Tlhopho Kgotla served as the Human Resources and Operations Manager for BHP from June 2019 to July 2020. She has over 14 years of experience in the Human Resources field having worked for various organisations serving in different capacities. Ms Kgotla's role was to provide strategic and management leadership to effectively deliver HR services at BHP. She holds a Master's Degree in Human Resources Management (HRM) and a Bachelor of Behavioural Sciences both from Griffith University in Australia.



Terence Mohammed
BSc

Mr Terence Mohammed is the Laboratory Operations Manager at Botswana Harvard AIDS Institute Partnership (BHP). His primary role is to oversee technical operations of the clinical laboratory; including the clinical trials processing labs and testing labs, logistics of operations, maintenance of the laboratory accreditation and DAIDS GLCP status, implementation of the quality management plan, compliance to regulatory and sponsor requirements. Terence is a Biomedical Scientist by training and has been at BHP since Dec 2007, rising through the ranks and receiving multiple research/training fellowships.



Nyaladzi Comfort Maphorisa
BSc

Mr Nyaladzi Comfort Maphorisa is a medical laboratory scientific officer registered with the Botswana Health Professions Council. He is a product of Curtin University of Technology in Perth, Australia. He possesses twelve years' work experience in the medical laboratory field for which six years were in managerial position. He is currently the Clinical Laboratory Manager at Botswana Harvard HIV Reference Laboratory (BHHRL). The Clinical Laboratory Manager (CLM) under delegated authority laboratory director is responsible for the technical and delegated administrative functions of the clinical laboratory day-to-day operations, including facilitating the conduct of BHP clinical research studies, maintenance of equipment, infrastructure and collaborative activities that involve laboratory operations. The CLM is required to ensure adherence to defined quality standards, regulatory and sponsor requirements, including timely, consistent, proficient and competent laboratory outputs.



Tshepho Theodorah Frank
BPharm

Tshepho Theodorah Frank completed her pharmacy degree at the University of West Indies, Trinidad and Tobago. She completed an internship through the Botswana Government pharmacy internship program, which involves rotation in different pharmacy disciplines. She joined BHP in August 2010 as a Pharmacist of Record for Clinical Trials Unit. She was promoted to Pharmacy Coordinator and Pharmacist of Record for multiple protocols and multiple sites in April 2013.



Tumulano Sekoto
RN, MPH

Tumulano Sekoto is a Registered Nurse, Midwife and a Family Nurse Practitioner all obtained from the then National Institutes of Health between 1989 and 1996. She holds BA (Psychological Counselling) and BA (Honors) Psychology from University of South Africa (UNISA) and Postgraduate Diploma in Health Research Ethics from University of Stellenbosch. She recently acquired her Masters in Public Health from UNISA. She joined BHP in 2000 as a Research Nurse based at the Mochudi Mashu Site. She is currently the BHP Regulatory Office Coordinator responsible for all issues of Ethical Conduct of research and Human Subjects Protection. She is passionate about Research Ethics.

e. Principal Investigators



Roger L. Shapiro
MD, MPH

Prof. Roger Shapiro is an Associate Professor of Immunology and Infectious Diseases at the Harvard TH Chan School of Public Health in Boston, and an Infectious Disease physician at the Beth Israel Deaconess Medical Center in Boston. He has been working with the Botswana-Harvard Partnership since 1999 on studies to prevent mother-to-child HIV transmission (PMTCT) and to improve pregnancy outcomes and childhood survival. In Botswana, he has led randomized clinical trials to evaluate optimal antiretroviral strategies for PMTCT at delivery and during breastfeeding; a randomized trial to study the efficacy of prophylactic cotrimoxazole among HIV exposed uninfected infants; nationwide surveillance studies to evaluate the mechanisms by which antiretrovirals impact adverse birth outcomes; an ongoing clinical trial of early antiretroviral treatment to improve clinical outcomes in HIV-infected infants; and an ongoing study of broadly neutralizing antibodies for HIV treatment in children.



Max Essex
DVM, PhD

Prof. Max Essex, DVM, PhD, is the founding Chair of the Botswana Harvard AIDS Institute Partnership (BHP), and, at Harvard University, Lasker Professor of Health Sciences and Chair of the Harvard T.H. Chan School of Public Health AIDS Initiative (HAI). Professor Essex retired as Chair of both BHP and HAI in 2018. He was one of the first to link animal and human retroviruses to immunosuppressive disease, sharing the Lasker Award with Gallo and Montagnier in 1986 for this research. With his student T. H. Lee, he was also the first to identify gp120, the surface protein of HIV-1 that is used for blood screening and diagnosis of AIDS. He has published over 650 papers and 12 books, the latest being *Saturday Is for Funerals*. His current research includes comprehensive “test-and-treat” approaches to controlling the HIV epidemic, molecular epidemiology, the role of host genetic factors, and chemoprophylaxis.



Shahin Lockman
MD, MPH

Dr. Lockman is an infectious-disease trained clinician (Associate Professor at Harvard Medical School/Brigham and Women's Hospital and adjunct at HSPH). She has conducted epidemiologic and clinical trials investigation related to HIV-1 and tuberculosis with colleagues in Botswana since 1996, including randomized trials of antiretroviral treatment among pregnant and postpartum women with HIV; trials and observational studies aimed at optimizing the health and neurodevelopmental outcomes of HIV-exposed children, and community-based interventions to prevent HIV transmission (including the Botswana Combination Prevention Project). She helped establish and co-leads our BHP Clinical Trials Unit. Dr. Lockman mentors many early stage investigators in both Botswana and the US on a range of clinical research projects and is supported by a K24 mentoring grant to do so.



Kathleen M. Powis
MD, MPH, MBA

Dr. Kate Powis is board certified in both Internal Medicine and Pediatrics and has held a medical license to practice medicine in Botswana since 2008. Her primary research is focused on HIV and maternal-child health, with a particular focus on understanding short- and longer-term health and developmental outcomes of children with exposure to HIV and antiretroviral drugs in utero who remain HIV-uninfected. She currently is the Principal Investigator of three NIH funded studies being conducted at BHP and provides mentoring to BHP clinicians who are early career researchers.



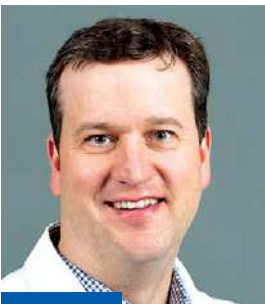
Bruce Chabner
MD

For the past 48 years Prof. Chabner has devoted himself to a career in cancer research and drug development. He directed the Drug Development Program and the clinical trials efforts of the National Cancer Institute, as Director of the Division of Cancer Treatment, for 14 years (1981-1995), and have designed, participated in, and reported clinical and laboratory studies of new agents, including maytansine, folate analogues, paclitaxel, fludarabine, and yondelis. He moved to Harvard Medical School and the Massachusetts General Hospital 20 years ago, where he was Chief of the Division of Hematology/Oncology from 1995-2006 and Clinical Director of the MGH Cancer Center from 1995-2010.



Jennifer Jao
MD, MPH

Dr. Jennifer Jao is an Associate Professor at the Northwestern University Feinberg School of Medicine in the Departments of Pediatric and Adult Infectious Diseases whose research focus is HIV maternal child health. She obtained her BA in French Literature at Tulane University and MD at the Medical College of Georgia. She went on to complete a combined Internal Medicine/Pediatrics residency at Rush University Medical Center in Chicago and her Infectious Disease Fellowship along with her MPH degree at the Icahn School of Medicine at Mount Sinai. Dr. Jao has led NIH-funded cohorts of pregnant women with HIV and their children both in the U.S. and Africa, and as a translational researcher, her research portfolio targets the long-term metabolic effects of in utero exposure to HIV and antiretroviral medications. She is a member of the U.S. Panel on the Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission Guidelines Panel, Co-Chair of the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) network P1115 protocol "Very Early Intensive Treatment of HIV-Infected Infants to Achieve HIV Remission" and Co-Chair of the Nutrition, Growth, and Metabolic Working Group in the Pediatric HIV/AIDS Cohort Study (PHACS).



Scott Dryden-Peterson
MD, MSc (epi)

Dr. Dryden-Peterson's research centers on epidemiology and therapeutic approaches for cancers arising in the context of HIV. He directs one of the largest prospective cohorts of HIV-associated cancers at BHP. Ongoing projects include evaluation the impact of HIV and ART on the cancer burden in sub-Saharan Africa, development of new diagnostics and diagnostic approaches to cancer in LMICs, treatment outcomes of HIV-associated cancers in Botswana, and strategies to improve access to timely oncology care in resource constrained settings. He is co-founder of Botswana Oncology Global Outreach (BOTSOGO).



Vladimir Novitsky
MD, PhD

Dr. Vladimir Novitsky, MD, PhD, is a Principal Research Scientist in the Department of Immunology and Infectious Diseases at the Harvard T.H. Chan School of Public Health. Dr. Novitsky has made a number of significant contributions to the virological and immunological study of HIV-1 infection. The main focus of Dr. Novitsky's research is molecular analysis of the HIV-1 subtype C epidemic, genotypic and phenotypic characterization of the HIV-1 subtype C genome, and potential associations between virological and immunological parameters in early and acute HIV-1 subtype C infection. He contributed significantly to the design, planning, capacity building, and supervision of the Botswana-Harvard AIDS Institute Laboratory in Botswana.



Laura Bogart
PhD

Dr. Laura Bogart, PhD, Senior Behavioral Scientist at RAND Corporation, is a social psychologist with expertise in behavioral factors in HIV prevention and treatment. In collaboration with BHP, she previously conducted a study to examine individual and social network-level factors associated with viral suppression among people living with HIV and their treatment partners, and she is now conducting a study to develop and pilot test a clinic-based intervention to improve the effectiveness of treatment partners in Botswana. In Uganda, she is conducting a community based PrEP intervention among fisher folk, as well as research to develop a program for people living with HIV to promote HIV prevention in their social networks. Her U.S. work includes interventions to reduce HIV-related health inequities.



Mosepele Mosepele
MD, MSc

Professor Mosepele Mosepele is a Research Associate with BHP since 2014. As an Infectious Disease Consultant and Clinical Epidemiologist, his research focuses on HIV-associated complications such as cardiovascular disease and immune dysregulation. Professor Mosepele is the Botswana site Principal Investigator on several protocols funded by partners in Europe and the US, including the AMBITION-cm trial (High Dose AMBISOME on a Fluconazole and Flucytosine Backbone for Cryptococcal Meningitis Induction Therapy in sub-Saharan Africa: A Randomised Controlled Non-Inferiority Trial), the REPRIEVE trial (Randomized Controlled Trial of Prevention of Vascular Events in HIV) at BHP and also acts as Co- PI on a pilot study focusing on social network-level factors associated with viral suppression among HIV-infected patients at a Gaborone HIV Clinic, also at BHP. Professor Mosepele has been working as the Deputy Coordinator for the Botswana Presidential COVID-19 Taskforce since March 2020.



Neo M. Tapela
MD, MPH

Dr. Tapela is an internal medicine physician, epidemiologist and implementation researcher who is currently a Senior Research Fellow at the University of Oxford's Nuffield Department of Population Health. Her research specializes in understanding the determinants and outcomes of chronic non-communicable diseases (NCDs) in sub-Saharan Africa, and designing innovative equity-driven interventions to address these conditions in integrated ways and particularly serving rural and poor populations. She has over a decade's experience leading funded research in the region, and her ongoing projects include a cluster-randomized trial evaluating a multicomponent intervention for early diagnosis of cancer (Potlako+ study), a feasibility cluster randomized trial developing mobile phone adherence support for hypertension management (Lerato ka Mogala), and a prospective pilot assessing a point-of-care, low-cost, nurse-operated device for breast cancer screening (Phemelo). Her research and consultancy work is informed by experience in health policy, NCD strategic planning and program leadership in Rwanda (Director of NCDs based in Rwanda with the international NGO Partners In Health) and Botswana (former Head of Botswana's National NCDs Program). Her role as a global health advocate has been recognized in selection as an African Cancer Leaders Institute Awardee, an Aspen Institute New Voices Fellow.



Jason A. Efstathiou
MD, DPhil

Dr Jason Efstathiou serves as Associate Professor of Radiation Oncology at Harvard Medical School and the Massachusetts General Hospital (MGH) and holds an Associate Researcher position with BHP. He is the Director of the Genitourinary Division in Radiation Oncology and Clinical Co-Director of The Claire and John Bertucci Center for Genitourinary Cancers Multidisciplinary Clinic at MGH. He holds a B.S. from Yale University, M.D. from HMS, Ph.D. from University of Oxford, and completed his residency training in the Harvard Radiation Oncology Program. Dr. Efstathiou's clinical practice focuses on treatment of patients with prostate, bladder, testicular and other urologic cancers, as well as proton beam and brachytherapy. He co-founded and co-directs BOTSOGO (Botswana Oncology Global Outreach).



Joseph Jarvis
MBBS, BSc, MSc, MRCP,
PhD, DTMH

Prof. Joe Jarvis is a Research Associate at the Botswana Harvard AIDS Institute Partnership, and a Professor at the London School of Hygiene and Tropical Medicine, based full time in Gaborone, Botswana. His main research interests are advanced HIV disease, opportunistic infections, cryptococcal meningitis, and strategies to rapidly and safely initiate ART in individuals with low CD4 counts. In addition to being the Chief Investigator for the AMBITION-cm trial examining new treatments for HIV-associated cryptococcal meningitis, he recently worked as Research Director for the CDC Implementation Protocol of the Botswana Combination Prevention Project (BCPP). He is also a member of the external review group for the WHO Guidelines for Managing Advanced HIV Disease and Rapid Initiation of Antiretroviral Therapy, and a guidelines development group member for WHO guidelines on preventing, diagnosing, and managing cryptococcal disease in HIV infected adults, adolescents and children.



Tomer Barak
MD, MSc TMIH, DTMH

Dr. Tomer Barak graduated from Tel-Aviv University's Sackler Faculty of Medicine in Israel and holds a Masters in Tropical Medicine & International Health from the London School of Hygiene & Tropical Medicine, UK. He completed his internal medicine training at Beth Israel Deaconess Medicine Center (BIDMC), Boston, US. As head of the Botswana Harvard Partnership's Clinical Capacity Building Program at Scottish Livingstone Hospital (SLH) from 2013 to 2020 he helped lead clinical stewardship, medical education, quality improvement and research initiatives at SLH and the surrounding Kweneng East district. He also served as head of the department of medicine at SLH, regional program director for Botswana's Medical Internship Training Program and a member of Botswana's HIV Guideline Committee. Dr. Barak has recently handed over the program leadership role to Dr. Sara Schwanke and continues to support the program as a consultant.



Ava Avalos
MD

Dr. Ava Avalos, a research associate with BHP, is an HIV/TB specialist physician who has been living and working in Botswana for the past 18 years. She has extensive clinical, research, policy, and programmatic experience, serving as a clinical advisor to the Department of HIV/AIDS Prevention and Care in the Botswana Ministry of Health and Wellness, since 2006. Her area of clinical research and technical expertise focus on ART treatment failure, HIV drug resistance, programmatic implementation and health economics. She is a member of the HIV & TB Clinical Care Guidelines Committee, the University of Botswana IRB, and serves as vice-chair on the board of the International Treatment Preparedness Coalition (ITPC).



Chelsea Morroni
MBChB, DFSRH, MPH, PhD

Dr. Chelsea Morroni is a research associate at the Botswana-Harvard AIDS Institute where she directs the Botswana Sexual and Reproductive Health Research Initiative (BSRHI). She is an epidemiologist and medical doctor with over 20 years of experience in Southern Africa. She has an undergraduate degree from Harvard, an MPH and medical degree from the University of Cape Town, and a PhD from Columbia University. She has lived with her family in Botswana for 8 years. Here, she conducts mixed-methods research and provides clinical care relating to women's and girls' sexual and reproductive health (SRH), particularly prevention of unintended pregnancy and HIV/STIs. Chelsea is a Chancellor's Fellow and a Reader in Global SRH at the University of Edinburgh Centre for Reproductive Health, an honorary Professor of Women's Health at University of Cape Town, and Co-Director of the UK Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit.



Rebecca Zash
MD

As an assistant professor at Harvard medical school, Dr. Rebecca Zash is an infectious diseases physician and performs research focused on the impact of HIV and antiretroviral medications on pregnancy, and holds a research associate position with BHP. Dr. Zash went to medical school at the University of North Carolina, and completed internal medicine residency and infectious disease fellowship at Beth Israel Deaconess Medical Center in Boston, USA. She has been working with BHP since 2013 and currently serves as PI for one study to understand why HIV-infected women on ART have an increased risk of adverse birth outcomes and one study to evaluate cardiometabolic adverse effects of ART in post-partum women and their infants. She also helps to lead a large birth outcomes surveillance study, Tsepamo, which examines the comparative safety of antiretroviral treatments in pregnancy.



Lisa Butler
MA, MPH, PhD

Dr. Lisa Butler is a research associate with BHP. She is a behavioral scientist and epidemiologist with methodologic expertise in the development and evaluation of community-based interventions to improve health and mental health outcomes for vulnerable and low-literacy populations in sub-Saharan Africa (SSA), particularly in high HIV prevalence settings. Her interventional research often incorporates the use of media (e.g., video, photography, radio, comics) and mobile technology. In collaboration with BHP, she is the PI of Monona ke Isago (Youth are the Future), a multi-component intervention designed to raise awareness and reduce stigma related to perinatal depression, and to identify and provide support to adolescents with symptoms of depression during pregnancy or in the early postpartum period.



Rosemary Musonda
PhD

Dr. Musonda is a BHP Research Associate and former Laboratory Director. She is also a Research Associate at the Harvard T.H. Chan School of Public Health. Her main interests are in understanding the molecular structure of HIV, its pathogenesis, and the nature of host immunity to the virus. She is involved with capacity building and training young investigators in Africa. Dr. Musonda holds several grants dedicated to postgraduate training of African scientists in southern Africa.



Simani Gaseitsiwe
BSc, PhD

Dr. Simani Gaseitsiwe is with Botswana Harvard AIDS Institute Partnership (BHP) as well as with the Harvard T. H. Chan School of Public Health. He is the Botswana Principal Investigator for the H3ABioNet and SANthe grants. His research focuses on HIV-1 subtype C drug resistance, Hepatitis B Virus and TB molecular epidemiology in Botswana and more recently he is also involved in SARS-CoV-2 molecular epidemiology studies. Simani is responsible for overall supervision of basic science research laboratory, and for guidance and mentorship of research fellows, scientists, and students. He has over 90 publications in peer-reviewed journals.



Tendani Gaolathe
BS, MD

Dr. Tendani Gaolathe graduated from St Georges U. School of Medicine in Grenada in 1996 and residency in Internal Medicine from Seton Hall University. Dr Gaolathe as a clinician has managed public health programs and conducted observational and clinical trials related to the HIV/AIDS epidemic in Botswana since 2001. She joined BHP in 2005 as Director for the Master Trainer Program, BHP's flagship training program that has been instrumental in securing success of the Botswana's Antiretroviral program clinic rollout, task shifting, laboratory decentralization, and national Monitoring and Evaluation efforts. She was also the Project Director for BCPP. She is currently a lecturer at the University of Botswana within the Faculty of Medicine and she is the Assistant Program Director of the Department of Internal Medicine.



Rebecca Lockett
MD, MPH

Dr. Rebecca Lockett, M.D., M.P.H., is the Assistant Programme Director and Adjunct Senior Lecturer in the Department of Obstetrics and Gynecology (OBGYN) at the Medical Center and she is an Assistant Professor of Medicine at Harvard Medical School. Dr. Lockett graduated *summa cum laude* from the University of Notre Dame before pursuing her Master of Public Health and medical degree at the Mount Sinai School of Medicine. She completed her residency in obstetrics, gynecology, and reproductive biology at the Harvard Integrated Residency Program at Brigham and Women's and Massachusetts General Hospitals. An active educator, Dr. Lockett facilitated the development the first ever OBGYN residency training program at the University of Botswana and participates in resident and undergraduate medical education. She has also worked to improve intern education at the district level. She spearheads a four-week international clinical elective for US-based OBGYN residents in Botswana and serves as a mentor for OBGYN residents and medical students. Dr. Lockett conducts most of her clinical work in Botswana, where she has a broad generalist practice. Her research interests include cervical cancer screening, diagnosis and treatment and she has sought to expand these services in Botswana. She also spends 6 weeks per year at Beth Israel Deaconess Medical Center conducting clinical care and participating in medical education.



Emily Shava
MBChB, MSc

Dr Emily Shava is a Clinician who is also a Research Associate at the Botswana Harvard AIDS Institute Partnership and at Harvard T. H. Chan School of Public Health. She holds an MBChB from the University of Zimbabwe College of Health Sciences and an MSc from London School of Hygiene and Tropical Medicine. She was previously a Co-Investigator and Study Physician for HIV Prevention Trials Network within the Clinical Trials Unit at BHP from 2009-2019. She is interested in HIV prevention amongst high risk populations and is currently conducting a study to pilot HIV self-testing in female sex workers in Gaborone (Ikitse Study).



Ponego Ponatshego
MD, DTMH

Dr. Ponego Ponatshego is the Study Physician/Coordinator for IMPAACT studies in the Botswana Harvard AIDS Institute Partnerships's Clinical Trials Unit (CTU). He is the lead doctor for the InterCARE trial (Integrating Hypertension and Cardiovascular Disease Care into Existing HIV Services Package in Botswana). Dr Ponatshego holds a medical degree from Rostov State University, Russia; Diploma in HIV Management from Colleges of Medicine of South Africa; a Professional Diploma in Tropical Medicine and Hygiene from the London School of Hygiene and Tropical Medicine and a postgraduate Diploma in Public Health from University of South Africa. He is also an AIDS Clinical Trials (ACTG) Fellow currently conducting clinical research termed Albuminuria and Frailty association in HIV Infection.



Motswedi Anderson
BSc, PhD

Dr. Motswedi Anderson is a Wellcome International Training Fellow /BHP Research Associate. She has been with Botswana Harvard AIDS Institute Partnership since 2006. Her research interests are in viral hepatitis (B, C, D and E) and human immunodeficiency virus. She completed her PhD in Biological Sciences in 2018 and her project was '*Prevalence and molecular characterization of hepatitis B virus infection in Botswana*'. She did Bsc in Biomedical Sciences with University of KwaZulu Natal, Durban, South Africa in 2005. She currently holds a Wellcome International Training Fellowship and an EDCTP-AREF training Fellowship. Her current project is '*Occult Hepatitis B Virus Infections in HIV-1-Infected Individuals in Botswana: Incidence, Kinetics and Mechanisms*'. She aspires to be a renowned researcher and to play a key role in viral hepatitis elimination.



Lucy Mupfumi
PhD

Dr. Lucy Mupfumi is an infectious disease scientist with interests in the epidemiology of HIV and tuberculosis (TB) co-infection in HIV-prevalent settings in sub-Saharan Africa. Over the past 6 years, Lucy's work has revolved around HIV-associated TB and point of care diagnostics. She has over 18 publications describing the impact of Xpert MTB/RIF on patient outcomes, incident TB in ART programs, biomarkers for HIV and TB treatment response, and point of care diagnostics for HIV. Lucy is currently a Fogarty Global Health Fellow and is modelling the trajectory of the TB epidemic in Botswana with expanded ART.



Gbolahan Ajibola
MD, MPH

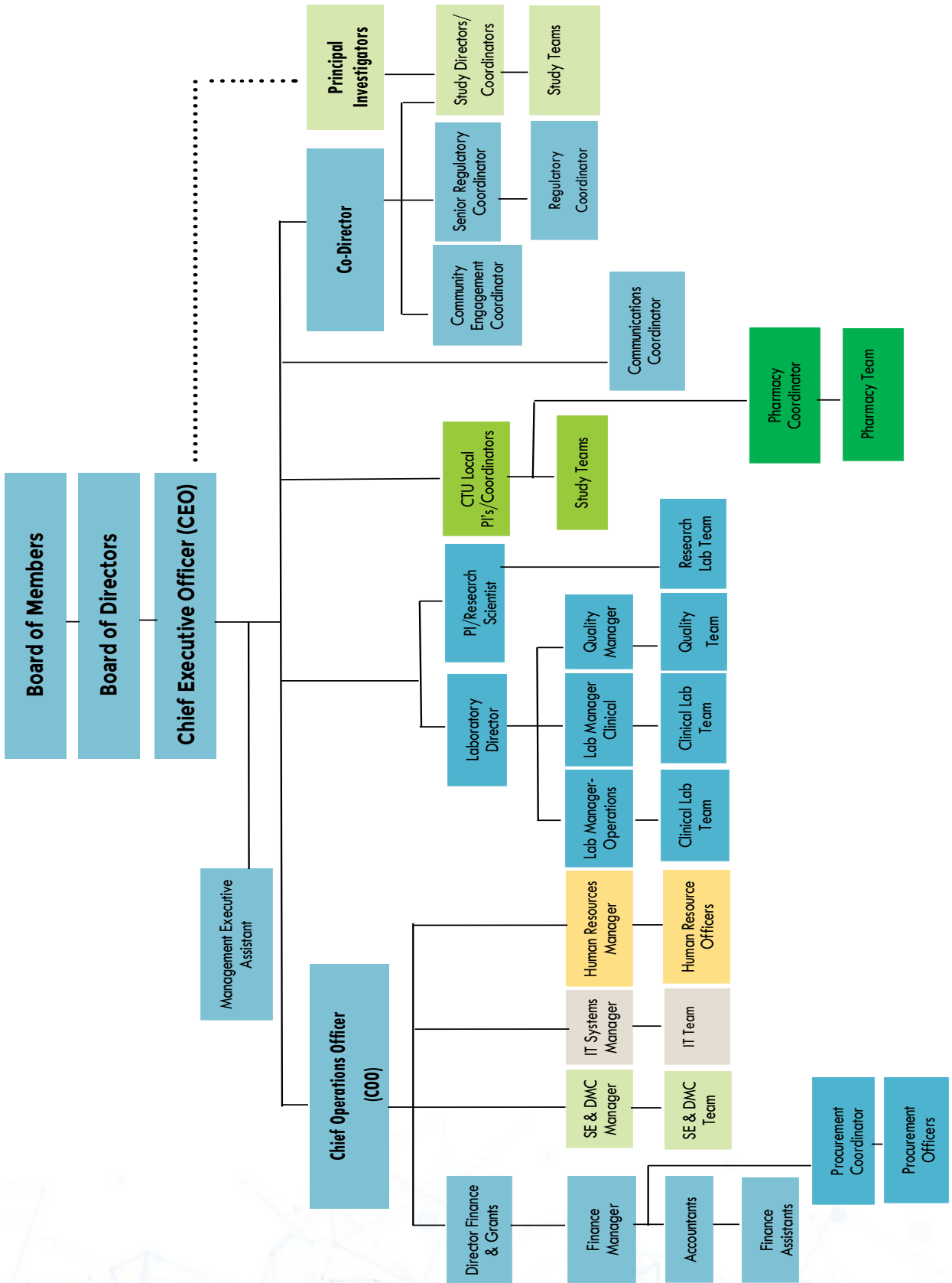
Dr Ajibola is a trained physician with a Master's in Public Health and over 10 years experience in clinical research at Botswana Harvard AIDS Institute Partnership (BHP). His research focuses on maternal-child health. He is Co-Investigator and Study Coordinator/ Physician for the Early Infant Treatment Study (EIT) and the follow-up Tatelo study entitled "A Clinical Trial to Evaluate the Impact of Broadly Neutralizing Antibodies (bNAbs) VRC01LS and 10-1074 on Maintenance of HIV Viral Suppression in a Cohort of Early-Treated Children in Botswana". While working on these projects, he has developed several sub-studies including one that investigated the prevalence of antiretroviral drug resistance mutations among HIV-infected women following cessation of triple ARV prophylaxis used for preventing mother-to-child HIV transmission in Botswana and this presented him with his first opportunity to function as a Principal Investigator. Building logically on his prior work, and expertise, he was awarded an early-stage investigator grant by the EDCTP for his proposal to evaluate the risk of HIV acquisition among infants born preterm to women living with HIV and to quantify haematological toxicities of antiretroviral prophylaxis in preterm infants compared to infants born full-term. Dr Ajibola has served as a study physician routinely performing clinical evaluations on mothers and infants enrolled in both observational and interventional clinical trials and has authored and co-authored several publications.



Kaelo Seatla
MBBS, DTMH

Dr Seatla's primary research interests are in the development and implementation of low-cost HIV drug resistance (HIVDR) testing assays and monitoring for HIVDR mutations amongst people living with HIV in low and middle income countries (LMICs). As a Medical Doctor since 2011, he has been caring for HIV-1 infected individuals in clinics in Botswana, including patients with extensive drug resistance mutations. He has worked on ACTG, IMPAACT and HPTN network trials for over 5 years. Dr Seatla has developed one of the largest sequence datasets of HIV-1 subtype C infected individuals experiencing virological failure whilst on dolutegravir-based treatment. He has also developed a new low cost assay that tests for resistance to dolutegravir at about a quarter of the cost of a commercial/licensed HIVDR assay. Dr Seatla is currently pursuing his PhD in Health Sciences at the University of Botswana where he also serves as Clinical Skills Tutor in the Faculty of Medicine.

4. ORGANISATIONAL STRUCTURE



5. ACRONYMS

ACEI	Angiotensin Converting Enzyme Inhibitors
ACTG	AIDS Clinical Trials Group
AIDS	Acquired Immuno-Deficiency Syndrome
AORTIC	African Organization of Research and Training in Cancer
AMNET	Ambition Meningitis Network
ARB	Angiotensin Receptor Blockers
ART	Antiretroviral Therapy
BCPP	Botswana Combination Prevention Project
BHRL	Botswana Harvard HIV Reference Laboratory
BHP	Botswana Harvard AIDS Institute Partnership
BIDMC	Beth Israel Deaconess Medical Center
BIUST	Botswana International University of Science & Technology
bNAbs	Broadly Neutralizing HIV-1 Antibodies
BOTSOGO	Botswana Oncology Global Outreach
BSC	Balanced Score Card
CAB	Community Advisory Board
CAB LA	Cabotegravir Long Acting
CDC	Centers for Disease Control and Prevention (Botswana-USA)
CE	Community Engagement
CEM	Contrast Enhanced Micro-holography
CFAR	Centers for AIDS Research
CHB	Chronic Hepatitis B
CODA	Contraceptives & Dolutegravir-based ART
CROI	Conference on Retroviruses and Opportunistic Infections
CTU	Clinical Trials Unit
DAIDS	Division of AIDS
DHMT	District Health Management Team
DLM	Delamanid
DNA	Deoxyribonucleic Acid
DTG	Dolutegravir
EDC	Electronic Data Capture
EDCTP	European and Developing Countries Clinical Trials Partnership
EFV	Efavirenz
EIT	Early Infant Treatment
EQA	Eternal Quality Assurance
GCP	Good Clinical Practice
HAART	Highly Active Anti-Retroviral Treatment
HAI	Harvard AIDS Initiative
HBV	Hepatitis B Virus
HEU	HIV Exposed uninfected
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immuno-Deficiency Syndrome
HPTN	HIV Prevention Trials Network



HPV	Human Papilloma Virus
HSPH	Harvard TH Chan School of Public Health
HTC	HIV Testing and Counselling.
HVTN	HIV Vaccine Trials Networks
HU CFAR	Harvard University Center for AIDS Research
HU	Harvard University
HUU	HIV Unexposed Uninfected
IMPAACT	International Maternal, Pediatrics, and Adolescents AIDS Clinical Trials
IRB	Institutional Review Board
LMICs	Low and Middle Income Countries
MBA	Master of Business Administration
MBBS	Bachelor of Medicine, Bachelor of Surgery
MD	Doctor of Medicine
MoHW	Ministry of Health and Wellness
MPH	Master of Public Health
MRCP	Membership of the Royal Colleges of Physicians of the United Kingdom
MRI	Magnetic Resonance Imaging
MSc	Master of Science
NAHPA	National AIDS and Health Promotion Agency
NCI	National Cancer Institute
NHL	National Health Laboratory
NIH	National Institutes of Health
NTDs	Neural Tube Defects
PBMCs	Peripheral Blood Mononuclear Cells
PCR	Polymerase Chain Reaction
PhD	Doctor of Philosophy
PI	Principal Investigator
PK	Pharmacokinetic
PMTCT	Prevention of Mother to Child Transmission
PMS	Performance Management System
PrEP	Pre-Exposure Prophylaxis
RCR	Responsible Conduct of Research
REPRIEVE	Randomized Trial to Prevent Vascular Events
SANTHE	Sub-Saharan Network for TB/HIV Research Excellence
SLH	Scottish Livingstone Hospital
SMS	Short Media Message
TB	Tuberculosis
TDF /FTC	Tenofovir Disoproxil Fumarate/Emtricitabine
TESA	Trials of Excellence in Southern Africa
UB	University of Botswana
USA	United States of America
USD	United States Dollar
WHO	World Health Organisation

6. FOREWORD BY BOARD CHAIRMAN



BHP Board Chairman

Prof. Roger Shapiro

I am delighted to share with you the Annual Report on the activities and accomplishments of the Botswana Harvard AIDS Institute Partnership (BHP) in the year 2019/20. This has been a challenging year in many ways, with much of the world's focus turned to the emergent COVID-19 pandemic. However, BHP's work continues on all fronts, and our dedication to fight HIV/AIDS and other emerging public health challenges is buoyed by the positive impact that our research studies continue to have in strengthening health systems in Botswana and globally.

With each passing year since our establishment in 1996, BHP has made progress in advancing science through relevant health research with outcomes that have informed local, regional, and global policy and practice. We have continued to expand and diversify our research portfolio beyond HIV/AIDS to ensure that we touch as many lives as possible as we address public health challenges. As a research institute, we are committed to developing health solutions that are relevant to the needs of the people. No challenge better exemplifies this than the emergence of COVID-19.

Since the beginning of the epidemic, BHP has been leading efforts in Botswana to actively participate in global and local research for effective therapeutic and preventative strategies. BHP staff have become frontline health workers for testing and treatment, for epidemic planning and response, and most importantly, by collaborating with the National Health Laboratory and MOHW to augment the Government's SARS-CoV-2 testing efforts.

As we look toward the future in these challenging times, we anticipate a difficult but rewarding year, where we hope to see the arrival of vaccines in Botswana to end the COVID-19 epidemic. We also look forward to a year of further research growth and the generation of knowledge that addresses the many health challenges in the country. We will continue to build a rigorous body of science that will improve health systems and benefit individuals and communities in Botswana and around the globe.

I know that working conditions during COVID-19 have been far from ideal, but I commend our scientists and staff for their commitment and dedication during this crisis. We strive for scientific solutions to address the many public health problems that impact Botswana and continue to threaten human life, and our commitment shall ensure that we remain a world-renowned public health institute.

With sincere gratitude,

A handwritten signature in black ink that reads "Roger L Shapiro".

Prof. Roger Shapiro
BHP Board Chairman

7. CHIEF EXECUTIVE OFFICER'S REMARKS



BHP Chief Executive Officer

Dr Joseph Makhema

I am happy to report stable progress that has been made to achieve our mandate to fight HIV/AIDS and other emerging public health challenges. We do so by providing needs-based research in different areas of health science and we have made significant progress across our various studies, disciplines and projects.

As we reflect on the year under review, we are pleased to share some of our highlights. During the period BHP increased the number of active Principal Investigator (PI) initiated research projects from the 10 achieved in the previous year to 16 and maintained nine (9) active Network Clinical trials despite close out of three while we also have at least four CTU protocols that are at an advanced stage of initiation with another four in development which the BHP has expressed participation in. Non Network studies have also significantly increased the breadth of our portfolio with 15 substantive on going studies

during this period. We have also increased the number of BHP and BHP associated published manuscripts in peer-review journals from 56 to 80 publications, publications, which represent an impressive 43% increase.

The Annual Financial and Generally Acceptable Government Auditing Standards audits (GAGAS) audit once again remain unqualified, testament to robust, prudent financial management systems and strict compliance to sponsor grant agreements and strong risk management best practices.

While we been experiencing a decline in both subcontract and prime awards in terms of total value of awards, this financial year has seen the largest number of both prime awards (19) and subcontracts (41), with a significant increase in the number of local PIs and early investigators. This reflects an uptake in local PIs and early investigator research, which is an indication of the success of BHP's training and mentorship program. BHP has recorded 38 solicited projects and 7 unsolicited projects.

We continued to grow our footprint and expand our research portfolio with the introduction and participation in new studies, eg the COVID-19 cohort study and the STI study. This expansion is anchored on our resolve to become a fully-fledged public health institute providing health solutions to health challenges affecting our people while at the same time impacting on global health practice and policies. As we continue to grow our base in generation of scientific knowledge, we have confidence that research outcomes will help Botswana advance into the knowledge-based economy it strives for.

We are resolute in developing and conducting relevant research and providing technical assistance and capacity building and training, all geared towards informing evidence-based health programmes and interventions as well as informing policy development. We are motivated by the quality of our research outputs and the impact of our technical support to different national health programmes and committees.

I once again extend my profound gratitude to the BHP Board of Directors for their relentless support and wise guidance over the years and going forward. I commend BHP investigators, Research Associates, Scientists, Staff and Collaborators who continues to serve to ensure that we produce quality research outputs that save lives.



.....
Dr. Joseph Makhema
BHP Chief Executive Officer



8. EXECUTIVE SUMMARY

The performance results of the reporting period 2019/2020 show that BHP continues to grow consistent with its strategic objectives as stated in its 2017 – 2022 Strategic Plan. The implementation of the strategic plan focused on 5 strategic themes, namely: Research Excellence, Capacity Building and Training, Operational Excellence, Public Policy and Advocacy, and Sustainability.

By close of the reporting period in June 2020, BHP had 60 (the largest number ever) research and capacity building projects running, 19 of which were prime awards to locally based Principal Investigators and early investigators. In total, despite the SARS-COV-2/ COVID-19 pandemic, BHP presented 34 abstracts at national and international conferences and published 80 manuscripts in peer-reviewed journals, surpassing the previous year's achievement of 65 publications.

To build a community of scholars, new and upcoming investigators and scientists, BHP continues to apply for funding for training and capacity building initiatives. At postgraduate level, BHP had 1 post-doctoral fellow, 4 PhD candidates, two of whom graduated, and 9 Masters, one of whom graduated and one upgraded to PhD. BHP continues to maintain employee diversity of 218 employees in total. Six percent of the employees are expatriates from 5 different countries, and the employees are mainly of 'Scarce Skills' category.

The Botswana Harvard HIV Reference Laboratory (BHHRL) has maintained its SADCAS ISO accreditation status. This demonstrates the laboratory's competence to deliver reliable timely, accurate, and reliable results.

The organization continues to achieve a positive balance sheet and unqualified financial and GAGAS audits, thanks to its prudent financial management across the organization. BHP has seen the largest number of both prime awards (19) and subcontracts (41), with a significant increase in the number of local PIs and early investigators. BHP recorded 38 solicited projects and 7 unsolicited projects. Research results from BHP studies has had positive impact on informing health policies and treatment guidelines in Botswana and globally.

Apart from conducting research, BHP investigators continue to be active members of both international and several MOHW technical teams where they give expert advice on different health matters, including the current COVID-19 pandemic. Local audience is reached through different fora like media and/or community based engagements.

A Pharmacy as part of the BHP Business Enterprise under Sesikalla Investment (Pty) Ltd has been set up at a private clinic in Gaborone with further expectation to provide private clinical services in advanced HIV/ AIDS care and treatment as part of an enterprise to diversify revenue streams. Sesikalla Pharmacy space modifications, equipment and software purchase and installations, signage, licensing and registrations have been largely completed. BHP continues to actively seek funding opportunities for long-term sustainability of Sesikalla and the BHP as a whole.



9. INTRODUCTION

Botswana Harvard AIDS Institute Partnership (BHP) was established in 1996 as collaboration between the Government of Botswana represented by the Ministry of Health and Wellness (MOHW) and the Harvard University (HU) represented by the Harvard T.H. Chan School of Public Health (HSPH), in response to the HIV/AIDS pandemic that was ravaging Botswana.

BHP's scientists and their international collaborators continue to respond to the public health environment in Botswana by identifying emerging public health challenges that may be addressed through research and capacity building.

This report highlights how BHP has responded to these challenges during the 2019/2020 reporting period, in alignment to its strategic objectives. It covered 15 research projects, encompassing Principal Investigator initiated studies, Laboratory-based research and Network studies covering different research areas.

The report also records Capacity building and Training initiatives as BHP endeavours to train and capacitate future research scientists and health workers in general.

It also includes a list of manuscripts published in different scientific journals and abstracts presented at different local and international conferences to advance science and share with relevant stakeholders BHP research and its impact on global health policies and systems.





10. RESEARCH EXCELLENCE

1) Clinical Research Projects

BHP has continued to provide quality research through its conduct of both HIV/AIDS Clinical Trials Networks initiated studies and Principal Investigator (PI) initiated studies. The Clinical Trials Unit (CTU) remains the anchor for BHP research and conducts network studies in collaboration with the AIDS Clinical Trials Group (ACTG), HIV Prevention Trials Network (HPTN)/HIV Vaccine Trials Network (HVTN) and International Maternal Paediatric Adolescent AIDS Clinical Trials Network (IMPAACT) Networks.

NETWORK CLINICAL TRIALS

CTU PI: Dr Shahin Lockman MD, MPH

The Botswana Clinical Trials Unit comprises of three clinical trials networks, HIV Prevention Trials Network / HIV Vaccine Trials Network (HPTN/HVTN), International Maternal Paediatric Adolescent AIDS Clinical Trials Network (IMPAACT) and AIDS Clinical Trials Group (ACTG). These networks are aimed at conducting quality clinical research investigating the prevention and treatment of HIV/AIDS and associated infections through the use of therapeutics, vaccines and integrated strategies in the general population (adults, children, pregnant women etc).

In this reporting period, the CTU had 7 new studies applied for, 3 new studies approved, 02 studies closed, and 9 studies continued from previous years. Active studies during the period are HPTN 084, HVTN 703/HPTN 081, REPRIEVE, PHOENIX, IMPAACT 2010 IMPAACT 2008, IMPAACT 2005, P1093 and P1026s.

A. HPTN/HVTN STUDIES

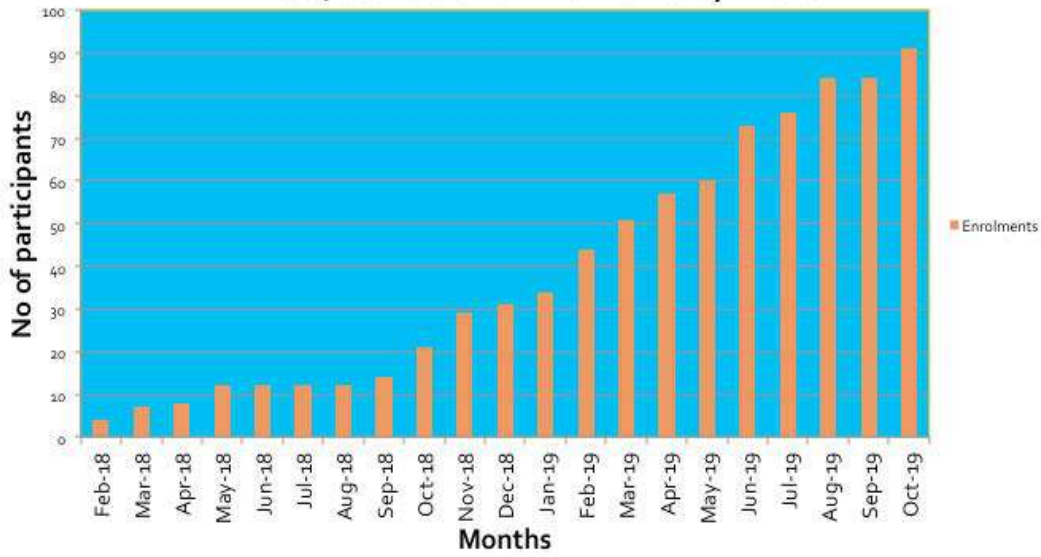
The HIV Prevention Trials Network /HIV Vaccine Trials Network (HPTN/HVTN) is a worldwide collaborative clinical trials network that develops and tests the safety and efficacy of interventions designed to prevent the transmission of HIV. The HPTN was established in 2000, building on the work of the HIV Network for Prevention Trials (HIVNET). HPTN's Leadership and Operations Center (LOC), is based at FHI 360, Durham, NC. Its Laboratory Center (LC) is at Johns Hopkins University, Baltimore, MD and its Statistical and Data Management Center (SDMC) is housed within the Statistical Center for HIV/AIDS Research and Prevention (SCHARP) at the Fred Hutchinson Cancer Research Center in Seattle, Washington.

i) HPTN 084: A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women

This is a five-year PrEP study being conducted in women at 20 sites across Sub-Saharan Africa. The study seeks to evaluate the safety and efficacy of injectable cabotegravir and oral TDF/FTC for pre-exposure prophylaxis in HIV-uninfected women. Gaborone Clinical Research Site (CRS) enrolled their first participant, out of the target of 150 participants, in February 2018, and to date 91 participants have been enrolled on the study. The Botswana site stopped enrolment in October 2019 following the Study Monitoring Committee (SMC) recommendations, based on the fact that data collected this far seems to indicate that the enrollees in Botswana were of relatively lower risk of contracting HIV as compared to other sites, thus limiting the remaining enrolments for sites with participants with highest risk.



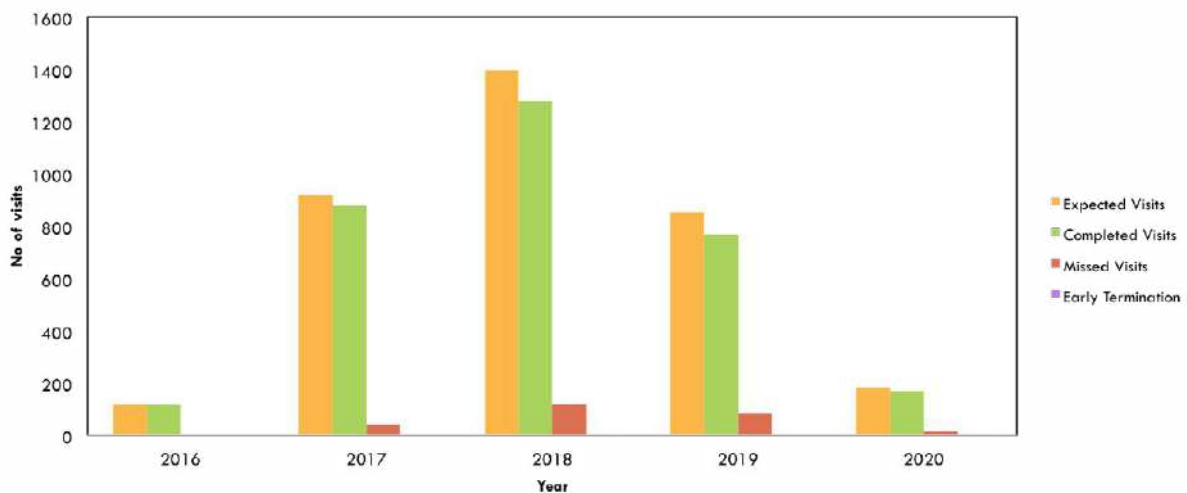
HPTN 084 Cumulative Enrolments by Month



ii) HVTN 703/HPTN 081 (AMP Study): A phase 2b study to evaluate the efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection in women in Sub-Saharan Africa.

The study started in 2016 and enrolled a total of 1924 participants globally and 150 participants in Botswana. Participant follow-up continues and as at June 2020, 124 participants had completed study follow up leaving 26 still on the study. Retention remains a challenge due to participant relocation out of the study area. The study has implemented interventions that have seen some improvement in retention. In summary, Gaborone site has maintained 92% visit retention, 7.4% of the total visits were missed while 4% of the participants terminated early from the study.

GABORONE SITE HPTN 081 VISIT RETENTION JULY 2016-SEPTEMBER 2020



B. ACTG STUDIES

The mission of the ACTG is to cure HIV infection and reduce the burden of disease due to HIV infection and its complications, including tuberculosis and viral hepatitis. The ACTG supports the largest Network of expert clinical and translational investigators and therapeutic clinical trials units in the world, including sites in resource-limited countries. These investigators and units serve as the major resource for HIV/AIDS research, treatment, care, and training/education in their communities.

- i) **REPRIEVE (A5332):** A randomized trial to prevent vascular events (such as stroke and heart attack) in people living with HIV.

People living with HIV are about 1 ½ to 2 times more likely to develop heart attack and stroke than people without HIV even if one is on effective HIV treatment. REPRIEVE seeks to investigate if the use of a cholesterol lowering medicine (Pitavastatin) may reduce the risk of heart attack or stroke in HIV infected individuals.

The study fully accrued its global sample size with 7560 enrolled into the study. Botswana enrolled a total of 281 participants from the Greater Gaborone area out of the planned target of 350. Amendments to study inclusion criteria as per the Data Safety Monitoring Board (DSMB) recommendations resulted in stricter inclusion criteria which posed challenges to accrual. Despite this, as at the study closure in March 2019, the Botswana site was the 3rd highest enroller overall out of about 118 international participating sites.

- ii) **PHOENIX (A5300B):** Protecting Households on Exposure to Newly Diagnosed Index Multidrug Resistant TB patients.

High risk household contacts of MDR-TB patients are disproportionately predisposed to contracting TB due to close exposure from the index patients living within the same household. This study seeks to assess the efficacy and safety of Delamanid (a novel anti-TB drug) compared with Isoniazid (standard of care) for protection of high risk Household Contacts (HHCs) against acquiring TB.

The study opened in 2019 with a global sample size of 5160 participants to be enrolled over 3 years. Botswana has enrolled 9 participants out of its target of 300 (75 index cases and 225 household contacts). The site faced some challenges to accrual at when it was first opened in Botswana due to some national programmatic challenges with availability of testing facilities that resulted in difficulty identifying patients with MDR-TB who

met the study requirements. Additionally, the on going COVID-19 pandemic has posed a significant challenge to accrual with study accrual being paused temporarily by the network to ensure participants and study teams safety.

C. IMPAACT STUDIES

The IMPAACT Network is a global collaboration of investigators, institutions, community representatives and other partners organized for the purpose of evaluating interventions to treat and prevent HIV infection and its consequences in infants, children, adolescents and pregnant/postpartum women through the conduct of high quality clinical trials.

- i) **IMPAACT 2010** - This is a Phase III, three-arm, randomized, open-label study to compare the virologic efficacy and safety of three antiretroviral regimens for HIV-1-infected pregnant women and their infants. The three antiretroviral regimens are: 1) Dolutegravir plus Emtricitabine/Tenofovir alafenamide [DTG+FTC/TAF], 2) Dolutegravir plus Emtricitabine/Tenofovir Disoproxil Fumarate [DTG+FTC/TDF] and 3) Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate [EFV/ FTC/TDF].

It is very likely that both DTG and TAF will be used with increasing frequency in the future, potentially as components of first-line recommended ART globally. Data on DTG and TAF use in pregnancy is limited as noted in the WHO 2015 guidelines update. If DTG and TAF are included in future WHO-recommended first-line regimens in resource-limited settings as anticipated, it will be important to have data regarding their efficacy and safety in pregnancy (given the desire to use the same first-line ART regimens in pregnant and non-pregnant patients, for programmatic simplicity). These data will also be relevant to Botswana as the Botswana HIV National Treatment guidelines already include Dolutegravir in the first-line regime for all adults (including pregnant women).

A total of 643 mother-infant pairs were enrolled globally, 51 mother-infant pairs in Botswana. As of June 30th, 2020, 2 of the 51 enrolled mother-infant pairs were still on the study while 49 had completed the study follow up. The sites had an excellent retention rate (above 96%).

- ii) **IMPAACT 2008** is a Phase I/II, multisite, two-arm, randomized, controlled, open-label study to evaluate the safety and antiviral activity of VRC-HIVMAB060-00-AB, a recombinant human immunoglobulin G1 (IgG1) monoclonal antibody (VRC01) among Human immunodeficiency virus 1 (HIV-1)-infected infants initiating Combination antiretroviral therapy (cART) within 12 weeks of birth.



The study enrolled 61 infants globally across seven sites and seven infants in Botswana. The study was closed to accrual in March 2020. Study follow up is going with three infants still on study and four have successfully completed study follow up. The last participant is expected to complete follow up in February 2021.

- iii) **P1093** - Phase I/II, Multi-Centre, Open-Label Pharmacokinetic, Safety, Tolerability and Antiviral Activity of Dolutegravir, a Novel Integrase Inhibitor, in Combination Regimens in HIV-1 Infected Infants, Children and Adolescents.

Global enrolment target was 300 and 181 participants were enrolled before the study closed to accrual in February 2020. Botswana enrolled 5 out of its target of 18 participants and follow up is ongoing.

- iv) **IMPAACT P1026** – Pharmacokinetic (PK) Properties of Antiretroviral Therapy and Related Drugs During Pregnancy and Postpartum.

The study seeks to evaluate the PKs of antiretroviral medicines when used alone or core-administered with TB medicines during pregnancy and the pharmacokinetics parameters of lopinavir/ritonavir and atazanavir/ritonavir/tenofovir in women postpartum before and after starting hormonal

contraceptives. The study also evaluates the concentrations of ethinyl estradiol, etonogestrel and other progestins in women using hormonal contraceptives and protease inhibitors.

Botswana sites enrolled 2 participants who have successfully completed study follow up. The study had a target of 15 participants across both sites (Gaborone and Molepolole). The study closed to accrual on December 2019. There was a challenge of finding pregnant women who have TB and are HIV infected.

- v) **IMPAACT 2005** - Phase I/II Open-label, Single-Arm Study to Evaluate Pharmacokinetics (PK), Safety, and Tolerability of Delamanid (DLM) in Combination with Optimized Multidrug Background Regimen (OBR) for Multidrug Resistance-Tuberculosis (MDR-TB) in HIV-infected and HIV-uninfected Children with MDR-TB.

The study envisioned to enrol 48 participants globally, 10 in Botswana. Four participants have been enrolled globally to date. Botswana is yet to enroll any participant as the site has not been able to identify potential eligible participants at the TB clinics. Additionally, the study was paused temporarily for screening and enrolled due to COVID-19 pandemic.



PRINCIPAL INVESTIGATOR INITIATED RESEARCH PROJECTS

a) The **AMBITION-cm** study

International PI: Professor Joseph Jarvis, MBBS, BSc, MSc, MRCP, PhD, DTMH

The Ambition study (<http://blogs.lshtm.ac.uk/ambition/>) aims to determine whether a single, high-dose of liposomal amphotericin B is as effective as 7- day amphotericin B based treatment courses in averting all-cause mortality in 850 HIV positive patients presenting with a first episode of cryptococcal meningitis. The study takes place at hospitals in South Africa, Zimbabwe, Uganda and

Malawi. Botswana aims to recruit 90 patients by 2020.

The study is sponsored by the London School of Hygiene and Tropical Medicine and hosted by BHP with Prof Mosepele Mosepele as the local PI. As of June 2020, the Botswana site had enrolled 66 participants all recruited from Princess Marina Hospital.

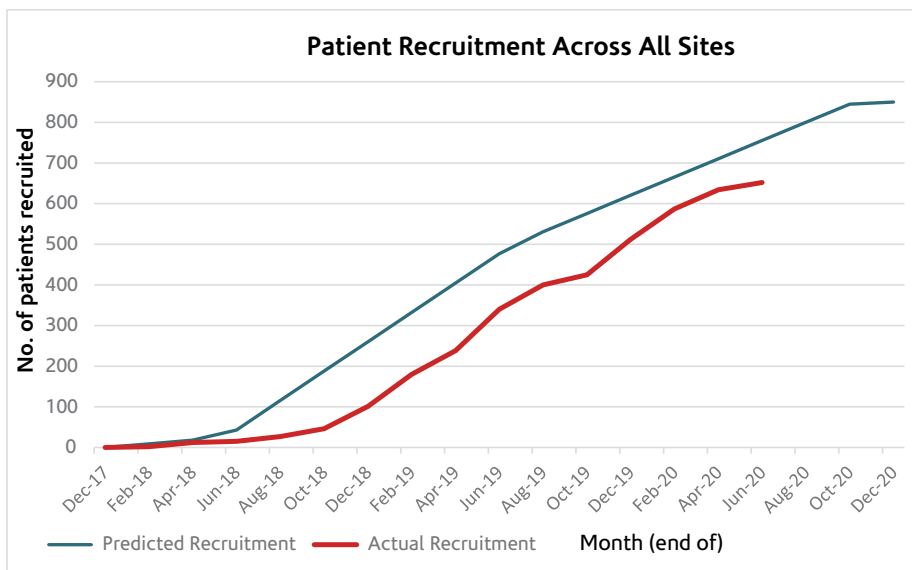


Figure 1: Ambition study - Recruitment graph across all sites

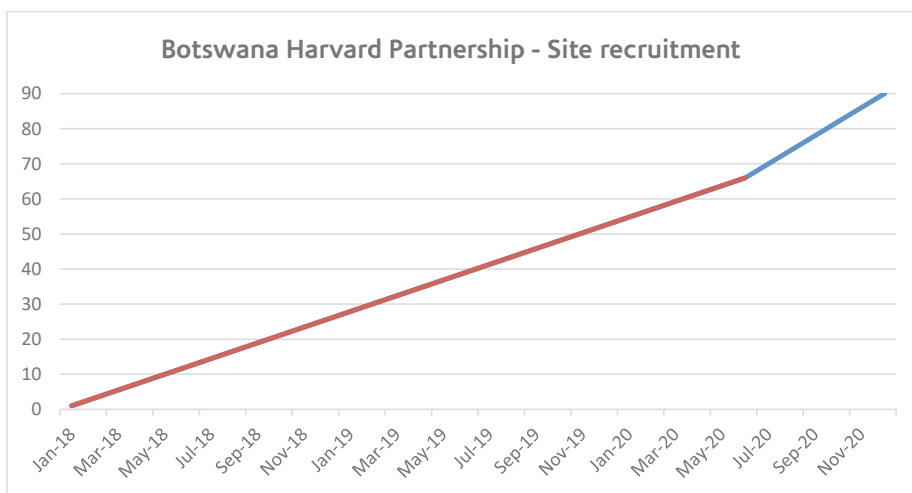


Figure 2: Ambition study - Recruitment graph at BHP

AMBITION supports The African Meningitis Trials Network (AMNET) a collaboration initiative that brings together African and American researchers. AMNET's objective is to build on existing experience, resources and infrastructure to facilitate future trials in Sub-Saharan Africa beyond AMBITION study.



Achievements

1. Charles Muthoga won a sponsorship to AIDS 2020 to present a poster entitled 'Impact and cost-effectiveness of expanding CrAg screening to include patients with CD4 100-200 cells/ μ L in Botswana.'
2. Katlego Tsholo also won a sponsorship to AIDS 2020, for a poster entitled 'Reasons for presentation with advanced HIV disease among HIV infected individuals in Botswana.'
3. Nabila Youssouf won a £1,000 grant from the London School of Hygiene and Tropical Medicine and Medical Research Council to develop a Public and Patient Engagement event in Botswana. The event occurred on 02/11/2019, with Katlego Tsholo, Ikanyeng Rulaganyang and Nabila

leading an educational workshop aimed at demystifying lumbar punctures among members of the community. The event called 'Changing the views of Lumbar Punctures in the community: an educational workshop to reduce mortality associated with Cryptococcal Meningitis in Botswana' was attended by members of the BHP Community Advisory Board (CAB). The event was summarised as poster and presented at the World AIDS Day celebrations in Maun in December 2019.

4. Professor Mosepele Mosepele and Dr David Lawrence attended the 11th European Conference on Tropical Medicine & International Health

(ECTMIH) in September 2019 where Prof Mosepele gave a presentation titled "CNS Infections in Africa: Epidemiology, Diagnostics, and Treatment in 2019."

Nabila Youssouf presented 'Challenges in conducting trials in resource limited settings: experiences and reflections from the AMBITION-cm trial' at the UK Trial Managers Network (UKTMN) Annual Conference held in Birmingham, UK in October 2019. Nabila won the Best Oral Presentation following a unanimous vote from the UKTMN Executive Group.

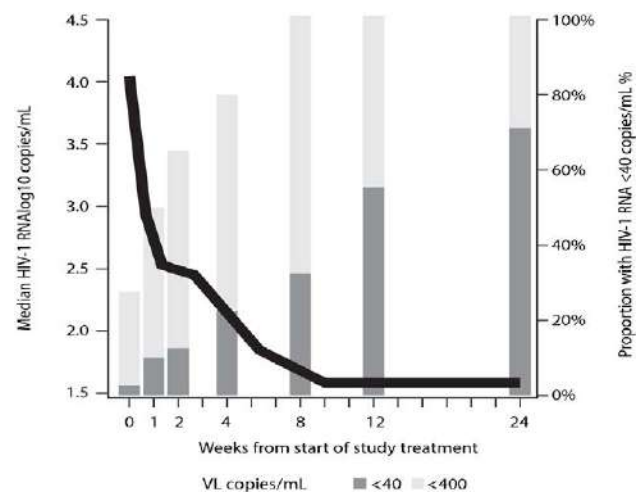
b) Early Infant Treatment Study: A Clinical Trial of HIV Positive Infants in Botswana

PI: Professor Roger L. Shapiro, MD, MPH

Early Infant Treatment Study (EIT) is a single arm non-randomized clinical trial of early ART in antepartum and peripartum infected children. As part of this study, HIV-exposed infants are tested at birth and, if HIV positive, offered immediate (within 72 hrs from birth) antiretroviral therapy. The overall objective of the study is to determine whether very early antiretroviral treatment (ART) initiation in HIV-infected infants limits the occurrence of viral reservoirs and maintains immune responses.

The study has completed accrual and retention remains excellent (100%), with minimal citations during Site Monitoring visits and a small percentage of participants with ongoing adherence challenges. Published results shows that a pediatric HIV treatment strategy starting NVP, ZDV, and 3TC in the first week of life and then transitioning to LPV-r, ZDV, and 3TC, was safe and effective in Botswana. The study findings support a NVP treatment dose of 6 mg/kg BID from the first week of life and showed success in achieving median HIV RNA and proportion suppressed to <40 copies/mL and <400 copies/mL, by treatment week (Fig 1).

Fig1: Median HIV RNA and proportion suppressed to <40 copies/mL and <400 copies/mL, by treatment week. Abbreviations: HIV, human immunodeficiency virus; VL, V=viral load.



c) A Clinical Trial to Evaluate the Impact of Broadly Neutralizing Antibodies VRC01LS and 10-1074 on Maintenance of HIV Suppression in a Cohort of Early-Treated Children in Botswana (Dual bNAb Treatment in Children)/ Tatelo Study

PI: Professor Roger Shapiro, MD, MPH

Tatelo Study is an interventional clinical trial of dual treatment with two broadly neutralizing monoclonal antibodies (bNABs), VRC01LS and 10-1074 for the

maintenance of HIV suppression in HIV-1 infected virally suppressed children. Non-Antiretroviral Therapy (ART) viral suppression strategies are a priority for children

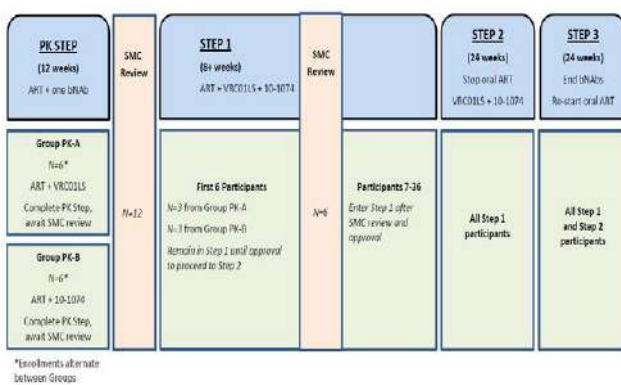
because of several factors including adherence issues with long-term ART use and accumulated toxicities to ART over time. Early-treated HIV+ children may be the ideal candidates for use of broadly neutralizing monoclonal antibodies (bNAbs) as an alternative to antiretroviral treatment (ART) because of their low HIV viral reservoir at enrolment and after 84 weeks of ART.

Study Objectives:

- To determine the safety, pharmacokinetics, dosing and antiviral efficacy of up to 24 weeks of maintenance VRC01LS and 10-1074 immunotherapy in early-treated HIV-1 infected children in Botswana.
- To evaluate effects of treatment with VRC01LS and 10-1074 on the size and cellular composition of residual viral reservoirs.
- To investigate the influence of VRC01LS and 10-1074 treatment on the magnitude and quality of antiviral innate and adaptive immune responses.

The study is comprised of four steps (Fig 1): PK Step, Step 1, Step 2, and Step 3. In the PK Step, background antiretroviral treatment (ART) is continued with either VRC01LS or 10-1074. Participants will undergo safety and PK testing for each bNAB used. In Step 1, ART is continued with dual bNAB treatment with PK confirmation of dual bNAB dosing. In Step 2, ART is withdrawn for fully suppressed children and dual bNAB maintenance treatment occurs. In Step 3, dual bNAbs will be discontinued and participants will be re-started on ART.

Figure 1: Study Schematic



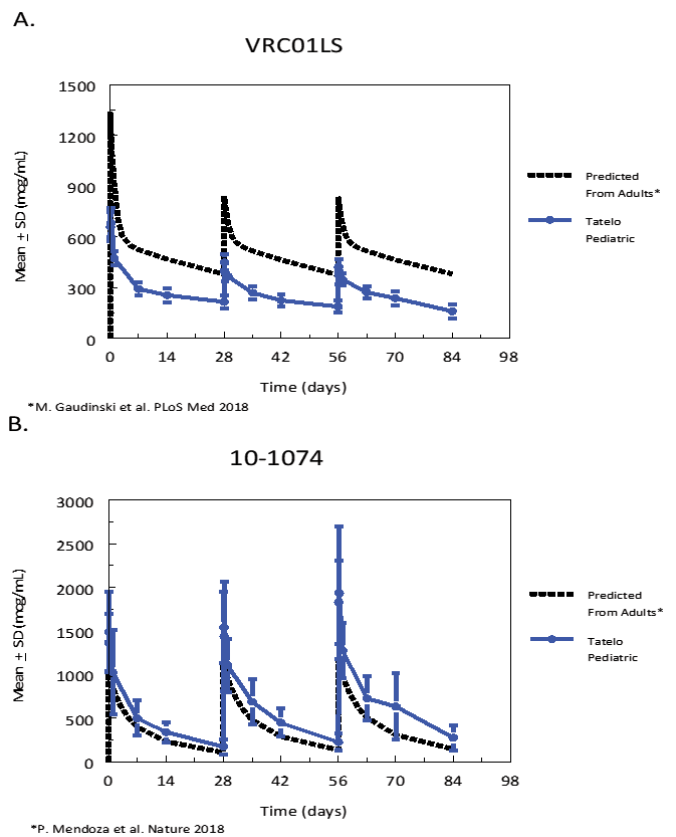
Study progress:

The PK Step was completed in October 2019. The Safety Monitoring Committee (SMC) responsible for reviewing each step of the study in terms of safety and Pharmacokinetics (PK) data met in December 2019 and made the following recommendations based on the PK findings from PK Step (Fig 2):

- Maintenance dose of VRC01LS modified from 10mg/kg to 15mg/kg dosing; Paediatric PK of VRC01LS differed from PK in adults hence an increased maintenance dose of 15mg/kg may be needed to achieve concentrations similar to adults when dosed monthly (Fig 2A). Note: Paediatric PK of 10-1074 slightly exceeded predicted adult concentrations when given at 30mg/kg monthly (Fig 2B).
- Study to proceed to step 1 for the first 6 participant per design (no safety concerns).

Following the SMC recommendations, Step 1 of the Study was commenced in March 2020 and it is still ongoing.

Figure 2: VRC01LS (A) and 10-1074 (B) pharmacokinetic profiles after intravenous administration in HIV+ children



d) Tshilo Dikotla Study: Metabolic Outcomes of Children HIV/ARV-Exposed Uninfected in Botswana.

PI: Dr Jennifer Jao, MD, MPH.

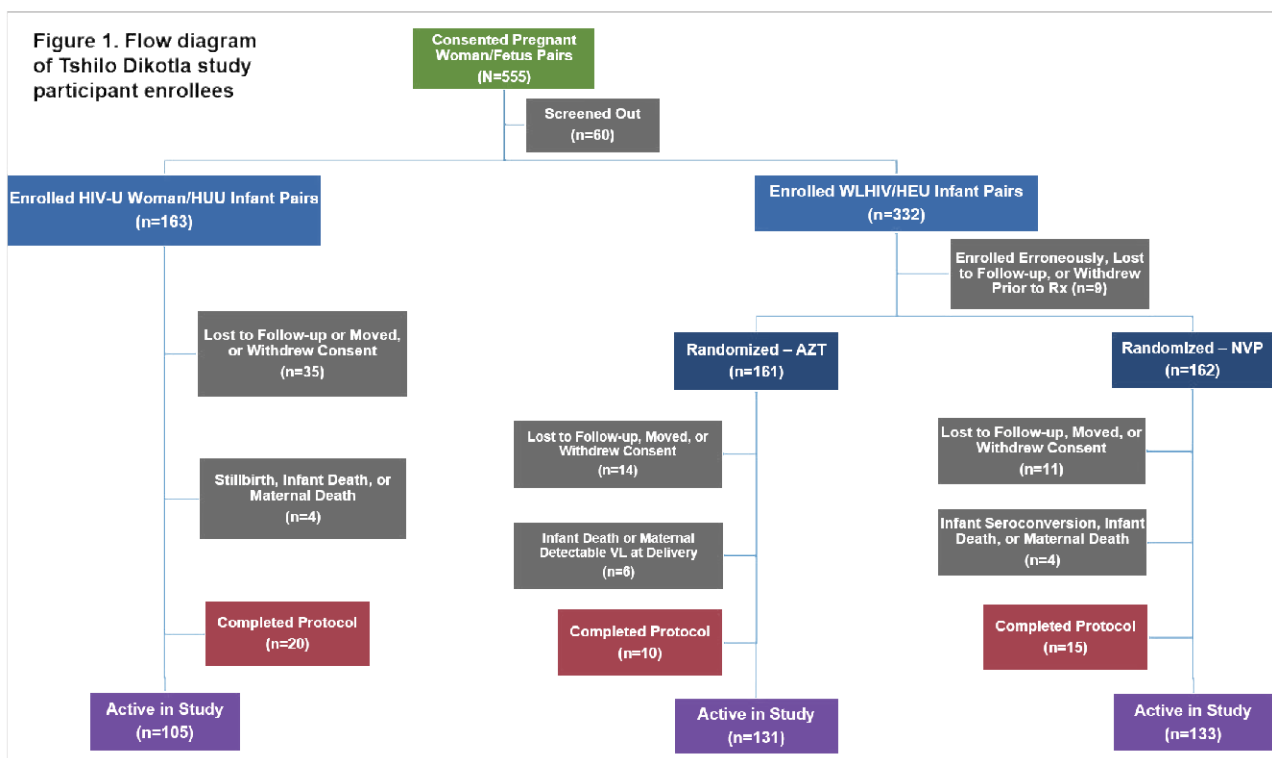
Tshilo Dikotla is a prospective observational study in pregnant women living with and without HIV and their infants. The study aims to assess the metabolic effects of *in utero* and neonatal exposure to HIV medications in the first three years of life in HIV Exposed Uninfected (HEU) children in Botswana.

In addition, using innovative metabolomics techniques, the study investigates whether a specific signature of metabolites is predictive of adverse metabolic health such as insulin resistance or mitochondrial dysfunction. If metabolic complications such as insulin resistance

are found, this could impact current diabetes treatment and prevention strategies in HEU children and argue for further research to identify HIV medication regimens with superior efficacy in the prevention of mother-to-child transmission of HIV but minimal adverse effects to the exposed fetus and infant.

The study enrolled 495 mother/infant pairs between August 2016 and May 2019. Although the study closed in the last reporting period, participants follow-up is ongoing with retention at approximately 84%. (Figure 1).

Figure 1: Tshilo Dikotla Study Enrolment flowchart



Retention Challenges

- Relocation of study participants out of study area.
- Covid-19 related restrictions resulting in partial closure of the study clinic and movement restriction to study participants.

e) The Karabo Study: Immune Correlates of Tuberculosis and non-Tuberculosis Infectious Morbidity in Southern African HIV-Exposed, Uninfected Infants

PI: Dr Kathleen Powis, MD, MPH

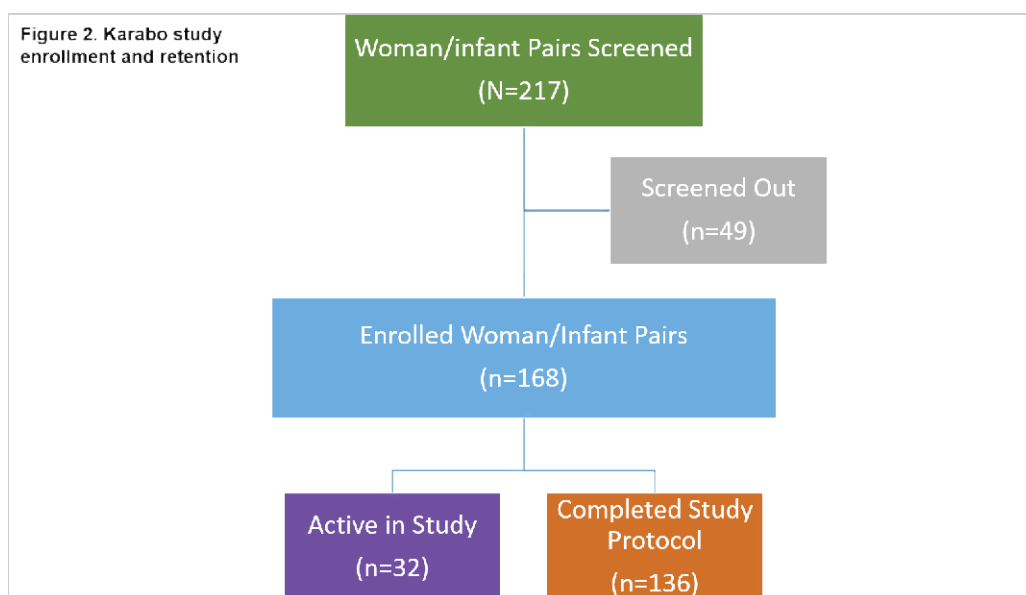
The Karabo study is evaluating TB and non-TB correlates of immunity in Bacille Calmette-Guérin (BCG) vaccinated infants who are HIV-exposed and uninfected (HEU) and HIV-unexposed and uninfected (HUU). The study will compare rates of latent tuberculosis infection (LTBI) between the BCG-vaccinated infants who are HEU and those who are HUU through 18 months of life.

The study will evaluate the combined outcomes of infectious morbidity and mortality and compare by the child's HIV exposure status. The findings from the

Karabo study may inform TB vaccine development for all newborns regardless of HIV exposure status and could offer the additional benefit of identifying interventions to decrease the higher rate of infectious morbidity and mortality experienced by infants who are HEU compared to those who are HUU.

The study enrolled 168 mother/infant pairs since July 2019. To date retention is 100%. A total of 136 mother-infant pairs have completed the study and participant follow-up is ongoing. (Figure 2).

Figure 2; Karabo Study Enrolment and Retention



f) Characterization of Anthracycline induced Cardiotoxicity Using Cardiac Magnetic Resonance in Botswana: A Prospective Observational study (Breast Cancer MRI Study).

PI: Dr Scott Dryden-Peterson, MD, MSc

The Breast Cancer Magnetic Resonance Imaging (MRI) Study aims to evaluate the effect of high-dose anthracyclines in patients treated for breast cancer. This is because anthracyclines are cardio toxic even though they are the main first line treatment for breast cancer. The study enrolls both patients living with and without HIV and it has enrolled 17 patients since September 2019 from Gaborone Private Hospital (GPH), Bokamoso

Private Hospital and Princess Marina Hospital (PMH). Patients undergo MRI scan to evaluate for possible differences in cardiac changes following treatment by HIV status. The study aims to recruit 25 participants, a reduction from the initial enrolment sample of 50 participants due to budget limitations as well as technical and human resource challenges at Village Imaging where patients undergo the MRI imaging.



g) Feasibility and Accuracy of Nanosensor-based cancer diagnosis at the point of care (Chedza Study).

PI: Dr Scott Dryden-Peterson, MD, MSc

Point-of-Care (POC) diagnostics would be of high value considering limitation in the number of pathologist and a late diagnosis of Cancer. Contrast Enhanced Micro-holography assays have been proven effective. CEM lymphoma platform can distinguish between benign and malignant B-cells better than flow Cytometry. Chedza Study aims to assess if Contrast Enhanced Micro-holography (CEM) can be used for point-of-care diagnosis of Lymphoma and Breast Cancer in Botswana.

To date the study has enrolled 170 participants with suspected breast cancer and lymphoma since July 2019. The study aims to enroll 350 participants and it is scheduled to be completed in July 2021. Enrolment sites are Nyangabwe Referral Hospital, Princess Marina Hospital and the National Health Laboratory (NHL). Challenges to the progress of the study have been COVID-19 related restrictions and technical errors on the machine.

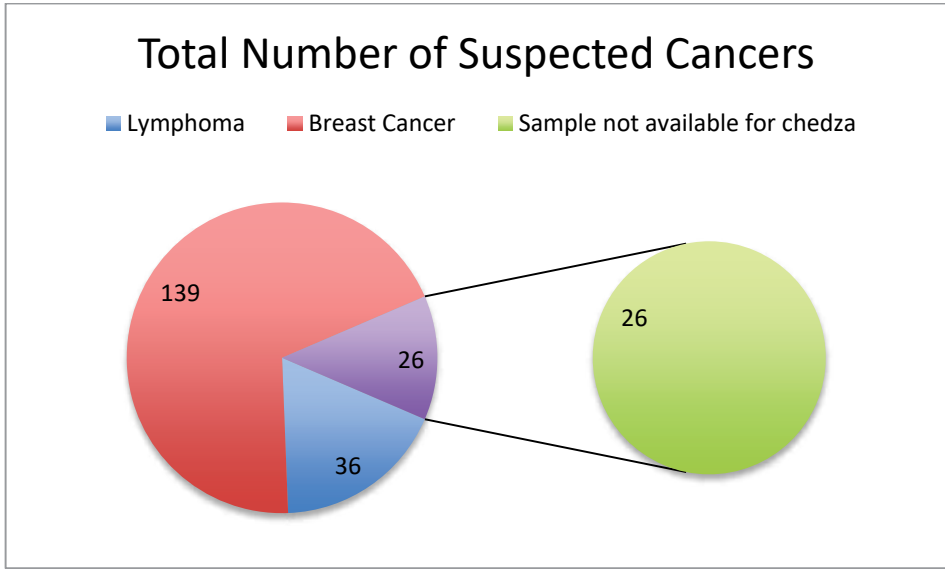


Figure 1: The number of suspected cancer enrolled in Chedza study from August 2019 to July 2020. 139 of the total participants enrolled were suspected breast cancer cases. Of the 170 participants enrolled, 26 participants did not have their samples taken because upon sample collection, it was discovered that the mass was small and the participants were put on observation.

h) HIV and Malignancy in Botswana: An observational Study of Medicine Toxicity of Concurrent Treatment and Clinical Outcomes (Thabatse Study)

PI: Dr Scott Dryden-Peterson, MD, MSc

Thabatse is a prospective cohort study which aims to evaluate the risk factors for cancer and describe the response to treatment for patients who are HIV positive but not on Antiretroviral Therapy (ART) and those on ART. The study started in 2010 and is scheduled to finish in 2022 with a target sample of 6500 participants. The study enrolls biopsy-confirmed cancer cases that present for specialized oncology care and to date, 4577 participants have been enrolled into the study. The enrolments sites are Princess Marina hospital,

Nyangabwe Referral Hospital, Bokamoso Private Hospital and Gaborone Private Hospital.

The Thabatse team has been doing a weekly surveillance of COVID-19-like illnesses and symptoms on the participants of the study where they were asked specifically about COVID-19-like symptoms (sore throat, fever, cough, rhinorrhoea) in order to provide counselling and linkage to care for screening and testing for COVID-19 as and when need arises.

i) Potlako: A Programmatic Multi-Facility Level Intervention to Improve Access to Timely Oncology Care in Botswana.

PI: Dr Scott Dryden-Peterson, MD, MSc & Dr Neo M. Tapela, MD, MPH

Potlako Study was an NIH-funded prospective pilot study initiated in April 2016 which evaluated a complex health system intervention in improving earlier diagnosis and treatment initiation of major cancers among residents in rural Kweneng-East district.

The study worked with 35 public health facilities in the

district and has delivered intervention components, which included supporting patients in navigating the health system by providing transport support and clinic appointment reminders as well as supporting health system through better coordinated and algorithm-based referrals, bookings and follow up of pathology results. The study ended in May 2020.

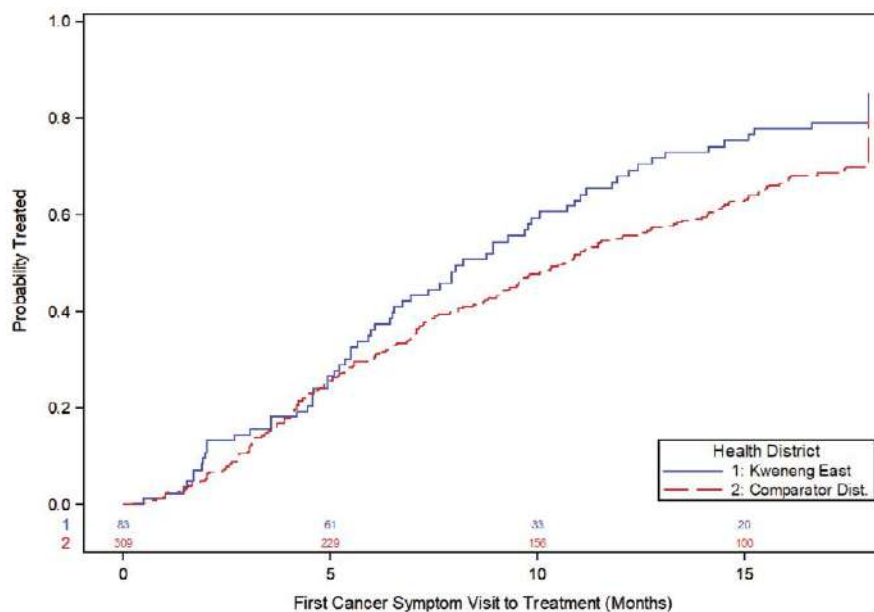


Figure 2: Time-to-Treatment Comparison

In Kweneng East, where Potlako was conducted, 50% of patients were initiated on treatment at 8.2 months,

compared to 50% of patients who were initiated at 10.2 months in comparator districts.

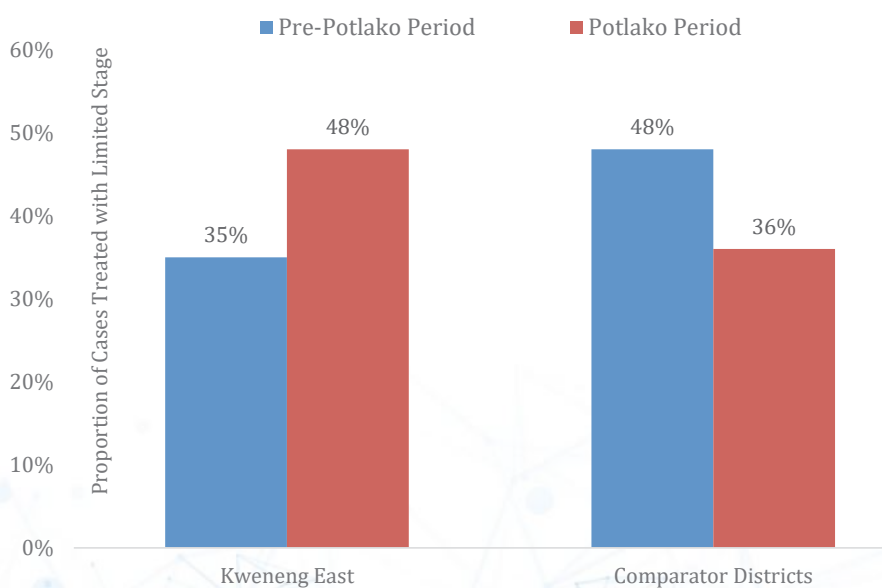


Figure 3: Limited Stage at Diagnosis Comparison



Over the Potlako study period, there was an increase in limited stage at diagnosis in Kweneng East, compared to the comparator districts that showed a decline in early cancer diagnosis over the Potlako period.

Based on the above study and the results therefrom, a five-year NIH grant was awarded to fund the next phase of the study dubbed Potlako+ described below.

j) Potlako +: A multilevel intervention to improve timely cancer detection and treatment initiation in Botswana.

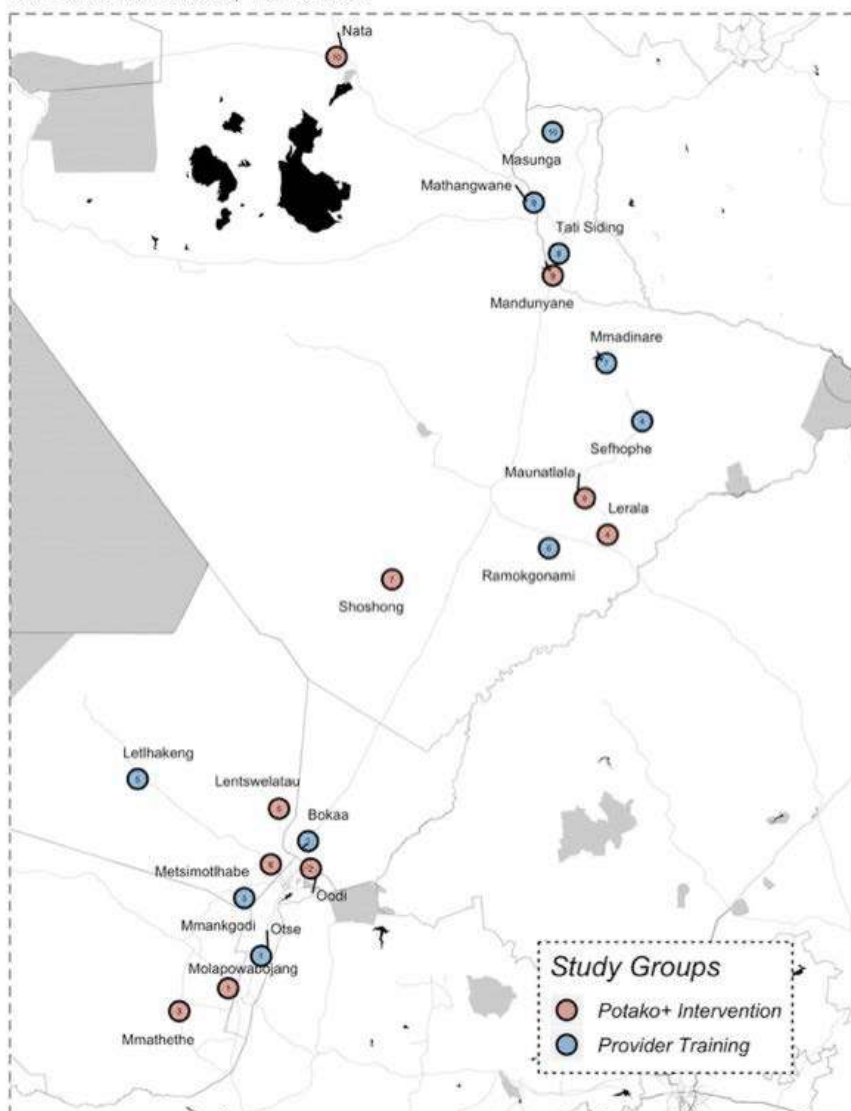
PI: Dr Scott Dryden-Peterson, MD, MSc & Dr Neo M. Tapela, MD, MPH

Potlako+ Study is a cluster-randomized trial involving 20 communities (multiple districts) that will more rigorously evaluate the multicomponent intervention's impact on earlier diagnosis and treatment initiation of cancer. Potlako+ intervention components will include patient navigation, health care provider training. The

study aims to develop a multicomponent intervention that is feasible in a resource limited setting and evaluate its impact on time from symptoms to presentation, time from presentation to cancer treatment initiation and proportion of cancers treated in early stage.

Participating Potlako+ Communities Botswana, 2020

Randomization Results, 4 June 2020



PARTICIPATING POTLAKO+ COMMUNITIES
BOTSWANA, 2020

By the end of the reporting period the grant (NIH R01) had been awarded and preparatory work, including the recruitment of study coordinator and study physician

had been completed. The 20 study communities have also been randomized into 10 intervention and 10 control communities.



Potlako + Study Randomization was performed by Kgosi Mosadi Seboko, Paramount Chief of Balete and Bishop Raphael Habibo of the Assemblies of God, Gaborone.

k) Human Papillomavirus (HPV) Cervical cancer screening study

PI: Dr Rebecca Lockett, MD, MPH

The HPV cervical cancer screening study was started in 2018 and recruited 300 women. The study evaluated two-stage cervical cancer screening algorithms using primary high-risk HPV testing followed by cytology, visual inspection with acetic acid and colposcopy in women living with HIV in Botswana.

The study is relevant because there are no evidence based International cervical cancer screening guidelines for HPV based screening in women living with HIV. Analysis of the results is on-going and will inform the appropriate screening intervals for HPV-based screening programs in women living with HIV.

Gynaecology to expand research in HPV primary screening for cervical cancer. The extended study will recruit 3000 women (both positive and negative for HIV) in South East District, Botswana to evaluate new technologies for triaging positive HPV results.

The new technology uses artificial intelligence technology to read visual images of the cervix. This new technology will be compared to visual inspection with acetic acid and colposcopy with biopsy as the gold standard. The study is expected to run over a 3-year period (October 2019 – September 2022).

Achievements

In October 2019, Dr. Lockett was awarded a Young Investigator Award from the Beth Israel Deaconess Medical Center, Department of Obstetrics and



l) The diagnosis and treatment of Chlamydia Trachomatis and Neisseria Gonorrhoea in Woman to prevent adverse neonatal consequences (STI Study).

PI: Dr Chelsea Moroni, MD, MPH, PhD

The STI study is a cohort study among antenatal patients to determine the burden of gonorrhoea and chlamydia infection among asymptomatic pregnant women in Botswana and to investigate the impact of gonorrhoea and chlamydia testing to prevent vertical transmission and associated adverse neonatal health outcomes. Chlamydia trachomatis and Neisseria gonorrhoea are bacterial sexually transmitted infections (STIs), and are neglected causes of adverse neonatal outcomes. Few countries provide routine antenatal testing.

In most countries, including Botswana, the syndromic approach is used, which utilises an algorithm to classify symptoms into STI syndromes and provide standardized

treatment. Syndromic management lacks specificity and sensitivity meaning that pregnant women are unnecessarily exposed to antibiotics and asymptomatic infections are often missed, putting neonates at risk. Through this study, we hope to inform stakeholders and policymakers as they work to improve management of STIs during antenatal care, in order to improve maternal and neonatal outcomes.

The STI Study is funded by the National Institute of Health (NIH). There have been some delays with implementation due to the COVID-19 pandemic and as a result, participant recruitment is expected to begin at the end of 2020. The study will enrol 500 participants.

m) Contraceptives and Dolutegravir-based ART (CODA) Study

PI: Dr Chelsea Moroni, MD, MPH, PhD

The Contraceptives and Dolutegravir-based ART (CODA) Study is a Phase IV, open label, non-randomized, parallel-arm, pharmacokinetic study, investigating whether drug-drug interactions occur when the subdermal contraceptive implant (levonorgestrel) or the depot medroxyprogesterone acetate (DMPA) injectable are concurrently used with dolutegravir (DTG)-based ART.

Provision of contraception is complicated in high HIV prevalence settings due to proven drug-drug interactions between some anti-retroviral therapy

(ART) agents and hormonal methods. Dolutegravir (DTG) is highly effective in managing HIV and is a WHO recommended first-line agent. However, thus far, there is little data on the effect of DTG on hormonal contraception. Rigorous and complete evidence on the risk of drug-drug interactions between hormonal contraceptives and DTG is urgently needed to inform local and international guidance. The CODA Study is funded by Viiv Healthcare. The study intends to start participant recruitment at the beginning of 2021.

n) Optimizing Maternal & Child Health and Development (Monana Ke Isago Study).

PI: Dr Lisa Butler, MA, MPH, PhD.

Monana Ke Isago Study is an intervention development study. Its aim is to develop, and pilot test a novel multi-component community-based adolescent-friendly intervention for mental health care designed with and for pregnant adolescents and new mothers aged 15-19 years old in Botswana. The study started on 7th February 2019 and aims to recruit 30 study participants. It is expected to end on 31st April 2021.

Perinatal depression is associated with numerous adverse effects on maternal and child health outcomes and poor developmental outcomes in children. In Low- and Middle-Income Countries (LMICs), between 19-25% of women experience depression during pregnancy and 10-19% of mothers experience depression in the postpartum period (6 weeks post-delivery). Evidence-based, scalable adolescent-friendly models of mental health care for young mothers are greatly needed in LMICs.

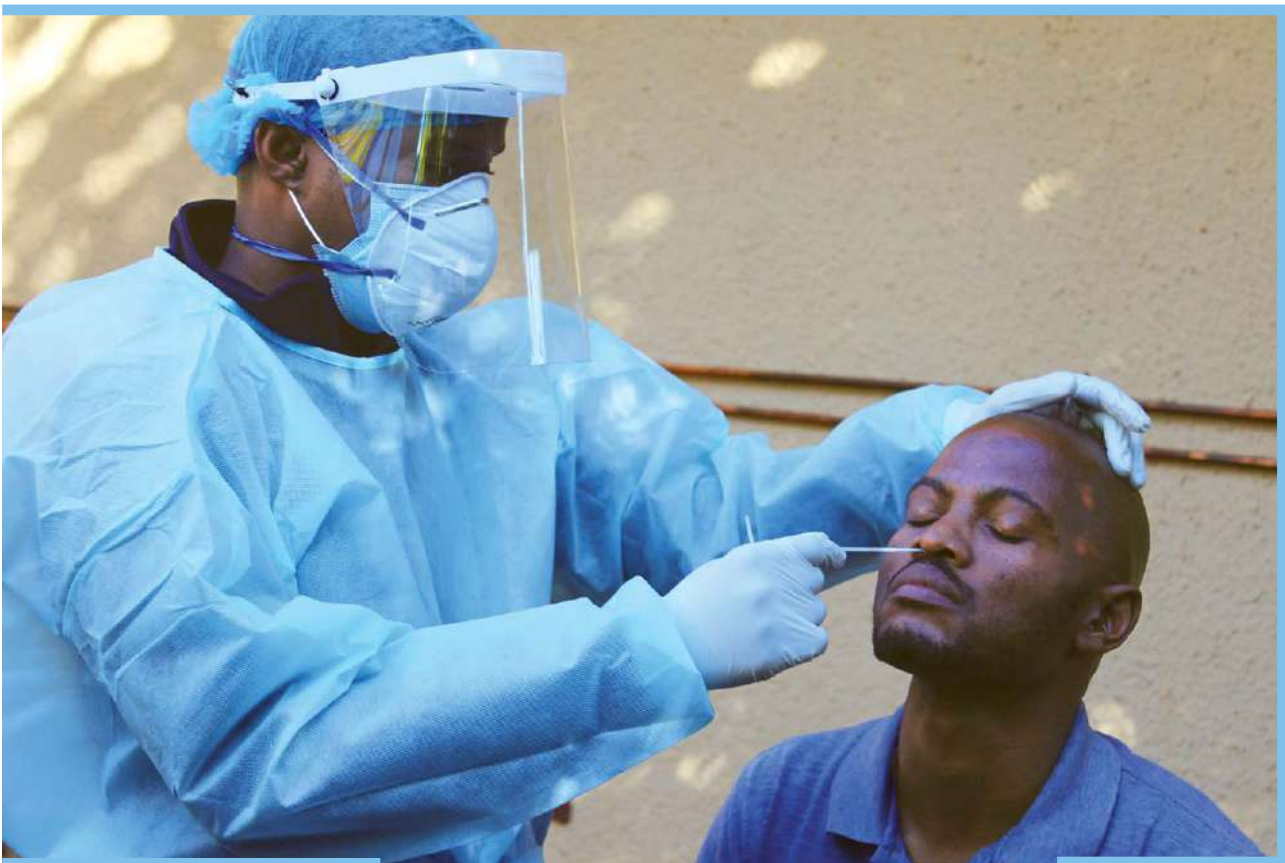
o) COVID-19: An observational cohort of cases treated in Gaborone, Botswana

PI: Professor Mosepele Mosepele, MD, MSc

The COVID-19 Study is an observational cohort study to describe the presentation, clinical course and outcome of individuals who are diagnosed and treated for COVID-19 in Gaborone, Botswana. The Study is recruiting consecutively eligible participants for a three months period and then conducting an interim analysis and review thereafter. The BHP is collaborating with the University of Botswana and the Sir Ketumile Masire Teaching Hospital for study conduct.

The Main Objectives are:

- To describe the presentation, severity, outcome and persistence of each case of COVID-19 managed in Gaborone.
- To compare the difference between cases in HIV-infected and HIV-uninfected individuals
- To determine if individuals with HIV infection remain infectious for longer than those without HIV infection
- To determine the impact of COVID-19 on HIV infection
- To establish a bio-repository to conduct future studies on host genetics and COVID-19.



COVID-19 Testing at BHP



p) Albuminuria Among Virally Suppressed HIV-infected Patients in Botswana: Longitudinal Changes and Association with Inflammation and ACEI/ARB Use in a Clinical Setting- Albuminuria Study

PI: Professor Mosepele Mosepele, MD, MSc

As more HIV-infected patients attain viral suppression and prolonged survival globally due to highly effective anti-retroviral therapy (ART), they are faced with multiple non-communicable diseases mostly characterized by accelerated end-organ dysfunction (e.g. cardiovascular disease, renal dysfunction, cognitive impairment), which threaten their long term health and longevity. While it is well known from Western populations that persistent albuminuria and inflammation is a marker of excess end-organ dysfunction and increased mortality among HIV-infected adults with undetectable HIV-1 RNA (viral load suppression on ART), the burden of albuminuria/inflammation has not been well characterized among black African patients. In addition, the role of widely globally available angiotensin converting enzyme inhibitors/angiotensin receptor blockers (ACEI/ARBs) in reducing albuminuria/inflammation in African HIV-infected patients has not been studied.

This is an observational prospective study in a high HIV prevalence clinical setting with the following three main objectives;

1. Describe the prevalence and longitudinal changes in albuminuria over a 12-month period among

treated HIV-infected adults overall, and in relation to the use of ACEI/ARB

2. Describe the association between albuminuria and inflammation among treated HIV-infected adults overall and in relation to the use of ACEI/ARB
3. Create a human bio-repository and HIV-CVD outcomes clinical registry for the study of long term clinical outcomes of albuminuria.

The EDCTP-sponsored study commenced enrolment in January 2020 and has to date enrolled 447 participants (target enrolment 1537) from Princess Marina Hospital IDCC. The study will be expanding enrolments to Gaborone DHMT Clinics (Bontleng and Nkoyaphiri Clinics).

As part of the award, Principal Investigator Professor Mosepele is mentoring IMPAACT Study Physician/Coordinator Dr Ponatshego on his ACTG International HIV Investigator Mentorship Program (IHIMP) award, looking at possible Albuminuria and Frailty Association, and ACTG Dr Chakalisa, who will examine urinary sodium and potassium excretion and their relationship with hypertension for her MSc in Clinical Epidemiology.

RESEARCH SUPPORT

i) Clinical Laboratory

The Botswana Harvard HIV Reference Laboratory (BHHRL) supports the clinical trials conducted by the Botswana Harvard AIDS Institute Partnership. In this reporting period, BHHRL continued to provide the needed coverage for all the clinical trials at BHP providing requisite data, from receiving and processing labs, cell separations and cryopreservation, diagnostic, safety and monitoring, as well as specialized research assays; providing high quality testing for the key assays for enrollment and management of study patients.

BHHRL continued to maintain its approved status in conducting clinical trials supported by the US National Institutes of Health, especially through the Division of AIDS (DAIDS) through the networks, ACTG, IMPAACT and HPTN. BHHRL maintained its accreditation to ISO 15189 through the Southern African Development Community Accreditation Service (SADCAS). This represents international recognition of quality and competency in all aspects of our medical laboratory services.



Activities of the Clinical Laboratory include Processing and Accessioning, Inventory and Archiving; Clinical Chemistry, Hematology, CD4, Viral load, Diagnostic DNA PCR, HPV PCR, Chlamydia and Gonorrhea, HIV Drug Resistance; Serological Assays including fourth generation HIV ELISA, Hepatitis B profiles, Hepatitis C Antibody, Syphilis RPR and TPHA, HIV-1 confirmatory assays (Genius), Incidence Assays [Limiting Antigen, Avidity, Bio-rad Avidity and BED capture enzyme immunoassay], QuantiFERON TB Gold Plus assay, Cepheid Point of Care Viral load, Gene Expert TB and SARS CoV 2 testing.



BHP Scientists at the Laboratory

Several research assays in-house or through referral laboratories are available including TB (AFB, Molecular, culture and Drug Sensitivity), Cytology/Histology, and inflammatory cytokines. The laboratory has registered all assays in External Quality Assurance (EQA) programs and the EQA performance has been satisfactory in all

tests during the past year. Specimen volumes received in the laboratory were fairly stable over the year however; the nature and type of visits were increasing in processing intensity and complexity, for instance pharmacokinetics sampling and PBMC isolation.



Highlights

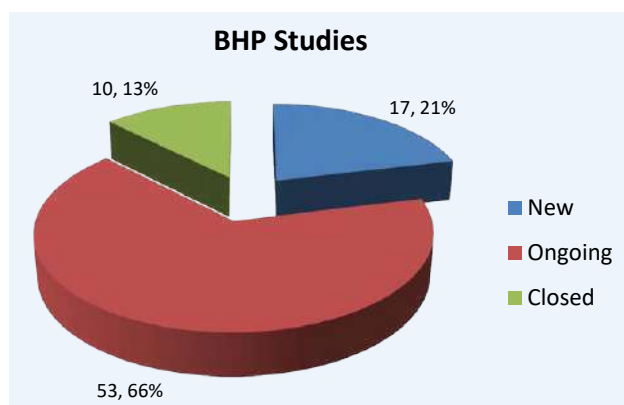
The lab added a number of new assays to its test menu. The acquisition and validation of the Abbott Architect enabled the lab to automate its serological assays. The HIV confirmatory testing was transitioned from the western blot assay to Geenius assay. The lab also developed capacity to do SARS CoV 2 testing for which on average 300 tests are done daily.

ii) Regulatory Office

Regulatory oversight forms an important part in the conduct of Human Research. BHP's regulatory office supports all studies to adhere or comply with the required health research regulations such as maintenance of valid ethics approvals throughout the duration of the studies.

Furthermore, the office is also mandated to support studies in continuous quality assurance activities and monitor compliance. Despite COVID-19 restrictions the office continued to function efficiently to avoid lapses in approval for ongoing studies. The local IRB Health Research and Development Committee (HRDC) has also been tremendously supportive in providing satisfactory turnaround times for COVID-19 related protocol applications.

The Regulatory office has also provided support to the network trials in Gaborone and Molepolole sites during Remote Monitoring Visits (rMV) necessitated by COVID-19 restrictions. In the current reporting period, the office supported approximately 80 studies, 53(66%) of which are ongoing, 17 new studies (21%) and 10 (13%) were closed out with IRBs after satisfying requirements for closure (figure 1).



iii) Pharmacy

BHP Pharmacy has established itself as a high standard clinical research department recognised by the Botswana Medicines Regulatory Authority (BoMRA) and Botswana Ministry of

Health and Wellness as well as Central Medical stores for its high standards of compliance to the requirements of the regulators and for ensuring that studies are conducted with compliance and integrity. It supports multiple studies with a population over 100 study participants.

For the report period the pharmacy department has facilitated the establishment of the Sesikalla Retail Pharmacy (BHP Business arm) headed by the pharmacy coordinator. The Retail Pharmacy will be operating to generate income for the Botswana-Harvard partnership research mandate.

Despite the COVID-19 pandemic the pharmacy department has continued to ensure access to study drugs, concomitant medication and drug counseling and participant counseling during the challenging time. It was an exercise that demanded drug delivery even to remote areas on the Greater Gaborone region and medication couriering to participants outside the region but also ensuring that data capturing and documentation is maintained.

Delivery was conducted to over 200 participants and medication couriering was done for 6 participants.

iv) Community Engagement

Community Engagement (CE) Department builds and maintains relationships with various stakeholders to ensure that they understand and appreciate BHP's mandate and its research projects.

To achieve these, BHP engages its stakeholders through different engagement platforms like National and International Commemorations, stakeholder meetings, presentations at meetings and conferences. BHP also has a Community Advisory Board (CAB), which helps ensure adequate communication between researchers and the communities to improve public understanding of the research. The BHP Community Engagement Office is also part of the membership of the Pre-Exposure Prophylaxis (PrEP) Technical Working Group of the Ministry Of Health and Wellness (MOHW), Ethics Working Group of the HPTN and Ethics Review Committees of the University of Botswana.

Some of the activities undertaken during this reporting period included conducting six (6) In-house meetings and community stakeholder engagements, and participating in one (1) national commemoration event (World AIDS Day).

The office has also taken part in a Community Education and Outreach activities that include addressing Kgotla meetings to discuss the PHOENIX Study as well as the Myth Buster Series aimed at demystifying and explaining misconceptions about medical procedures that are deemed controversial. The first of the Myth Buster Series focused on demystifying Lumber Puncture.

Pictures of people without masks were taken pre-COVID-19 period.



BHP Pharmacist, Obonwe Pule interacting with HPTN 084 Clinical Research Manager, Scott Rose at the Pharmacy during his visit to BHP.

Pictures of people without masks were taken pre-COVID-19 period.



Study Physician, Dr David Lawrence and CAB Member Ponoyame Segotsi at the Lumbar Puncture Workshop.

The BHP Community Engagement was also part of the two (2) community engagement projects carried out by two BHP Scientists, Dr Motswedi Anderson and Lucy Mupfumi. Dr Anderson's project was on Hepatitis B awareness that ran about 3 weeks with UB students while Mupfumi was TB/HIV education awareness among young people.

The Hepatitis B Awareness (HepBZero Project) culminated in the production of educational material

(Poster) on the symptoms and treatment of Hepatitis B virus designed by the participants. The posters will be printed both in English and Setswana and handed over to the Ministry of Health and Wellness for distribution at various health facilities around the country. The End TB project involved the participation of youth living with either HIV or TB discussing about different issues surrounding TB/HIV. The project produced a documentary on TB/HIV awareness that was shared with youth in secondary schools in Gaborone.



Pictures of people without masks were taken pre-COVID-19 period.

Secondary School students were part of the End TB Workshop



Study participants of the HepBZero study during training



Pictures of people without masks were taken pre-COVID-19 period.

Dr Lucy Mupfumi (2nd from left) had partnered with Eh!Woza media team from South Africa to conduct TB/ HIV Awareness Campaign and help produce a documentary on TB/HIV awareness.

v) Software Engineering & Data Management Center

The Software Engineering and Data Management Center (SE & DMC) at BHP serves to ensure a complete, accurate, compliant, auditable, confidential, secure and available research data.

Achievements

Dataverse: Deployment of a data repository to host all BHP data collected across studies. This repository will help with data archiving and make data sharing easy. This allows data to be more discoverable to the research community, and satisfies data management plans.

Senaite LIMS: Laboratory Information System. This system is used to help manage all data around research participants sample life cycle including result management. The system has been upgraded to allow more user functionality such as sample storage, export and import of sample into the system. The system also helps with lab data management and being able to have an inventory of all samples. The system can now also be integrated with other research systems for automated exchange of data. These new functionalities have allowed for good lab data management for the lab and also studies as well as easy management of results, and full automation of processes such as auto result importation from lab machines into the LIS reducing human errors that may occur.

RedCap: BHP has developed a redcap server which is a low cost data capturing tool hosted at BHP.

SMS Portal: The BHP has introduced an SMS portal for participant and staff communications. The same portal will also be used to send contract end reminders to staff or any important messaging as an alternative to email.

vi) Information Technology (IT)

The IT department is responsible for hardware support, managing BHP systems, network management and computer support for end users across the entire organisation. The overall goal is to provide a stable and secure computing environment that is aligned with industry best practices. The department tries by all means to provide the best solutions at minimal cost to the organisation. Majority of the systems are free and open source, even though that comes at a cost of needing skilled system administrators and support technicians. The department has built a data centre that runs on virtualized infrastructure and it aims to keep up with emerging technologies that are aligned with keeping the computing environment of BHP secure.

In the 2019 - 2020 year, the IT department set out to increase the security of both server-based systems and end-user devices. This goal was set due to an increase in the number of cyber threats in world from previous years. The department has setup systems and processes that helped reduce the risk of BHP employees falling victim to cyber attacks.

Goals and Achievements

1. Securing BHP Information and Communication

The confidentiality and integrity of BHP data is of utmost importance to stakeholders such as PI's, participants and researchers. The IT department has come up with systems that ensures that email communications are secure, and data stored in the organisations servers is protected from malicious access and tempering.

An owncloud server was rolled out. This platform allows users securely share documents over local network and the internet using web encryption technologies to encrypt data as its shared between users.

All web-based systems in the organisation are also protected by a valid DigiCert SSL certificate. This means that our systems' security are verified as secure from anywhere in the world.

2. Integration of Cloud Services

As the information and technology world moves towards cloud services were an organisation rents out server space on the internet and pays only for what they use, entities have move to the cloud. The advantage being that there are no infrastructure costs, and cost of maintenance is low.

The IT department has been experimenting with the technology with the hopes of one day fully transitioning to operating systems on the cloud and saving costs related to hardware and man-hours spent maintaining the hardware. The BHP website is the first system that is now cloud host-ed.

3. Support for Remote Work

Part of the 2019-2020 year was met with a crisis that forced part of the BHP work-force to find ways to perform their duties remotely. The IT department has had VPN system that specifically answered this need. Through VPN, employees are able to connect to BHP systems from anywhere over the internet. This connection is highly secure and protects data from being intercepted or manipulated over the internet.

Almost all essential BHP staff have been setup and oriented on the use of VPN by the IT department. This has helped to keep the working going even during national or regional shutdowns due to the Covid-19 pandemic.



11. CAPACITY BUILDING AND TRAINING

i) Research Laboratory

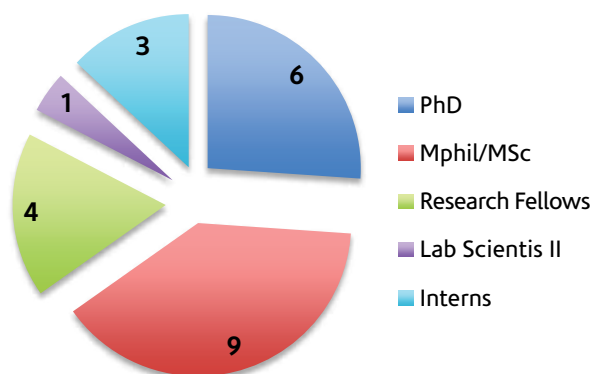
The BHP research laboratory team is a vibrant group of research fellows at various stages of training working on projects that are of public health importance in Botswana, the region and globally. The group works under the supervision of Dr Simani Gaseitsiwe, Dr Sikhulile Moyo and Dr Rosemary Musonda. Dr Motswedi Anderson who recently received a grant from Wellcome Trust and another from Africa Research Excellence Fund (AREF) as Principal investigator, takes a central role in driving the viral hepatitis research agenda at BHP. The group also boasts of international collaborators who assist in the supervision of fellows working on areas where there is limited capacity at BHP. The fellows are registered with various academic institutions including University of Botswana (UB), Botswana International University of Science and Technology (BIUST), Stellenbosch University, and University of Cape Town.

The main areas of research focus include: HIV drug resistance, HIV incidence and tools to determine HIV incidence, viral hepatitis, TB incidence and molecular epidemiology, and HPV molecular epidemiology. The fellows are supported by various grants including, SANTHE, Fogarty, H3ABioNet and TESA II.

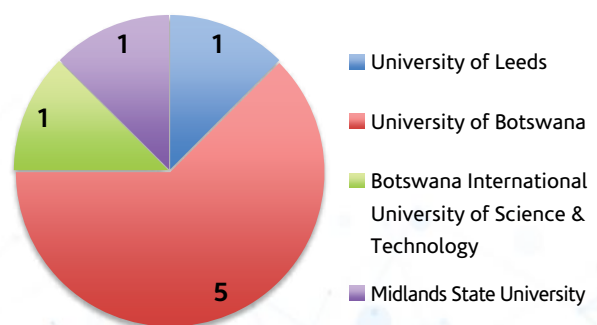
In the reporting BHP had 6 PhDs, 9 Masters Degrees, 4 Research fellows, 1 Laboratory Scientist II and 3 interns. Three fellows have submitted their thesis and

they are awaiting graduation (1 PhD Medical Sciences, 1 MPhil Medical Sciences and 1 MSc Biological Sciences). Eight Undergraduate students were attached to BHP for their projects (5 from UB, 1 BIUST, 1 Midlands State University and 1 from University of Leeds). Five graduated from UB (2 MPhil Medical Sciences and 3 BSc Biological Sciences).

Number of Trainees/Research Fellows



Number of Undergraduate students attached to BHP Laboratory



Trainings conducted or attended and Abstracts presented over the reporting period include:

Trainings Conducted

1. BHP through TESA II grant hosted a workshop on the 13th to 15th November 2019 on continuous improvement process important for implementing and maintaining laboratory quality management systems, GCLP and ISO accreditation critical for the conduct of clinical trials. This workshop was attended by participants from Botswana as well as other TESA network members such as Zimbabwe and Mozambique. The aim of the workshop was to provide participants with practical approaches to non-conformity identification, root cause analysis and monitoring effectiveness of corrective and preventive actions. The training is closely aligned with requirements of ISO 15189:2012 standard and used hands-on activity and field-tested job aids. BHP has decided to conduct a workshop on Continuous Improvement Process. A total of 20 trainees attended this workshop.
2. Next Generation Sequencing analysis and introduction to Linux ; 5-7 February 2020, Gaborone, Botswana.

Trainings attended and Abstracts presented

1. Epidemiology meets Phylogenetics, 9 - 13 September 2019, Durban, South Africa-Course. Title: Virologic Characteristics of Vertically Transmitted Hiv-1 Strains in Botswana And South Africa. Presenter – Natasha Moraka.
2. ID Week 2019, 2 – 6 October, 2019, Washington DC, USA, Poster presentation. Title: Child HIV Exposure and CMV Seroprevalence in Botswana: No Associations with 24-Month Growth and Neurodevelopment. Presenter – Natasha Moraka.
3. Africa 2020 ;10 – 14 February 2020, Cape Town, South Africa. Poster Presentation Title: Prevalence of Hiv-1 Drug Resistance Mutations in Newly Diagnosed Infants in Botswana (Conference). Presenter – Natasha Moraka.
4. Media, Public and Community Engagement, 19-21 September 2019, Durban, South Africa (Training).
5. Community & Public Engagement Inception Meeting, 28-30 September 2019, Nairobi, Kenya (Workshop).
6. SANTHE Annual General Meeting, 2-5 October 2019, Nairobi, Kenya. Oral Presentation. Title:

High incidence of TB in the Botswana National ART Program. Presenter – Lucy Mupfumi.

7. Keystone Symposium: Tuberculosis: Immunity and Immune Evasion, Santa Fe, New Mexico, USA. 16-20 January 2020, New Mexico, USA.
8. Drug Resistance Strategy Workshop, 26-30 August 2019, Gaborone, Botswana (Workshop).
9. HIV sequence and Immunology database workshop, 09 September 2019, Durban, South Africa (Workshop).
10. PANGEA Meeting (Epidemiology meets Phylogenetics) 11-13 September 2019, Durban, South Africa (Workshop).
11. Community and Public Engagement Workshop, 02 October 2019, Nairobi, Kenya (Workshop).
12. SANTHE Annual General Meeting, 2-5 October 2019, Nairobi, Kenya-Oral presentation. Title: High incidence of TB in the Botswana National ART Program. Presenter – Dorcas Maruapula.
13. Analysis of Next-Generation HIV Sequence Data Workshop; 5-7 February 2020 Gaborone, Botswana.
14. Dynamics & Evolution of HIV and other Human Viruses, May 11-13, 2020, Virtual conference, Poster presentation. Title: How to Enhance Hiv-1 Testing: Factors Associated with Undiagnosed Individuals In Botswana. Presenter-Lynette Bhebhe.
15. 28th International workshop on HIV Drug resistance and treatment strategy, 2019, South Africa. Oral and Poster presentation. Title: Comparison of HIV-1 Viral Load and Drug Resistance Mutations between Cerebrospinal Fluid and Plasma in Patients with HIV and Cryptococcal Meningitis Co-infection in Botswana. Presenter- Nametso Kelentse.
16. 17th European AIDS conference, 2019, Switzerland. Poster Presentation, Title: Comparison of HIV-1 Viral Load and Drug Resistance Mutations between CSF and Plasma of Individuals with HIV and Cryptococcal Meningitis Co-infection in Botswana.
17. Conference on Retroviruses and Opportunistic Infections, 8-11 March 2020, Boston, USA. Poster presentation. Title: HIV-1 Diversity in CSF and Plasma of Individuals with HIV and Cryptococcal Meningitis. Presenter- Nametso Kelentse.



2) The BHP Clinical Capacity Building Initiative at Scottish Livingstone Hospital

The initiative is collaboration between the Botswana Harvard AIDS Institute Partnership (BHP), Beth Israel Deaconess Medical Center (BIDMC), Boston and Oregon Health & Science University (OHSU), Portland. It aims to support healthcare capacity building clinical stewardship, medical education, quality improvement and research in Botswana. The initiative is supported by three Harvard clinical faculty who work full-time in Botswana in their respective programs in Internal Medicine, Obstetrics & Gynaecology and Anaesthesia and Critical Care.

In collaboration with local partners, the program provides clinical training to University of Botswana

medical students, interns and residents as well as local medical officers, nurses and other healthcare staff. The program also promotes systems/process improvement through quality improvement and research. In addition, the program regularly provides opportunities for rotating U.S. residents and fellows to participate in clinical, educational, quality improvement and research efforts. The program began at Scottish Livingstone Hospital and the Kweneng East district, where Internal Medicine continues to focus their work. The Obstetrics & Gynaecology and Anaesthesia & Critical Care have since been transitioned to the University of Botswana to support the residency training program.

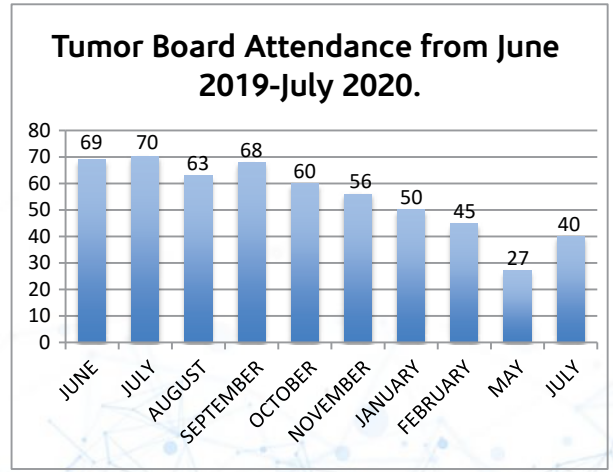


Medical Student Rotations at SLH Internal Medicine Department

3) Botswana Global Oncology Outreach (BOTSOGO)

BOTSOGO is a capacity-building initiative which continues to provide an opportunity for Botswana based health practitioners to engage with US based cancer experts using tele/video-conferencing technologies. Nine Tumor Board meetings were conducted in the past one year of which 8 were in person meetings and one virtual meeting in observance of COVID-19 protocols. In the wake of COVID-19, continuity of the meetings was compromised.

The graph below shows tumor board attendance in Gaborone from June 2019 to July 2020. May and July meetings were virtually attended meetings.





12. PUBLIC POLICY AND ADVOCACY

To demonstrate its commitment to producing high quality research that impacts policy and practice, BHP has presented about 34 abstracts at different international conferences and published 80 research papers in various scientific journals in this reporting period. Research results from BHP studies has had positive impact on informing health policies and treatment guidelines in Botswana and globally.

BHP continues to be a valuable research entity that shares its expertise in various local and international organisations. Apart from conducting research, BHP investigators continue to be active members of both international and several MOHW technical teams where they give expert advice on different health matters, including the current COVID-19 pandemic.

BHP staff and affiliated experts have been solicited to participate in the COVID-19 Presidential Task Force giving valuable advice on the control of the pandemic with Professor Mosepele Mosepele, a BHP Research Associate appointed Deputy Coordinator of the Task Force and The BHP Laboratory Director, Dr Sikhulile Moyo appointed Co-Chief Scientific Officer advising on laboratory scientific and testing strategy.

Below are some of the technical committees/ organizations where BHP staff is involved.

1. Presidential Task Force on COVID-19.
2. Cryptococcal Group (CryptoMAG)
3. African Meningitis Trials Network (AMNET)
4. Scientific Advisory Board for the African Cohort Study (AFRICOS)- Henry M Jackson foundation for US Military HIV Research Program/Water Reed Army Institute for Research
5. Board for Biomedical Research Training Institute, Zimbabwe,
6. University of Botswana IRB
7. HPTN Community Group Steering Committee – Executive Committee of the CWG
8. HPTN075 Protocol Team
9. HPTN Ethics Working Group
10. HIV/AIDS Network Coordination (HANC)
11. ACTG Performance Evaluation Committee
12. TB/HIV Surveillance (NAHPA)
13. Strategic Information Working Group, Estimates and Projections
14. National Working Group on Laboratory Reference Ranges
15. National HIV Treatment Guidelines Committee

BHP continues to raise awareness on HIV related issues and showcase its work through various community events such as World AIDS Day commemorations, radio and television broadcasts, and presentations at the Journal Club and local health facilities.



Journal Club Session



13. OPERATIONAL EXCELLENCE

i) Human Resources

The Human Resource Department plays an important role in strategic planning and company growth through various initiatives geared towards coordination of employees to achieve specific business objectives, fulfil staffing needs, ensuring staff welfare and the attraction and retention of personnel. The following were HR activities recorded for the period 1st July 2019 to 30th June 2020.

Staff Complement Trend per Month from July 2019 to June 2020

As at June 2020 (year-end), the staff complement at BHP was 218. The graph below indicates the number of staff per month for the period under review. As per the table below, the staff compliment reduced significantly from the month of April and this is attributed to the retrenchment exercise undertaken within CTU.

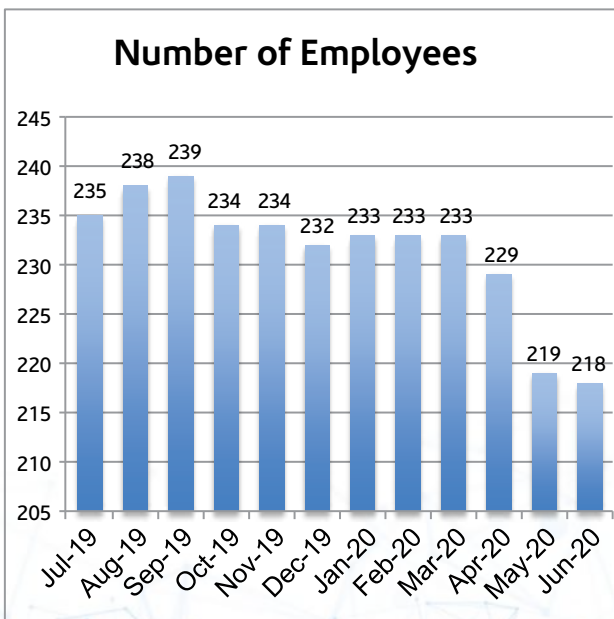


Fig 1: Staff Compliment trend per month

Nationality Distribution

Botswana Harvard Partnership comprises of diverse nationalities as per the table below;

Nationality	Number
Motswana	206
Zimbabwean	6
Malawian	1
Nigerian	2
Zambian	2
Swati	1

As the table above indicates, BHP has the highest number of citizens making a total of 206 employees out of 218 staff members. Non-citizens hold positions with scarce skills among locals. These were distributed in the positions as per below;

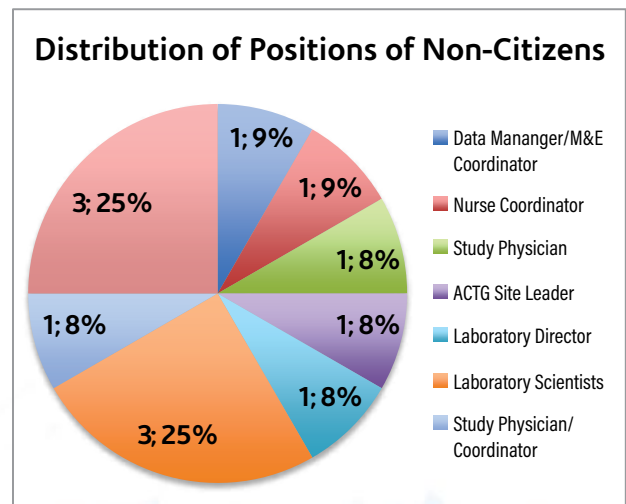


Fig 2: Distribution of positions of Non-citizens

Staff Contracts

Consistent with Botswana Harvard Partnership Funding, all staff is employed on a fixed term contract basis. Lengths of Contracts are contingent on the length of grant award ranging from six months for small scale projects largely for Research Assistants, to a maximum of two-year contracts for Key Professional staff working on large scale strategic projects and those anchoring administrative and technical support for projects. As a retention strategy, most of critical staff is offered two-year contracts. As at June 2020, the distribution was as follows; out of 218 members of staff, 12 were on a two-year contract, 189 on one year and 17 were on less than a year contract.

Staff Turnover

BHP recorded 51 separations during the reporting period. Most of the separations, 45.1 percent, were due to end of contracts, 31.4 percent were resignations, while 23.5 percent were due to retrenchment.

The chart below depicts separations between professional and non-professional staff for the period under review. The resignations, 69% of whom were professionals, were mainly because the employees pursued opportunities elsewhere which offered better packages.

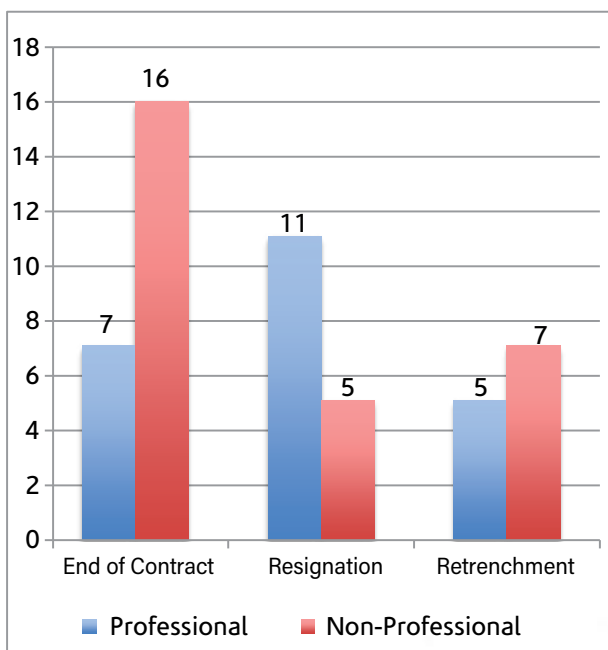


Fig 3: Separation between Professional and Non-Professional staff

Industrial Relations

There are two cases that have been referred for mediation at the Labour Office involving former employees.

Training and Development

Consistent with its mission for capacity building, training remains a key strategic mandate of the institution. Significant resources are invested in training and developing its employees' capacity to deliver and meet its strategic objectives for clinical and laboratory research while also strengthening clinical research capacity in Botswana.

The Training is in two broad categories: a) Aligned with Protocol and Study requirements, b) Professional Academic and Self-development. The latter includes 14 candidates undertaking studies at MSc, MPhil, PhD and Post-Doctorate levels.

For the period under review, one employee attained her Master's degree and two have successfully submitted their dissertations (MPhil & PhD) waiting to defend them.

For this reporting period, the below mandatory/ compliance trainings, Protocol specific meetings and conferences were attended by various employees locally, regionally and internationally to increase productivity and effectiveness.



Next-Generation Sequencing (NGS) Training

Accreditation

A strategic objective for BHP as a Research and Training institute is to accredit some of its programmes and Researchers as trainers. This has unfortunately not been achieved in this reporting period.

On- going Projects/Activities

a) **HR policies** – The department is currently reviewing all HR Policies and Procedures. This is to align the policies with the regulatory obligations, as well as aligning it with ever evolving labour laws and best practices. Below is a list of current policies and procedures and the three that have been presented to the Policy Review Committee.

List of Current Policies and Procedures

1. Benefits and Allowances
2. Grievance Procedure
3. Management of HR Records
4. Disciplinary Policy and Procedure
5. Recruitment Procedure
6. PMS Policy
7. Leave Policy
8. Onboarding & Probationary Policy
9. Training and Development Policy
10. Code of Conduct
11. Corporate Social responsibility
12. Disability policy
13. Salary Advance guidelines
14. Infectious Disease Policy

Policies and Procedures reviewed by the Committee

1. Grievance Procedure
2. Benefits and Allowances Policy
3. Overtime policy

b) **Employee Self-Service;** This has been implemented to enhance efficiencies and to provide opportunity for all employees to be able to process basic transactions by themselves that would otherwise prove time constraining if administered by HR Department manually. The system package includes Personal Information and Leave Management. Since its inception, however vendor support has been insufficient with the main Vendor having relocated to RSA. This has led to the system not being fully functional, and BHP is currently sorting a local agent to support the system.

Botswana Harvard Partnership is in the process of more effectively aligning its Performance Management System with its corporate Strategy, through the adoption the Balanced Score Card methodology. Timelines for these activities are yet to be determined jointly with the consultant BHP engaged for the Balanced Score Card approach to ensure implementation.

- c) Amendment to Confidentiality Agreement
- d) Due to COVID 19 outbreak, Botswana Harvard Partnership has established COVID-19 Response Team the objective of which is to advice management on how to respond to the pandemic. COVID 19 Guidelines were also formulated (drawing from the national guidelines) to guide the executive how to manage the pandemic at organization level.

ii) Finance & Grants

BHP's finance and grants department is responsible for the financial management and grants administration of BHP's overall finances as well as its entire grant portfolio. This includes ensuring compliance to financial reporting standards, local statutes and internal policies, compliance to sponsor grant agreements, risk management and the undertaking Annual Financial and Generally Acceptable Government Auditing Standards audits.

A funding cascade by type of agreement for the past 5 years.

Since 2017, BHP has experienced a decline in both subcontract and prime awards in terms of total value of awards held by BHP. However, in terms of the actual number of grants held in BHP's overall portfolio, FY2020 has seen the largest number of both prime awards (19) and subcontracts (41), with a significant increase in the number of local PIs and early investigators. This reflects an uptake in local PI and early investigator research and although this has initially yielded small to medium sized grant awards, it is an indication of the success of BHP's mentorship program. BHP's pipeline of grant applications reflects the same growing commitment from local PIs and early investigators with a representation of 10 out of 22 pending grant applications (45%). In FY2020, BHP recorded 38 solicited projects and 7 unsolicited projects.

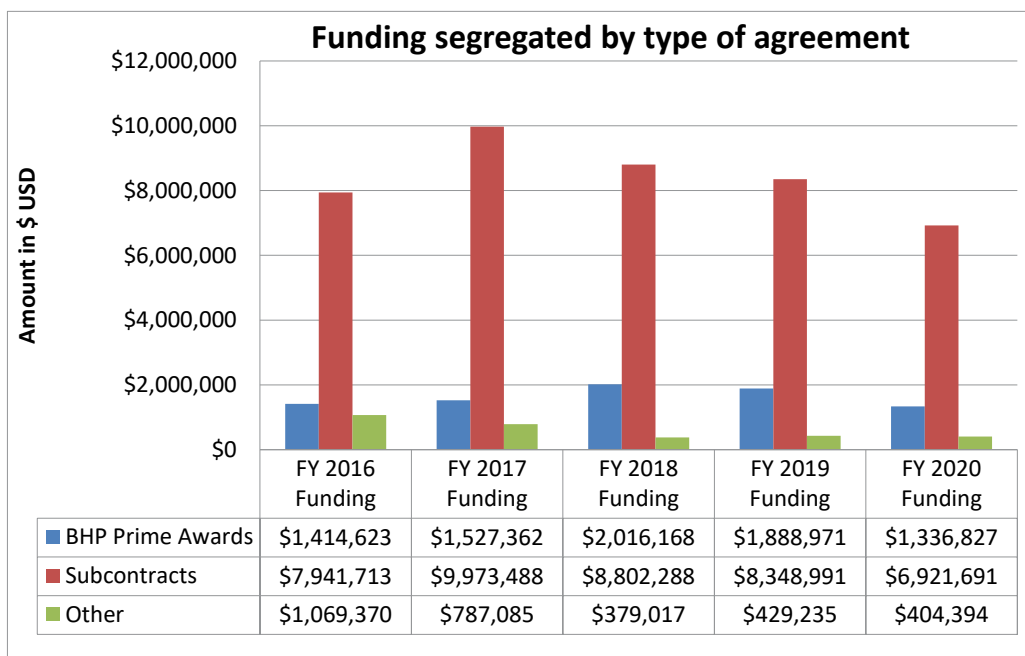
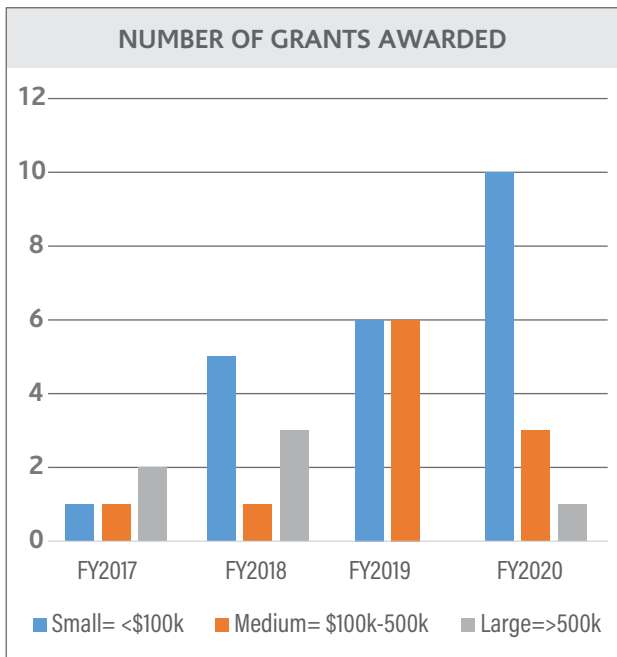


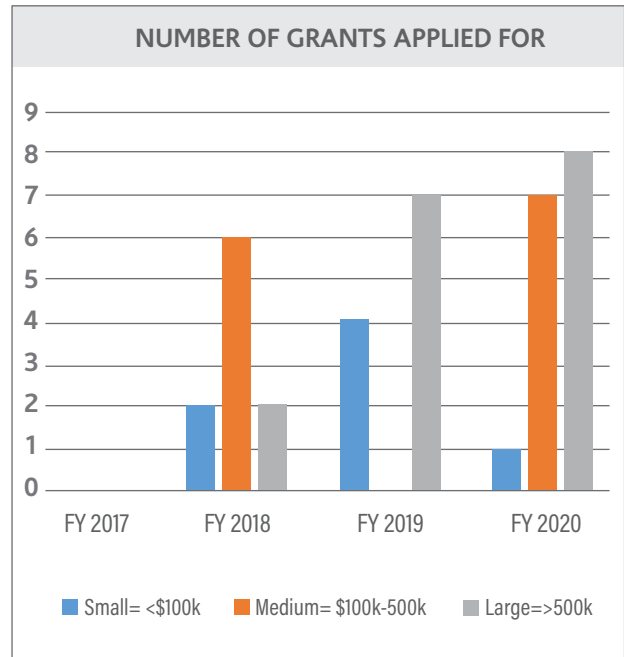
Fig 4: Funding segregated by type of agreement.

Number of Grants Awarded (Including unsolicited)



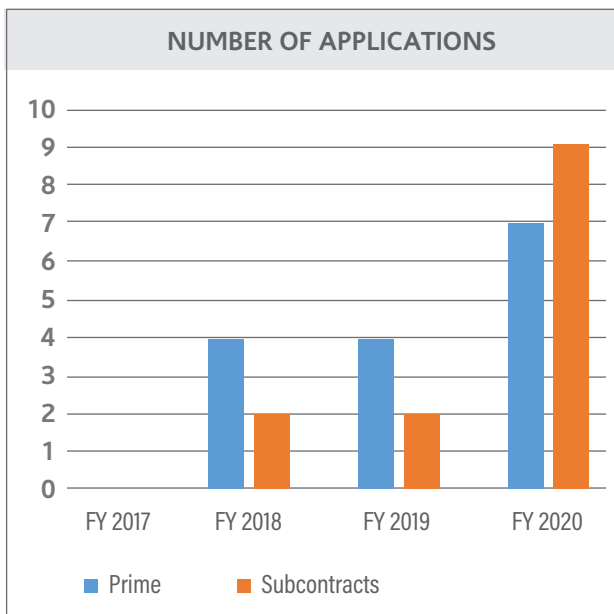
There were 12 grants awarded in the year 2019/2020 Vs a target of 15 grants.

Number of Grants applied for 2017 – 2020

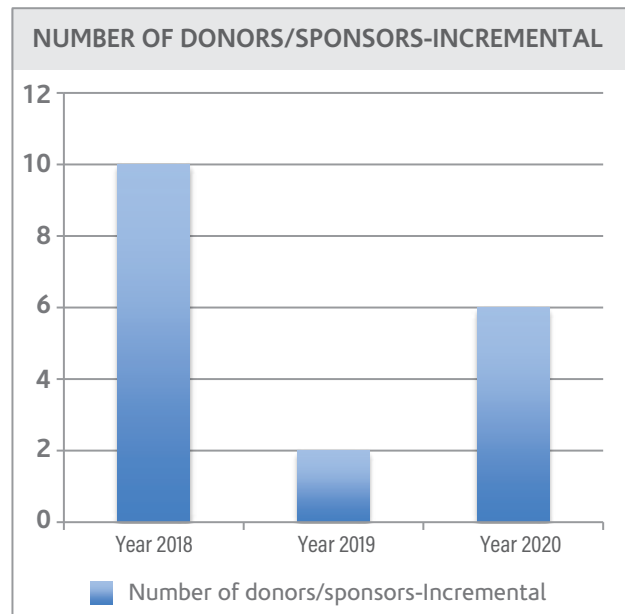


The 2020 grant application was targeted at 8 grants. 16 grants as indicated in table 'b' were applied for in 2020.

No of Applications Prime Vs Subcontracts



Number of Donors/Sponsors - Incremental

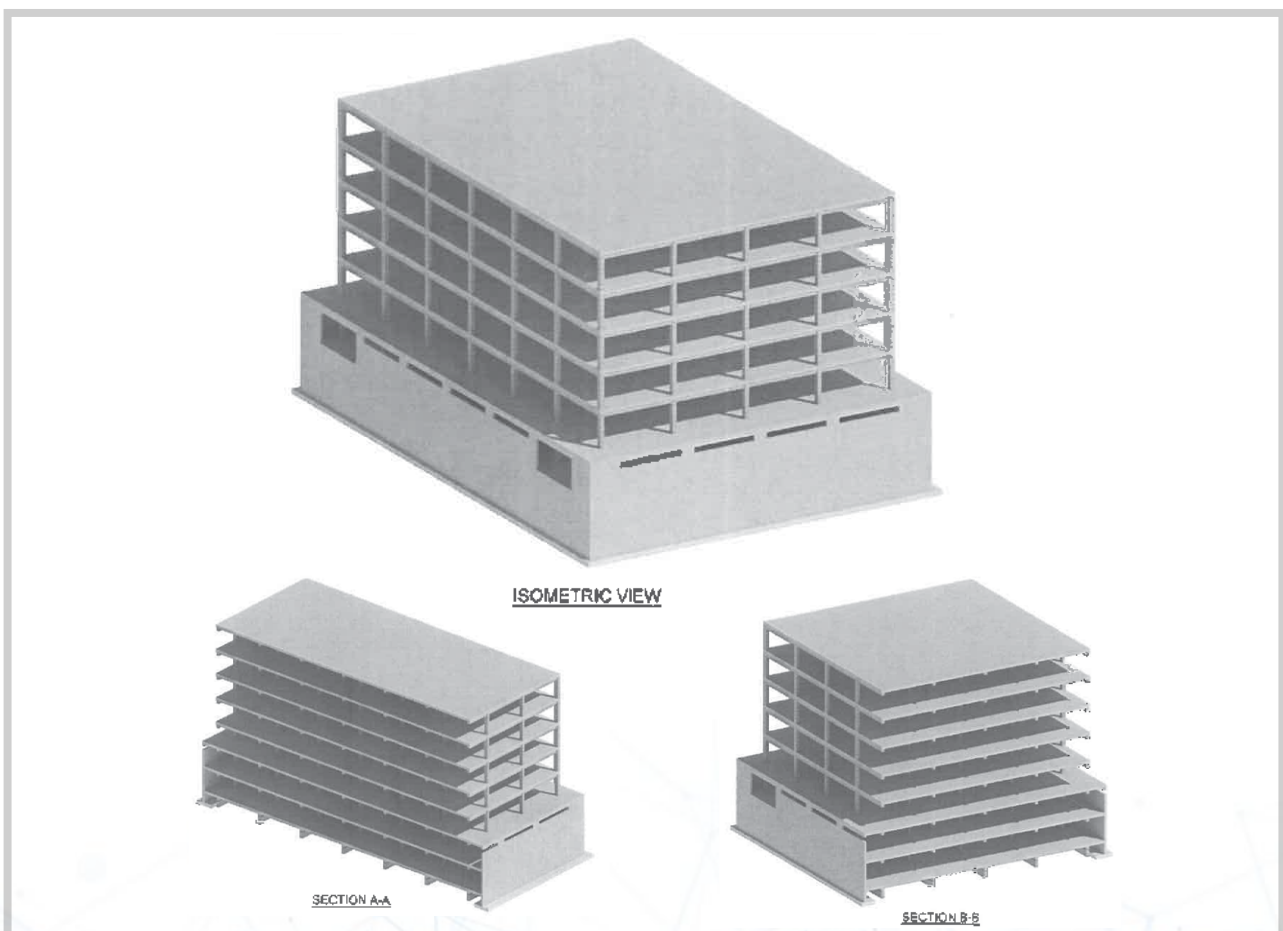


Of BHP's 50+ portfolio of grants, there were 18 different sponsors.



14. SUSTAINABILITY

The BHP Pharmacy as part of the BHP Business Enterprise under Sesikalla Investment (Pty) Ltd has been set up. Space modifications, Equipment and software purchase and installations, signage, licensing and registrations have been largely completed. The drug list has also been finalized. Final steps include licensing from BOMRA and registration with the medical aid providers. The launch is earmarked for the third week of August 2020. The overall implementation of Sesikalla Business Plan is at 75%.



Draft sketch plans for the envisaged Multipurpose BHP Building

ANNEXURE A: PUBLICATIONS AND ABSTRACTS

A) PUBLICATIONS

1. Kebaabetswe, P., K. Manyake, E. Kadima, C. Auletta-Young, U. Chakalisa, T. Sekoto, O. M. Dintwa, M. Mmalane, J. Makhema, R. Lebelonyane, P. Bachanas, R. Plank, T. Gaolathe, S. Lockman and M. P. Holme (2019). "Barriers and facilitators to linkage to care and ART initiation in the setting of high ART coverage in Botswana." *AIDS Care*: 1-7. Jul 2019.
2. Tawe, L., E. MacDuffie, M. Narasimhamurthy, Q. Wang, S. Gaseitsiwe, S. Moyo, I. Kasvosve, S. S. Shin, N. M. Zetola, G. M. Paganotti and S. Grover (2019). "Human papillomavirus genotypes in women with invasive cervical cancer with and without human immunodeficiency virus infection in Botswana." *Int J Cancer*. Jul 2019
3. Makhema, J., K. E. Wirth, M. Pretorius Holme, T. Gaolathe, M. Mmalane, E. Kadima, U. Chakalisa, K. Bennett, J. Leidner, K. Manyake, A. M. Mbikiwa, S. V. Simon, R. Letlhogile, K. Mukokomani, E. van Widenfelt, S. Moyo, R. Lebelonyane, M. G. Alwano, K. M. Powis, S. L. Dryden-Peterson, C. Kgathi, V. Novitsky, J. Moore, P. Bachanas, W. Abrams, L. Block, S. El-Halabi, T. Marukutira, L. A. Mills, C. Sexton, E. Raizes, S. Gaseitsiwe, H. Bussmann, L. Okui, O. John, R. L. Shapiro, S. Pals, H. Michael, M. Roland, V. DeGruttola, Q. Lei, R. Wang, E. Tchetgen Tchetgen, M. Essex and S. Lockman (2019). "Universal Testing, Expanded Treatment, and Incidence of HIV Infection in Botswana." *N Engl J Med* 381(3): 230-242. Jul 2019.
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5. Zash, R., L. Holmes, M. Diseko, D. L. Jacobson, S. Brummel, G. Mayondi, A. Isaacson, S. Davey, J. Mabuta, M. Mmalane, T. Gaolathe, M. Essex, S. Lockman, J. Makhema and R. L. Shapiro (2019). "Neural-Tube Defects and Antiretroviral Treatment Regimens in Botswana." *N Engl J Med* 381(9): 827-840. Aug 2019.
6. Nachman, S., C. L. Townsend, E. J. Abrams, M. Archary, E. Capparelli, P. Clayden, S. Lockman, P. Jean-Philippe, K. Mayer, M. Mirochnick, J. McKenzie-White, K. Struble, H. Watts and C. Flexner (2019). "Long-acting or extended-release antiretroviral products for HIV treatment and prevention in infants, children, adolescents, and pregnant and breastfeeding women: knowledge gaps and research priorities." *Lancet HIV* 6(8): e552-e558. Aug 2019.
7. Tenforde, M. W. and J. N. Jarvis (2019). "HIV-associated cryptococcal meningitis: ongoing challenges and new opportunities." *Lancet Infect Dis* 19(8): 793-794. Aug 2019.
8. Shava, E., S. Moyo, R. Zash, M. Diseko, E. N. Dintwa, L. Mupfumi, J. Mabuta, G. Mayondi, J. Y. Chen, S. Lockman, M. Mmalane, J. Makhema and R. Shapiro (2019). "Brief Report: High Rates of Adverse Birth Outcomes in HIV and Syphilis Coinfected Women in Botswana." *J Acquir Immune Defic Syndr* 81(5): e135-e140. Aug 2019.
9. Marukutira, T., L. Block, M. G. Alwano, S. Behel, J. N. Jarvis, U. Chakalisa, K. Powis, V. Novitsky, W. Bapati, H. Wang, F. Ussery, R. Lebelonyane, L. A. Mills, J. Moore and P. Bachanas (2019). "Comparison of knowledge of HIV status and treatment coverage between non-citizens and citizens: Botswana Combination Prevention Project (BCPP)." *PLoS One* 14(8): e0221629. Aug 2019.
10. Cassidy, A. R., P. L. Williams, J. Leidner, G. Mayondi, G. Ajibola, J. Makhema, P. A. Holding, K. M. Powis, O. Batlang, C. Petlo, R. Shapiro, B. Kammerer and S. Lockman (2019). "In Utero Efavirenz Exposure and Neurodevelopmental Outcomes in HIV-exposed Uninfected Children in Botswana." *Pediatr Infect Dis J* 38(8): 828-834. Aug 2019.
11. Dlamini, M. T., R. Lessells, T. Iketleng and T. de Oliveira (2019). "Whole genome sequencing for drug-resistant tuberculosis management in South Africa: What gaps would this address and what are the challenges to implementation?" *J Clin Tuberc Other Mycobact Dis* 16: 100115. Aug 2019.
12. Ramokolo, V., A. E. Goga, A. L. Slogrove and K. M. Powis (2019). "Unmasking the vulnerabilities of uninfected children exposed to HIV." *Bmj* 366: l4479. Aug 2019.
13. Caniglia, E. C., R. Zash, S. A. Swanson, K. E. Wirth, M. Diseko, G. Mayondi, S. Lockman, M. Mmalane, J. Makhema, S. Dryden-Peterson, K. Z. Kponee-Shovein, O. John, E. J. Murray and R. L. Shapiro (2019). "Methodological Challenges When Studying

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B) ABSTRACTS

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3. Ross M, Klinger A, Lewis B, Barak T. Assessment of healthcare provider knowledge and perceived competence regarding VTE prophylaxis at a district hospital in Botswana. Poster presented at: Institute of Quality Improvement in Healthcare Conference, Cape Town, 2019.
4. Klinger A, Malenfant J, Mpapho B, Barak T. A low-tech intervention to improve the documentation of missed medication doses among hospitalized patients at a district hospital in Botswana. Poster presented at: Institute of Quality Improvement in Healthcare Conference, Cape Town, 2019.
5. Klinger A, Ross M, Lewis B, Barak T. Assessment of healthcare provider knowledge, perceived competence and practices regarding appropriate use of urinary catheters at a district hospital in Botswana. Poster presented at: Institute of Quality Improvement in Healthcare Conference, Cape Town, 2019.
6. Lewis B, Radimpe D, Letshwiti F, Palai D, Barak T. Suicidal desperation in rural Botswana: a retrospective review of patients admitted to Scottish Livingstone Hospital following a suicide attempt. Poster presented at: Sustaining the Global Struggle for Health Equity Locally: Building Across Difference. 4th Annual Conference of the Social Medicine Consortium, Chiapas, Mexico; 2019.
7. Painter H, Erlinger A, Simon B, Morroni C, Ramogola-Masire D, Luckett R. Impact of cervicitis on performance of primary high-risk HPV testing followed by visual evaluation in women living with HIV. Oral presentation accepted for the International Papilloma Virus Conference, Barcelona, Spain, 2020. *Note: This presentation was postponed to an e-meeting July 20-24, 2020 due to a COVID-19 travel ban.*
8. Painter H, Kohler R, Li HJ, Simon B, Howett R, Morroni C, Ramogola-Masire D, Luckett R. Knowledge and beliefs about cervical cancer prevention among women living with HIV in Botswana. International Papilloma Virus Conference, Barcelona, Spain, 2020. *Note: This presentation was postponed to an e-meeting July 20-24, 2020 due to a COVID-19 travel ban.*
9. High-risk HPV persistence and incidence following one round of hrHPV-based screening and treatment in women living with HIV in Botswana. Luckett R, Painter H, Simon B, Erlinger A, Hacker M, Esselen K, Feldman S, Shapiro R, Morroni C, Ramogola-Masire D. International Papilloma Virus Conference, Barcelona, Spain, 2020. *Note: This presentation was postponed to an e-meeting July 20-24, 2020 due to a COVID-19 travel ban.*
10. Impact of cervicitis on performance of cervical cancer screening using HPV testing in women living with HIV. Painter H, Erlinger A, Simon B, Morroni C, Ramogola-Masire D, Luckett R. AORTIC Conference, Maputo, Mozambique, 2019.
11. Impact of cervicitis on performance of primary high-risk HPV testing followed by visual evaluation in women living with HIV. Painter H, Erlinger A, Simon B, Morroni C, Ramogola-Masire D, Luckett R. Oral presentation accepted for the International Papilloma Virus Conference, Barcelona, Spain, 2020. *Note: This presentation was postponed to an e-meeting July 20-24, 2020 due to a COVID-19 travel ban.*
12. Knowledge and beliefs about cervical cancer prevention among women living with HIV in Botswana. Painter H, Kohler R, Li HJ, Simon B, Howett R, Morroni C, Ramogola-Masire D, Luckett R. International Papilloma Virus Conference, Barcelona, Spain, 2020. *Note: This presentation was postponed to an e-meeting July 20-24, 2020 due to a COVID-19 travel ban.*
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14. Population-Level Viremia Predicts HIV Incidence Across Universal Test & Treat Studies. Maya L. Petersen, Joseph Larmarange, Kathleen Wirth, Timothy Skalland, Helen Ayles, Moses R. Kanya,

- Shahin Lockman, Collins C. Iwuji, François Dabis, Joseph Makhema, Diane V. Havlir, Sian Floyd, Richard J. Hayes. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
15. Maternal Biomarkers of Endothelial Dysfunction By HIV/Art Status And Birth Outcomes. Gaerolwe Masheto, Sikhulile Moyo, Terence Mohammed, Christina Banda, Charlene Raphaka, Mompoti O. Mmalane, Joseph Makhema, Roger L. Shapiro, Mosepele Mosepele, Rebecca Zash, Shahin Lockman. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 16. Changes in DTG Use Following The NTD Safety Signal in Botswana. Rebecca Zash, Chelsea Morroni, Gloria K. Mayondi, Modiegi D. Diseko, Judith Mabuta, Mompoti O. Mmalane, Joseph Makhema, Mimi Raesima, Tendani Gaolathe, Tumalano Sekoto, Shahin Lockman, Roger L. Shapiro. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 17. Sociodemographic Factors Associated With HIV Clustering Across Botswana Communities, Sikhulile Moyo, Kara Bennett, Simani Gaseitsiwe, Melissa Zahralban-Steele, Tapiwa Nkhisang, Jean Leidner, Dorcas Maruapula, Molly Pretorius Holme, Etienne Kadima, Tendani Gaolathe, Kathleen Wirth, Joseph Makhema, Max Essex, Shahin Lockman, Vlad Novitsky. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 18. Dolutegravir Use Is Associated With Higher Postpartum Weight Compared To Efavirenz. Jennifer Jao, Shan Sun, Justine Legbedze, Denise Jacobson, Keolebogile N. Mmasa, Samuel W. Kgole, Gosego Masasa, Joseph Makhema, Sikhulile Moyo, Mompoti O. Mmalane, Francis Banda, Bornaparte Nkomo, Mariana Gerschenson, Elaine J. Abrams, Kathleen M. Powis. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 19. Distinct Cord C-Peptide, Adipokine, And Lipidomic Signatures By In Utero HIV Exposure. Jennifer Jao¹, Lauren Balmert¹, Shan Sun², Thomas Kraus³, Brian Kirmse⁴, Mitchell Geffner⁵, Yunping Qiu⁶, Stephen M. Arpadi⁷, Elaine J. Abrams⁸, Derek LeRoith³, Rhoda Sperling³, Irwin J. Kurland. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 20. Maternal And Cord Plasma Bioactive Eicosanoid Profiles Differ In HIV+ And HIV- Women. Kayode Balogun, Lauren Balmert, Jennifer Jao, Shan Sun, Richard Bazinet, Lena Serghides. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 21. Serostatus Is A Marker For Sustained Viral Suppression In Early Treated Children. Gbolahan Ajibola, Pilar Garcia Broncano, Kenneth Maswabi, Kara Bennett, Michael D. Hughes, Sikhulile Moyo, Terence Mohammed, Patrick Jean-Philippe, Maureen Sakoi-Mosetlhi, Oganne Batlang, Shahin Lockman, Joseph Makhema, Daniel R. Kuritzkes, Mathias Lichterfeld, Roger L. Shapiro. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 22. High HIV Incidence In Young Women In The Botswana Combination Prevention Project. Faith Ussery, Pamela J. Bachanas, Mary Grace Alwano, Refeletswe Lebelonyane, Lisa Block, Kathleen Wirth, Gene Ussery, Baraedi W. Sento, Tendani Gaolathe, Etienne Kadima, William Abrams, Shahin Lockman, Janet Moore. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 23. Safety And Pharmacokinetics Of Intravenous VRC01LS And 10-1074 IN Young Children. Edmund V. Capparelli, Gbolahan Ajibola, Kenneth Maswabi, Kara Bennett, Michael D. Hughes, Molly Pretorius Holme, Kelly Seaton, Adrian B. McDermott, Marina Caskey, Lucio Gama, Patrick Jean-Philippe, Joseph Makhema, Daniel R. Kuritzkes, Mathias Lichterfeld, Roger L. Shapiro. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 24. Hepatitis B Virus Mutations Associated With Hepatocellular Carcinoma In Botswana. Sethunya Gotulweng, Motswedi Anderson, Wonderful Choga, Kabo Baruti, Lynnette Bhebhe, Tshepiso Mbangiwa, Bonolo B. Phinius, Sikhulile Moyo, Theresa K. Sebunya, Richard G. Marlink, Max Essex, Rosemary Musonda, Jason T. Blackard, Simani Gaseitsiwe. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 25. Evaluating The Immy Semi-Quantitative CrAg LFA In HIV-Positive Patients In Botswana. Kwana Lechiile, Mark W. Tenforde, Thandi Milton, Amber Boose, Tshepo B. Leeme, Leabaneng Tawe, Charles Muthoga, Fredah Mulenga, Ikanyeng Rulaganyang, Julia Ngidi, Madisa Mine, Joseph N. Jarvis. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
 26. Staging Of HIV-1C Infection Among Patients On Art In Botswana Using Proviral DNA. Manon Ragonnet-Cronin, Tanya Golubchik, Sikhulile Moyo,



- Christophe Fraser, Max Essex, Vlad Novitsky, Erik Volz, for the PANGEA Consortium. Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020, Boston, USA.
27. Natasha O. Moraka, Sikhulile Moyo, Ditiro Setlhare, Mompoti Mogwele, Segomotso Maphorisa, Nametso Kelentse, Patrick Mokgethi, Julia Ngidi, Gert U. VanZyl, Simani Gaseitsiwe. Virologic Characteristics of Vertically Transmitted Hiv-1 Strains in Botswana And South Africa. Short Presentation. Epidemiology meets Phylogenetics, 9 - 13 September 2019, Durban, South Africa.
 28. Natasha O. Moraka, Sikhulile Moyo, Ditiro Setlhare, Mompoti Mogwele, Segomotso Maphorisa, Nametso Kelentse, Patrick Mokgethi, Julia Ngidi, Gert U. VanZyl, Simani Gaseitsiwe. Prevalence of HIV-1 Drug Resistance Mutations in Newly Diagnosed Infants in Botswana. Poster Presentation. Virology Africa 2020 (Conference) 10 – 14 February 2020, Cape Town, South Africa
 29. Natasha O. Moraka, Sikhulile Moyo, Maryanne Ibrahim, Gloria Mayondi, Jean Leidner, Kathleen Powis, Adam R. Cassidy, Betsy Kammerer, Paige Williams, Christiana Smith, Adriana Weinberg, Rosemary Musonda, Roger Shapiro Simani Gaseitsiwe, Shahin Lockman. Child HIV Exposure and CMV Seroprevalence in Botswana: No Associations with 24-Month Growth and Neurodevelopment. Poster Presentation. IDWeek 2019, 2 – 6 October, 2019, Washington DC, USA.
 30. Lucy Mupfumi, Sikhulile Moyo, Sanghyuk S Shin, Qiao Wang, Nicola Zetola, Kesaobaka Molebatsi, Judith Nnawa, Botshelo T Kgwaadira, Lesedi Bewlay, Tony Chebani, Thato Iketleng, Tuelo Mogashoa, Joseph Makhema, Rosemary M Musonda, Max Essex, Ishmael Kasvosve, Simani Gaseitsiwe. High incidence of tuberculosis in the first year of antiretroviral therapy in the Botswana National antiretroviral therapy programme between 2011 and 2015. SANTHE Annual General Meeting, 2-5 October 2019, Nairobi, Kenya.
 31. Lynnette Bhebhe, Sikhulile Moyo, Simani Gaseitsiwe, Molly Pretorius-Holme, Etienne K. Yankinda, Mompoti Mmalane, Tendani Gaolathe, Joseph Makhema, Kathleen E. Wirth, Shahin Lockman, Max Essex, Vlad Novitsky, Manon Ragonnet-Cronin. How to Enhance HIV-1 Testing Factors Associated with Undiagnosed Individuals in Botswana. Poster Presentation. Dynamics and Evolution of HIV and other Human Viruses, May 11-13, 2020. Virtual Conference.
 32. Nametso Kelentse, Sikhulile Moyo, Mompoti Mogwele, Kwana Lechiile, Natasha O. Moraka, Dorcas Maruapula, Kaelo K. Seatla, Lerato Esole, Kesaobaka Molebatsi, Tshepo B. Leeme, David S. Lawrence, Rosemary Musonda, Ishmael Kasvosve, Thomas S. Harrison, Joseph N. Jarvis, Simani Gaseitsiwe. HIV-1 Diversity in CSF and Plasma of Individuals with HIV and Cryptococcal Meningitis. Poster Presentation, Interest 2020. Windhoek, Namibia, conference scheduled for 1-4 December 2020.
 33. Nametso Kelentse, Sikhulile Moyo, Mompoti Mogwele, Kwana Lechiile, Natasha O. Moraka, Dorcas Maruapula, Kaelo K. Seatla, Lerato Esole, Kesaobaka Molebatsi, Tshepo B. Leeme, David S. Lawrence, Rosemary Musonda, Ishmael Kasvosve, Thomas S. Harrison, Joseph N. Jarvis, Simani Gaseitsiwe. HIV-1 Diversity in CSF and Plasma of Individuals with HIV and Cryptococcal Meningitis. Poster Presentation, Conference on Retroviruses and Opportunistic Infections. Boston, USA, 8-11 March 2020.
 34. N. Kelentse, S. Moyo, M. Mogwele, K. Lechiile, N.O. Moraka, D. Maruapula, K. Seatla, K. Molebatsi, T.B. Leeme, D. Lawrence, R. Musonda, I. Kasvosve, T. Harrison, J.N. Jarvis, S. Gaseitsiwe. Comparison of HIV-1 Viral Load and Drug Resistance Mutations between CSF and Plasma of Individuals with HIV and Cryptococcal Meningitis Co-infection in Botswana: Poster presentation, 17th European AIDS conference. Switzerland, 2019.
 35. N. Kelentse, S. Moyo, M. Mogwele, K. Lechiile, N.O. Moraka, D. Maruapula, K. Seatla, K. Molebatsi, T.B. Leeme, D. Lawrence, R. Musonda, I. Kasvosve, T. Harrison, J.N. Jarvis, S. Gaseitsiwe. Comparison of HIV-1 Viral Load and Drug Resistance Mutations between Cerebrospinal Fluid and Plasma in Patients with HIV and Cryptococcal Meningitis Co-infection in Botswana: Oral and poster presentation at 28th International workshop on HIV Drug resistance and treatment strategy, South Africa, 2019.



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