

BOTSWANA
HARVARD AIDS INSTITUTE

PARTNERSHIP

FOR HIV RESEARCH AND EDUCATION



2018/19

ANNUAL REPORT

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VISION

To Be A World Renowned Public Health Institute.

MISSION

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**

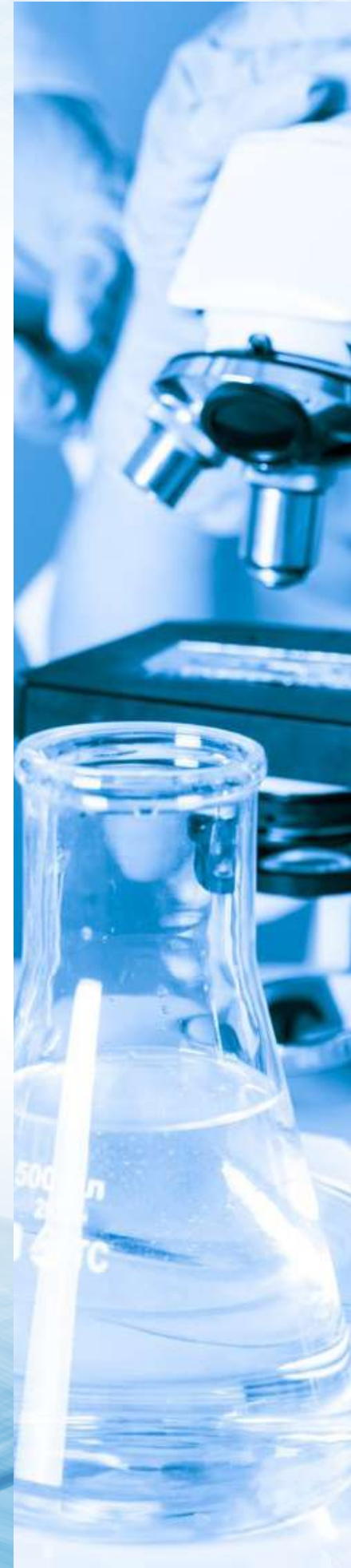
BHP recognizes that the fight against HIV /AIDS and other public health challenges will not be won by one individual or one institution. We commit and emphasize the importance of teamwork and collaborative research in our activities.

• **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 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: Armstrongs Attorneys, Notaries & Conveyancers

Main Bankers: Standard Chartered Bank & Stanbic Bank

3. GOVERNANCE

Board of Members



Prof. Michelle Williams

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



Dr Madisa Mine

Dr Madisa Mine - Consultant Virologist Botswana Harvard HIV Reference Laboratory (BHHRL) and Ministry of Health & Wellness (MOHW).



Dr Mark Elliot

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



Prof. Sheila Tlou

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



Prof. Eric Rubin

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. Michael Hughes

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

Board of Directors



Prof. Roger Shapiro

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



Ms Katie Hope

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



Dr Malaki Tshipayagae

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



Dr. George Matlho

Dr. George Matlho - General Manager, Botswana Vaccine Institute.



Mr Modise Modise

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



Dr Shahin Lockman

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



Joseph Makhema

Joseph Makhema- Chief Executive Officer BHP – Ex Officio.



Mrs. Ria Madison

Mrs. Ria Madison – Chief Operations Officer BHP - Ex Officio Member non-voting Director.

GOVERNANCE

Executive Management



Joseph Makhema, MB.,ChB, FRCP (UK)

Dr Makhema is an Internal Medicine Physician by training and is the CEO of the Botswana Harvard AIDS Institute Partnership (BHP), He oversee the research and training activities conducted at the BHP, including numerous US Government grants and various PI initiated research projects. He oversees and provides clinical mentorship for all Clinical Trials Unit trials affiliated to the ACTG, IMPAACT, and is Site PI for HPTN. He advises on the selection of the BHP clinical research portfolio. He has published and been involved in over 50 publications. He is particularly interested in community HIV prevention initiatives, translational policy issues, and health systems strengthening.



Mompoti Oganne Mmalane, MD, FRCS-Ed, MSc

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 Deputy 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

Ria Madison is Chief Operation's Officer of BHP, Providing overall oversight for Administration, Finance, Grants, Human Resources, and Operations. She is responsible for the oversight of all donor/grant funds, compliance of spending per donor requirements and meeting statutory and compliance audit. She also oversees the implementation and development of operating policies and strategic plan for Administration. Ms. Madison has been with BHP since its inception in 1999. She studied Accounts and Business Studies, Grants Management and Human Resource Management.

Senior Management



Sikhulile Moyo MSc, MPH, PhD

Sikhulile is a research associate and also oversees the design and implementation of the laboratory aspects of clinical trials conducted at BHP, as well as observational and surveillance studies. His is a former Harvard T.H Chan School of Public Health McGoldrick Fellow of Biostatistics. 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 120 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 and now serves as the Co-Vice chair. He participates in various international and local HIV technical working groups. Sikhulile was completed his NIH Global Health Post-doctoral fellowship with Harvard School of Public Health and BHP in 2017. He is a Site-Principal Investigator for some NIH funded projects, a Post-Doctoral fellow under Wellcome Trust funded DELTAS SANTHE program and is a supervisor/mentor for many fellows/researchers at BHP.



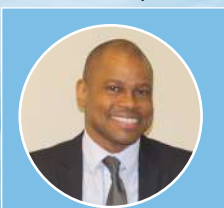
Simani Gaseitsiwe, BSc, PhD.

Simani Gaseitsiwe, is the Laboratory Director at Botswana Harvard AIDS Institute Partnership (BHP) and a Research Associate with the Harvard T. H. Chan School of Public Health. He is the Botswana Principal Investigator for the H3ABioNet and the SANTHE grants he also oversees the HIV genotyping component of the BCPP study. He has over 15 years of HIV research experience. He has broad interest in HIV research and associated co-infections, HBV, TB and HPV. He is responsible for overall supervision of the clinical laboratory, basic science research laboratory, and for guidance and mentorship of research fellows, scientists, and students. He has over 40 publications in per-reviewed journals.



Tendani Gaolathe, MD

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 currently is Project Director for BCPP.



Cornelius Gaetsalo

As Director of Finance and Grants, Gaetsaloe 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.

GOVERNANCE



Gaerolwe R. Masheto, MD



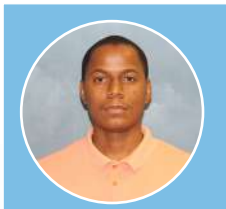
Ayotunde Omoz-Oarhe, MD



Coulson Kgathi, BSc



Dineo Tumagole, BAcc



Thuso Mokane



Tlhopho Kgotla

Dr. Masheto is a Clinical Research Site Leader for Botswana Harvard Partnership Clinical Trials Unit Gaborone site as well as the site Principal Investigator for IMPAACT Network Clinical Trials since 2015. He is a co-investigator for ACTG and HPTN Clinical trials. He is a Research Associate with Harvard T. H. Chan School of Public, Department of Immunology and Infectious Diseases. He joined Botswana Harvard AIDS Institute Partnership in 2011 as a Study Physician. Dr. Masheto graduated from Ross University School of Medicine with a medical degree (MD) in 2007. He graduated from Stellenbosch University in 2012 with postgraduate diploma in Family Medicine.

Dr Omoz-Oarhe has worked with Botswana Harvard AIDS Institute Partnership since 2010 where he has served in various capacities and gained a wealth of experience. He has over 15 years of clinical experience and a master's degree in public health (MPH) from the University of Liverpool. As a study physician/coordinator and now the ACTG principal investigator and Molepolole clinical research site leader at BHP, he has been at the forefront in the conduct and oversight of over numerous NIAID sponsored protocols covering the following public health topics: Tuberculosis, Oncology, Oral candidiasis, Contraceptive use and PMTCT. He has also served in various ACTG committees and has recently been elected into the Network Performance Evaluation Committee (PEC) .

Coulson Thabo Kgathi is a Software Engineering & Data Management Centre Manager at Botswana Harvard Partnership where he leads a group of software engineers and data managers. 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 aided in designing and implementing system that has contributed to the fundamental research data which contributes to policies in the ministry of health for the country. He has been able to assist 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.

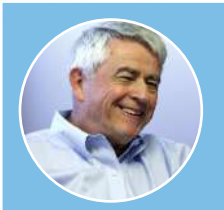
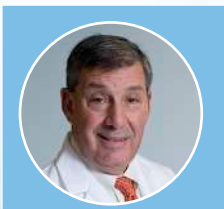
Dineo Tumagole is the Finance and Grants Manager at the BHP. Her role is to ensure effective management of BHP's funds through monitoring of Grant Budgets and compliance with sponsor regulations. She keeps tab of the internal control environment to ensure smooth Statutory and Yellow Book Audits. Dineo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

Thuso Mokane is a 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.

Tlhopho Kgotla is the Human Resources and Operations Manager for BHP. She joined BHP from Botswana Power Corporation (BPC) in June 2019 and she has 14 years experience in the Human Resources field from various organisations having served in different capacities. Ms Kgotla's role is to provide strategic and management leadership to effectively deliver HR services at BHP. She holds a Masters Degree in Human Resources Management (HRM) and a Bachelor of Behavioural Sciences both from Griffith University in Australia.

GOVERNANCE

Principal Investigators

**Roger L. Shapiro, MD, MPH****Max Essex, DVM, PhD****Rosemary Musonda, PhD****Shahin Lockman, MD, MPH****Kathleen M. Powis, MD, MPH, MBA****Bruce Chabner, MD****Jennifer Jao, MD, MPH**

Dr. 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, 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. M.

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.

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 in Botswana since 1996, including randomized trials of antiretroviral treatment among HIV-infected pregnant and postpartum women and of cotrimoxazole prophylaxis in HIV-exposed infants; observational studies of health and neurodevelopmental outcomes in HIV-exposed children, and community-based interventions to prevent HIV transmission. She helped establish and co-leads our BHP Clinical Trials Unit. She is also one of the co-PIs of BCPP. Dr. Lockman is quite involved in mentoring junior investigators in both Botswana and the US on a range of clinical research projects. Dr Lockman currently has a K24 mentoring grant.

Dr. Kate Powis is board certified in both Internal Medicine and Pediatrics and has held a medical license to practice in Botswana since 2008. Her primary research is focused on HIV and maternal-child health. She is currently the Principal Investigator of the “Gut microbiome evolution among HIV-exposed uninfected infants in Botswana” study, a study which explores how HIV and/or ART in-utero exposure of infants may compromise the development of the HIV exposed uninfected infant's immune system. Dr. Powis is also the Principal Investigator of the Bana Motswe study conducted in Molepolole, and a Co- Investigator of the Tshildio Dikotla study, investigating the longer-term metabolic impact of prophylactic exposure to either nevirapine or zidovudine.

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.

Dual certified in Internal Medicine and Pediatrics, 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 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 and Co-Chair of the Nutrition, Growth, and Metabolic Working Group in the Pediatric HIV/AIDS Cohort Study (PHACS).

GOVERNANCE



Scott Dryden-Peterson, MD, MSc (epi)



Vladimir Novitsky, M.D., Ph.D



Laura Bogart, PhD



Mosepele Mosepele, MD, MSc



Neo M. Tapela, MD, MPH



Jason A. Efstathiou, MD, DPhil



Joe Jarvis

Dr. Dryden-Peterson's research centers on epidemiology and therapeutic approach for HIV-associated malignancies in Botswana and other resource-limited settings. He directs one of the largest prospective cohorts of HIV-associated cancer. 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, role of HPV in the development of head and neck cancer in geographic regions heavily affected by HIV, and treatment outcomes of HIV-associated cancers in Botswana. He is co-founder of Botswana Oncology Global Outreach (BOTSOGO).

Vladimir Novitsky, M.D., Ph.D., 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, 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 conducted a community-based HIV testing intervention among fisherfolk, and is now conducting 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 disparities.

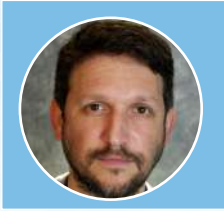
Prof. Mosepele Mosepele MD, MSc, Head of Internal Medicine at the University of Botswana, School of Medicine, is a Physician, Infectious Disease Consultant and Clinical Epidemiologist with experience in HIV clinical care and research focused on HIV-associated complications such as cardiovascular disease, immune dysregulation. Professor Mosepele is the Botswana site PI on Randomized Controlled Trial of Prevention of Vascular Events in HIV (REPRIEVE) at BHP and also Co- PI on another pilot study with Laura Bogart PhD focused on social network-level factors associated with viral suppression among HIV-infected patients at a Gaborone HIV Clinic also being conducted at BHP.

Dr Tapela is an internal medicine physician, epidemiologist (Harvard Medical School '06, Harvard School of Public Health '10) and global health activist interested in understanding the determinants of chronic non communicable diseases (NCDs) in sub Saharan Africa, and designing innovative equity-driven interventions to deliver care for these conditions particularly to rural poor/in resource-limited settings. Her research, including several NIH-funded projects, is informed by multi-disciplinary, hands-on experience in the public, non-profit, and academic sectors. She has served as special advisor on NCDs to the Rwanda Ministry of Health, as Director of NCDs Program with Partners In Health where she coordinated establishment of Butaro Cancer Center of Excellence, and as Head of the National NCDs Program in Botswana providing technical inputs relevant to NCDs for the 11th National Development Plan. Dr Tapela is a Research Associate at BHP, is currently a Senior Research Fellow at the University of Oxford's Nuffield Department of Population Health (Oxford, UK), and maintains appointment as Associate Physician at Brigham and Women's Hospital (Boston, USA). Her work as a global health innovator has been recognized in her selection as an Aspen New Voices Fellow and an African Cancer Leaders Institute Awardee.

Dr Efstathiou serves as Associate Professor of Radiation Oncology at Harvard Medical School and the Massachusetts General Hospital (MGH). 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).

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.

GOVERNANCE



Tomer Barak MD, MSc TMIH, DTM&H

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) he helps 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.



Ava Avalos, MD

Dr. Ava Avalos 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, a research associate of the Botswana Harvard AIDS Institute Initiative, and serves as vice-chair on the board of the International Treatment Preparedness Coalition (ITPC).



Chelsea Moroni

Chelsea Moroni is an epidemiologist and medical doctor with over 20 years of experience in Southern Africa. She has a undergraduate degree from Harvard, an MPH and medical degree from University of Cape Town, and a PhD from Columbia University. She has lived with her family in Botswana for 6 years. She conducts mixed-methods research and provides clinical care relating to women's and girl's sexual and reproductive health (SRH), particularly prevention of unintended pregnancy and HIV/STIs. Chelsea is an honorary research associate at the Botswana-Harvard AIDS Institute, the lead consultant for SRH at the Botswana UPenn Partnership, a Reader in International SRH at the Liverpool School of Tropical Medicine, and an honorary Professor in Women's Health at University of Cape Town.



Lisa Butler

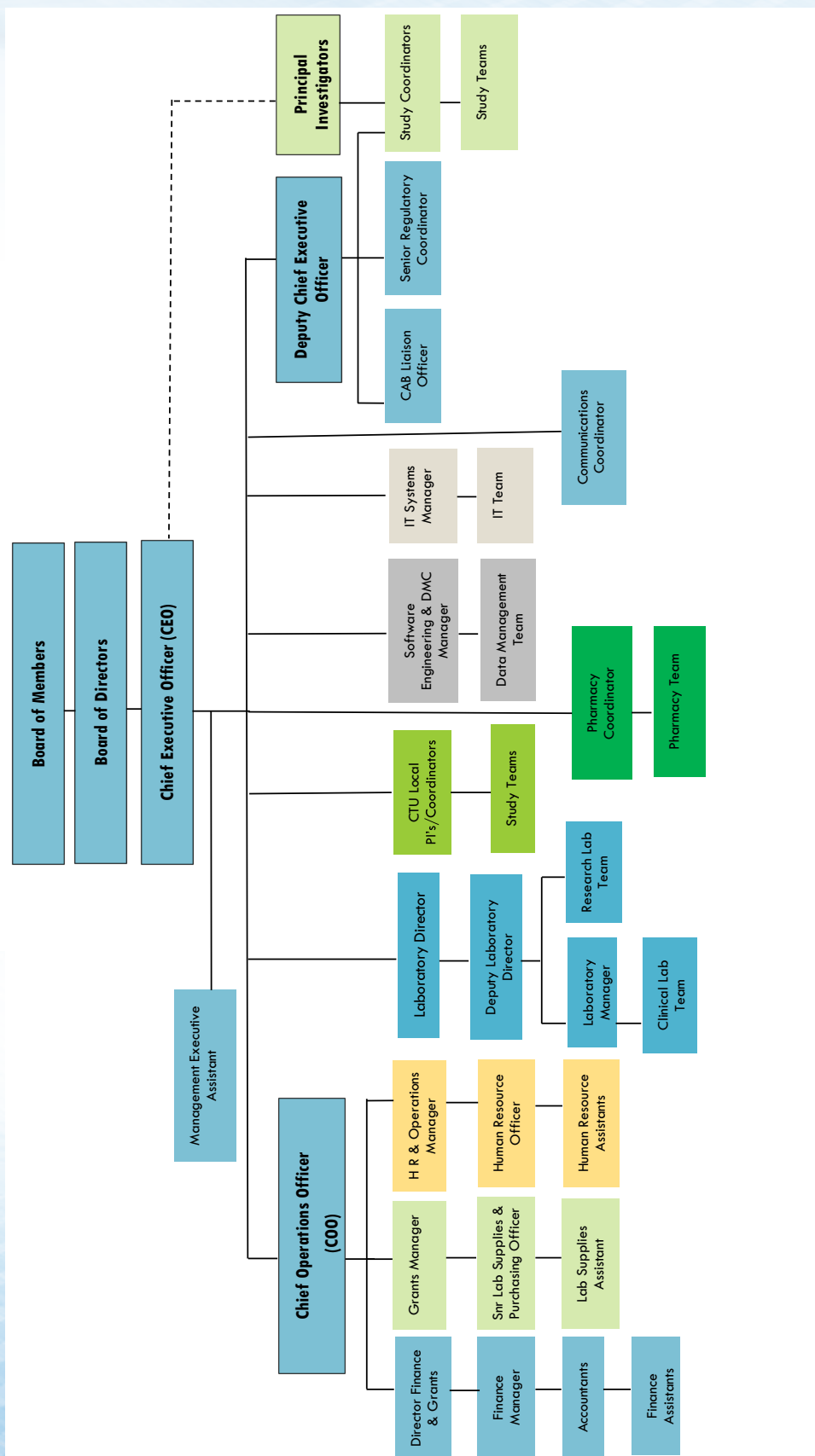
Dr. Lisa Butler is a behavioral scientist and epidemiologist with methodologic expertise in the development and evaluation of community-based interventions to improve health and mental health outcomes for vulnerable and low-literacy populations in sub-Saharan Africa (sSA), particularly in high HIV prevalence 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



Rebecca Zash

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. 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 a study to understand why HIV-infected women on ART have an increased risk of adverse birth outcomes. She also helps to lead a large birth outcomes surveillance study, Tsepamo, which examines the comparative safety of antiretroviral treatments in pregnancy.

4. ORGANISATIONAL STRUCTURE

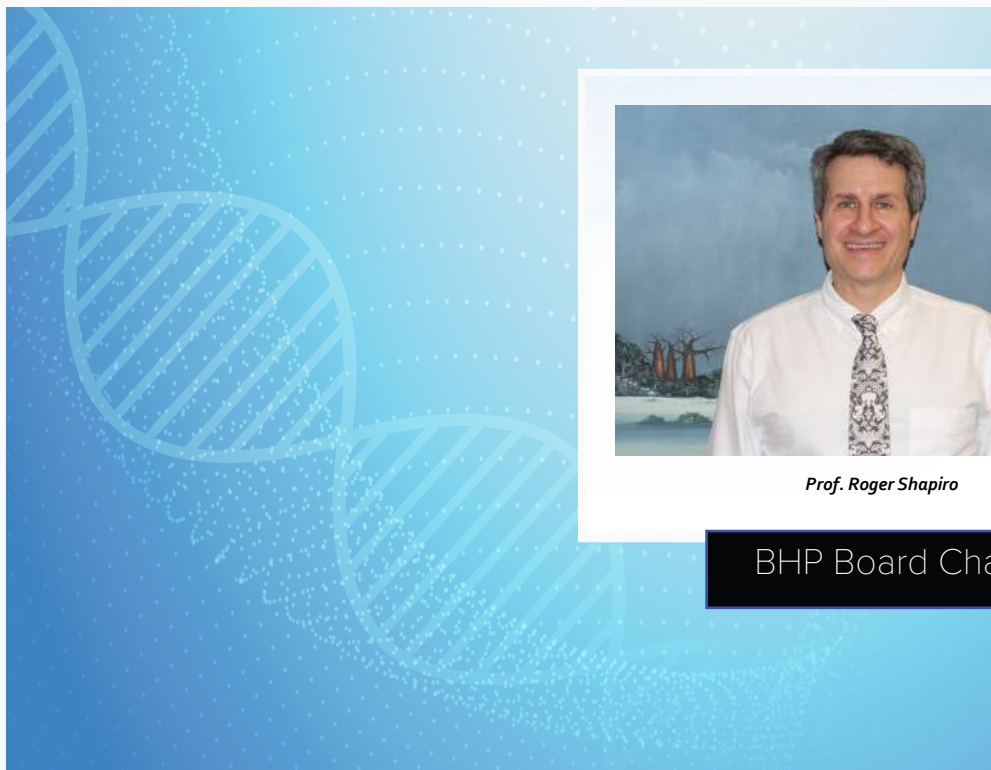


5. ACRONYMS

ACTG -	AIDS Clinical Trials Group
AIDS -	Acquired Immuno-Deficiency Syndrome
AORTIC:	African Organization of Research and Training in Cancer
AMNET -	Ambition Meningitis Network
ART -	Antiretroviral Therapy
BCPP -	Botswana Combination Prevention Project
BHHRL -	Botswana Harvard HIV Reference Laboratory
BHP -	Botswana Harvard AIDS Institute Partnership
BIDMC -	Beth Israel Deaconess Medical Center
bNAbs -	Broadly Neutralizing Antibodies
BOTSOGO -	Botswana Oncology Global Outreach
BPCC -	Botswana Prospective Cancer Cohort
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 Microholography
CFAR -	Centers for AIDS Research
CHB -	Chronic Hepatitis B
CROI -	Conference on Retroviruses and Opportunistic Infections
CTU -	Clinical Trials Unit
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
FSW -	Female Sex Workers
GCP -	Good Clinical Practice
HAART -	Highly Active Anti-Retroviral Treatment
HAI -	Harvard AIDS Initiative
HANC-	HIV/AIDS Network Coordination
HBV -	Hepatitis B Virus
HBeAg -	Hepatitis Be Antigen
HBsAg -	Hepatitis Bs Antigen
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
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
MDR-TB	Multi-Drug Resistant TB
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
PCR -	Polymerase Chain Reaction
PhD -	Doctor of Philosophy
PI -	Principal Investigator
PK -	Pharmacokinetic
PMTCT -	Prevention of Mother to Child Transmission
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
USD -	United States Dollar
WHO –	World Health Organisation

6. FOREWORD BY BOARD CHAIRMAN



Prof. Roger Shapiro

BHP Board Chairman

It is my pleasure and honour to present to you the 2018/19 Annual report for the first time as Chairman of the Botswana Harvard AIDS Institute Partnership (BHP) Board of Directors, a position that I have assumed following the retirement of the founding Chairman, Professor Max Essex who retired in 2019 after diligently serving BHP for 22 years. I wish my predecessor well in his retirement and I also thank him for building the BHP and overseeing its establishment to the fully-fledged and globally recognized research institute that it is today.

BHP aims to be a leading research institute in Africa, and to remain resilient during times of financial and research uncertainty. This is epitomized by diversification of our research portfolio, which has increased over the years beyond HIV/AIDS to address other health challenges including Tuberculosis, Hepatitis, Malignancies, and various other Non Communicable Diseases. As we expand our portfolio, it is necessary that we also expand our training and capacity building initiatives to address critical skills shortages in Clinical and Laboratory research. Thus training opportunities for Masters, PhDs, and Post PhD fellowships through various capacity training opportunities from grants such as SANTHE, TESA, AMBITION, and FOGARTY will continue to be fostered.

To ensure that we stay relevant, we shall also continue review of our

strategies and keep up with the latest technology to advance our research output. This year the Department of Software Engineering and Data Management successfully implemented and deployed the Senaite Laboratory Information Management System (LIMS) for excellent performance and stability. This system is meant to improve on data integrity as it helps provide comprehensive research participant data management for the entire research cycle.

While there may have been some challenges, the past year has seen much research success. BHP investigators published 65 manuscripts in peer reviewed journals and over 40 abstracts were presented at different scientific conferences either as poster or oral presentations by BHP and BHP affiliated Investigators and Scholars. Several BHP-led studies were locally, regionally and globally impactful.

I commend our scientists and staff who are committed to our mandate to ensure that we remain true to our vision of being a world-renowned public health institute whose mission is to fight HIV/AIDS and emerging public health challenges through innovative research, education, and capacity building that impacts policy and practice.

With sincere gratitude,

Roger L Shapiro

7. CHIEF EXECUTIVE OFFICER'S REMARKS



Dr Joseph Makhema

BHP Chief Executive Officer

BHP remains resolute in fighting against HIV/AIDS and emerging public health challenges through innovative research, education and capacity building that impacts on policy and practice. During the period under review, BHP had 10 active Principal Investigator (PI) initiated research projects and nine (9) active Network Clinical trials as well as publishing 65 manuscripts in peer-review journals.

We continue strengthening our systems and operational efficiencies in order to keep influencing national and global health policies. Based on recent findings from the Tsepamo Study on the use of DTG in pregnant women, World Health Organization (WHO) updated its recommendations on antiretroviral therapy and Dolutegravir (DTG) use for women, declaring it safe for use as first line treatment.

Our HIV Reference Laboratory was as of June 19, 2019 accredited by the Southern African Development Community Accreditation Services (SADCAS) with ISO 15189 standard after a rigorous assessment process that began in 2018. This achievement is a significant milestone in BHP's continued strengthening of its systems and confirms the immense capabilities and competence of its staff to meet the challenge of delivery of high quality laboratory services for both clinical trials and routine medical care for participants and patients.

Although faced with decline in research funding, BHP is currently managing at least 45 grants from 12 different sponsors. While some Prime awards have declined since 2014 due to loss of some BHP's PEPFAR programs this has been compensated by increasingly widening the source of research support beyond USA grant funding entities with an increase in funding from European

entities including the Wellcome Trust and EDCTP. Financial systems remain robust and both financial and compliance (GAGAS) audits have remained unqualified. During the financial year 2018/19 there was a decline in the BHP's liquidity ratio with the current liquidity ratio for 2019 sitting at 0.76 largely due to the winding down of the BCPP grant and the cyclical nature of grants versus expenditure. However BHP remains stable due to prudent financial management and cost saving initiatives across all the departments.

To meet its obligation of growing innovative research capability that impacts policy and practice of knowledge-based economy, BHP continues to review its systems in an effort to strengthen and align all its efforts with its strategic plan. In June 2019, BHP appointed a Human Resources and Operations Manager to provide strategic and management leadership to effectively deliver HR services.

A BHP Business Enterprise incorporated as Sesikalla Investments to diversify the BHP revenue streams towards long-term viability and sustainability of the BHP and its research is also at an advanced stage. It is aimed at generating additional and alternative revenue funds for BHP to augment its funding for capacity building and research.

Lastly, I would like to thank the BHP Board of Directors, for their support and wise guidance throughout the year, BHP investigators, Research Associates, Scientists, Staff and Collaborators for their contributions towards the attainment of the BHP mandate of scientific knowledge generation during this period and future endeavours.

A handwritten signature in black ink, appearing to read 'J. Makhema', written over a light blue background.

8. EXECUTIVE SUMMARY

The Botswana Harvard AIDS Institute Partnership (BHP) continues to be the leading HIV/AIDS health research organization in Botswana. It continues to deliver impactful research outcomes in line with its mandate of being 'To fight HIV/AIDS and emerging public health challenges through innovative research, education, and capacity building that impacts policy and practice', guided by its strategic plan of 2017 – 2022. The BHP research portfolio has however progressively expanded to other public health challenges including Tuberculosis, Hepatitis, Cryptococcal meningitis, malignancies, and Non communicable diseases. The strategic plan has five strategic themes, namely:

- Research Excellence
- Capacity Building and Training
- Operational excellence
- Public Policy and Advocacy
- Sustainability

The above strategic themes are being driven by 18 strategic objectives on BHP's corporate Balanced Score Card (BSC), whose measures and targets for the reporting period, 2018-19, were used to gauge BHP's performance during this second year of the plan. The performance results of the reporting period show that BHP continues to grow consistent with the planned strategic direction, albeit the reduction in research funding, more especially in the some areas of HIV/AIDS has limited the full potential and aspirations. The performance results can be summarized as follows:

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BHP's investigators research continues to be informed by identified current and future predicted public health challenges for Botswana, region and globally. Major focus of current research includes, a) Prevention eg Long Acting Carbotegravir Injection, Pre-Exposure Prophylaxis (PrEP) and broadly neutralizing antibodies (bNAbs), b) HIV Treatment Outcomes and surveillance research eg birth outcomes following ART exposure especially post introduction of dolutegravir as standard of care in HIV treatment, and health outcomes of HIV Exposed Uninfected (HEU) children, c) HIV Cure research eg Early Infant Treatment and bNAbs, d) .New treatment modalities eg Ambisome (L-AmB) in cryptococcal meningitis, e) Epidemiology eg cancer epidemic and care in Botswana, f) laboratory research on tuberculosis, hepatitis, and ARV drug resistance

In the past year BHP surpassed its target of 15 peer-reviewed publications by achieving 65 publications. Of the 65 publications

41 were from Botswana based BHP staff with 27 of them having Botswana based staff as first, second, third and last author. Four publications were in high impact journals (Impact factor ≥ 10). Additionally, BHP research contributed to changes in the HIV treatment guidelines on the use of Dolutegravir in women of childbearing age.

In the reporting period, 42 abstracts were presented at national and international conferences by BHP investigators. An internationally impactful publication is from the Tsepamo study, which showed that the risk of adverse birth-outcomes from women who conceive whilst on dolutegravir (DTG) is 3 times higher than on other ARVs. This led to WHO releasing new guidelines, which recommend that despite this risk, DTG is still the best first-line drug to use weighing its effectiveness and tolerability against the small risk of developing neural tube defects.

CAPACITY BUILDING AND TRAINING

BHP continues to apply for funding for capacity building of upcoming future investigators from Botswana and internationally. Major projects that drive capacity building include the SANTHE, EDCTP, Forgaty, NIH grants, BOTSOGO, and the BIDMC projects. At postgraduate level BHP had 1 post-doctoral fellow, 6 PhD candidates, 9 Masters candidates and 3 research fellows.

OPERATIONAL EXCELLENCE

BHP has established itself as a leading research institute with experienced research teams, hence is able to attract unsolicited projects (2), and collaborative grants (though the set target of 19 in 2019 was not met (5/19)). The number of investigators applying for research associate status continues to grow. Currently this number stands at 6. On financial side the organization continues to achieve a positive balance sheet and unqualified financial and GAGAS audits. The laboratory is ISO 15189 accredited

PUBLIC POLICY AND ADVOCACY

Research results from studies conducted at BHP are presented and disseminated to both general and scientific communities nationally and internationally through conferences and publications in peer-reviewed journals, to allow policy makers to make research-based informed decisions. Major policy impacting finding during the reporting period has been on the use of DTG during pregnancy. Despite a small risk of increased neural tube defect for children born to mothers who have been on DTG from conception based on Tsepamo (and subsequent other equivalent studies) WHO has recommended that the benefits of using DTG against this risk, is of greater Public Health benefit and has recommended that this

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drug continue being used as first line drug of choice on persons on ARVs, even for women of childbearing potential.

The BCPP/Ya Tsie study also continues to influence policy on HIV Testing and Linkage to Care. HIV cascade coverage before and after the BCPP Universal Test and Treat community intervention showed that the population that knew their status increased from 84% to 93%, those that were diagnosed and on ART increased from 85% to 93% , and those virally suppressed on ART were 97% pre and post study resulting in overall cascade viral suppression of 88% which exceeded the 95-95-95 UNAIDS target of 86%. The overall population level viral suppression by sex was greater in women 72% at baseline increasing to 90%, while in men it increased from 66% baseline to 86%. Furthermore, the National Programme has extended HIV treatment services including ART for Non-Citizens.

The population viral coverage in youth remained lower than in older adults increasing from baseline of 43% to 76% amongst 16-24 years while it increased from 72% at baseline to 90% in those above 25 years old. The impact of the results was to advise the National HIV treatment programme to focus interventions for testing, linkage and retention in care on men, adolescents

and youth. Innovative strategies including self-testing are now being piloted among men.

Locally BHP has increased its community engagement activities to include targeted media engagement through initiatives like 'Media science café, as well as appearance in both print and electronic media. All these in a bid to educate the public on work done at BHP and on research in general.

SUSTAINABILITY

BHP continues to actively seek funding opportunities for long-term sustainability Infrastructure remains a major challenge for the organization as most of our research projects are still housed in government facilities. Grant funding has been on decline and the organization in its bid to foster future growth and sustainability, has embarked on developing diversification of funding by development of a new business model through which additional revenue stream would be created. A business enterprise called Sesikalla Investments (Pty) Ltd. has been registered and is at advanced stage of providing fee for specialized HIV/AIDS clinical services in a private clinic in Gaborone.

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 responding to the public health environment in Botswana by identifying emerging public health challenges that may be addressed through research and capacity building.

In this regard, BHP revised its strategic foundations in 2016 and amended its vision and mission statements, to encompass any other emerging public health challenge. The mission statement in the new (2017 – 2022) strategic plan reads: To fight HIV/AIDS and emerging public health challenges through innovative research, education, and capacity building that impacts policy and practice. Our aspiration is: to be a world-renowned public health institute. Additionally, BHP's research and capacity building projects portfolio has broadened to align with the new mission statement in the current strategic plan statement.

Current HIV prevention and treatment public health challenges facing Botswana and the world at large include;

- Unacceptably high HIV incidence, particularly among the youth and young adults.
- Elusive search for an effective vaccine against HIV infection
- Increasing population of people on lifelong anti-retroviral (ARV) drugs, the long-term effects of which remain undetermined.
- Development of HIV mutations and ARV drugs resistance.
- The fast-evolving discovery and introduction of new ARV molecules and combinations/regimen for HIV treatment with unknown long-term effects.
- Increasing ageing HIV infected population presenting with HIV related none communicable diseases such as malignancies and cardiovascular diseases and metabolic disorders that require treatment interventions that may give rise to drug-drug interactions, thus complicating anti-retroviral treatment (ART).

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- Growing population of HIV Exposed but Uninfected (HEU) children through PMTCT (children born to women who were HIV infected during pregnancy, and are exposed to HIV as well as ARVs taken by the mother during pregnancy, but are themselves not HIV infected).
- High prevalence of other diseases like malignancies, tuberculosis, human papilloma virus infections, hepatitis

virus infections, and rotavirus related diarrheal diseases.

- Limited local research expertise, research infrastructures, as well as funding for research.

This report will highlight how BHP has responded to these challenges during the 2018/19 reporting period, in alignment to its strategic objectives' performance targets of that year.

10. RESEARCH EXCELLENCE

The BHP research portfolio and performance has grown significantly over the years, including in the current reporting period. In 2018/19 the organization had over 30 active research projects. These research projects fall into 3 categories; Principal Investigator (PI) initiated clinical studies, Network studies conducted under the Clinical Trials Unit (CTU), and Laboratory-based basic sciences research projects. The projects covered, among others, research in the following areas:

- Prevention: i) HIV- long acting injectable ARV's and bNAbs ii) TB- multi-drug resistant tuberculosis (MDR-TB)
- Treatment: HIV, TB, Ambisome (L-AmB) in meningococcal meningitis, broadly neutralizing antibodies (bNAbs), long acting injectable ARVs, and pharmaco-kinetic studies on ARV drugs on adults, children, pregnant women, and anti-TB drugs.
- Drug-drug interactions and drug resistance in patients on ARVs.
- Drug surveillance for adverse events
- Epidemiological/surveillance studies on malignancies, birth and development, and metabolic outcomes of children born to infected and HIV uninfected mothers,
- Laboratory research on Hepatitis B (HBV), TB, and Human Papilloma Virus (HPV), and diagnostics in cancers and HIV.

The above study areas are all of great importance to Botswana and the scientific community at large. This report will include summary presentations of all the projects undertaken during the reporting period. However, 3 studies that have already impacted Botswana's health policies, or are likely to do so in the near future will be highlighted in the section below.

a. RESEARCH HIGHLIGHTS OF THE YEAR

1) Tsepamo Study on Birth Outcomes and Congenital Abnormalities

Tsepamo is a birth outcomes surveillance funded by the National Institutes of Health/National Institute of Child Health and Human Development (NIH/NICHHD). The study started in August 2014 at 8 maternity facilities in Botswana, covering approximately 45% of all births in the country. The primary aims of the study are: 1) to evaluate the impact of HIV infection and specific antiretroviral medications on birth outcomes and 2) to determine if there is an increased risk of neural tube defects among infants exposed to specific antiretroviral medications from the time of conception.

Tsepamo was powered to rule out a 2-fold increased neural tube defect risk with EFV exposures from conception.

In 2016, Botswana rolled out TDF/FTC/Dolutegravir [DTG] as first line ART, Tsepamo was thus able to collect data on the safety of TDF/FTC/DTG compared with TDF/FTC/EFV initiated during pregnancy. In May 2018 an interim analysis of Tsepamo data revealed a finding of 4 neural tube defects in 426 pregnancies with conception exposure to DTG (0.94%). This was significantly higher than for DTG initiated during pregnancy (0/2812, 0%), conception exposure to any non-DTG ART (44/11,300, 0.12%), conception exposure specifically to EFV (3/5787, 0.05%), or women without HIV (61/66,057, 0.09%). Due to relatively low numbers of exposures to DTG at conception, this was considered a preliminary safety signal that required further investigation and data..

After the initial signal was reported, Tsepamo increased the study sites from 8 to 18 and was able to cover 72% of all births in the country. Updated analysis, reported in July 2019, and found 1 additional NTD among 1275 additional exposures to DTG from

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conception, for a total of 5/1,683 preconception DTG exposures (0.30%). The prevalence of NTDs with DTG at conception remained statistically higher than all other comparator groups, but the absolute prevalence difference was small (0.20% to 0.27%). In the largest series to date, no concerns for NTDs associated with EFV have been identified.

Several studies have since published data on DTG-conception exposures following the initial Tsepamo report. To date there has been only 3 other studies outside of Tsepamo that had high-quality data, which included internal comparator groups, and ascertained neural tube defects among stillbirths. First; The Botswana MOH-CDC study which had findings consistent with Tsepamo (1 NTD among 152 DTG conception exposures, 0.66%). Second; The Antiretroviral Pregnancy registry, prospective surveillance also had consistent findings (1 NTD among 248 DTG conception exposures, 0.40%) while Third; The Brazil MOH study found 0 NTDs in 382 DTG-conception exposures. Basic science data showed no folate inhibition by DTG (Gilead) or only at high concentrations (ViiV, Baylor) as well as toxicity in zebrafish embryos exposed to high levels of DTG that was reversible with folate.

Policy Implications

With the additional data from 2018-2019, a persistent signal for NTDs with DTG-conception exposure exists, but the estimated size of the signal is much smaller than that in the May 2018 report. The absolute difference between DTG at conception and all other non-DTG ART at conception is 0.20%, meaning that 1 NTD per 1000 non-DTG exposures and 3 NTDs per 1000 DTG-conception exposures, or an additional 2 NTDs per 1000 births might be expected. This small risk needs to be weighed against the large benefits of DTG for public health — including increased population viral suppression and tolerability leading to the potential for improved maternal health and fewer sexual transmissions of HIV. This public health benefit becomes increasingly large if NNRTI resistance continues to grow in Botswana. This small risk of NTDs with DTG should also be viewed in the context of the significantly large risks (6.0%-12.0%) of other adverse birth outcomes of other ART's (specifically LPV-r and NVP) currently being used by many women in Botswana.

In response to the most recent Tsepamo data, the WHO has concluded that the risks of DTG are outweighed by its benefits in a public health approach to HIV treatment and have updated their most recent guidelines to a strong recommendation for DTG as first-line for all adults irrespective of pregnancy potential. Additionally, most PEPFAR countries are planning to expand DTG use, if not already being rolled out.

Based on this data Policy implications for Botswana are:

1. Recommend dolutegravir as the preferred ARV for all women who are already pregnant
2. Recommend dolutegravir as the preferred ARV for all women (and men) initiating ART
3. Recommend that all women on lopinavir-ritonavir and nevirapine be prioritized to switch to dolutegravir
4. Recommend that all HIV-infected women should be referred to Sexual Reproductive Health (SRH) facilities to access contraception, to better manage their reproductive health choices
5. Recommend folate supplementation for all HIV-infected women who start DTG, to improve population levels of pre-conception folate repletion

2) Potlako

Cancer prevalence and deaths are increasing worldwide, more so in the low and low middle income countries (LMIC). According to WHO, 50% of all cancers and approximately 72% of cancer deaths occur in LMIC, which includes Botswana. Globocan, in its 2018 report estimated the number of premature cancer related deaths at 343 635 per annum. Delays in diagnosis and initiation of cancer treatment are thus major contributors to these high premature deaths.

Potlako ("Hurry" in Setswana) is an NIH-funded prospective pilot study initiated in April 2016. It aims to evaluate a complex health system intervention for improving earlier diagnosis and treatment initiation of major cancers among residents in rural Kweneng-East district. The study collaborates with the 35 public health facilities in the district to deliver intervention components, which include a) supporting patients in navigating the health system by providing transport support and clinic appointment reminders, and b) supporting health system through better coordinated and algorithm-based referrals, bookings and follow up of pathology results.

Achievements during this period include:

- Continued participant enrollment and patient support: 151 patients were enrolled in the study. Forty-eight (31.8%) were HIV infected and 118 (78%) were female. During this time, 26 cancers were diagnosed; Cervical Cancer (30.8%), Breast Cancer (23.1%), Esophageal Cancer (7.69%), and

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- Other (38.5%).
- Analysis of the study data was completed in May 2018, reflecting that the intervention was effective in reducing time from symptom onset to treatment, and reducing stage at diagnosis (Figures 1 and 2). When compared with other cancer patients from other districts in the country, Potlako-supported patients started treatment 2.5 months earlier, and were more likely to be diagnosed with early/limited stage cancer.
- Application for further funding was submitted to NIH, which received a fundable score. If awarded, this grant would support rigorous evaluation of the Potlako intervention through a cluster randomized trial involving 20 communities (multiple districts).
- Dissemination of findings through presentations to Ministry of Health and Wellness and other stakeholders, in June 2019 (Figure 3). Development of a Policy Brief describing findings and recommendations is in progress; highlights of recommendations are outlined in Figure 4.
- Abstracts accepted to international conferences (listed below)
 - “Improved Time to Treatment and Cancer Stage with Provider Education and Cancer Navigation: Results from the controlled, non-randomized prospective Potlako pilot in rural Botswana” (oral), African Organization of Research and Training in Cancer 2019 (November), Mozambique
 - “Barriers to cancer evaluation follow-up: Reasons and predictors of missed visits in a rural population in Botswana” (e-poster), World Cancer Congress 2018, Malaysia

Figure 1: Effects of Potlako intervention on time to cancer treatment initiation.

Compared with analogous districts:

2.5 months earlier treatment

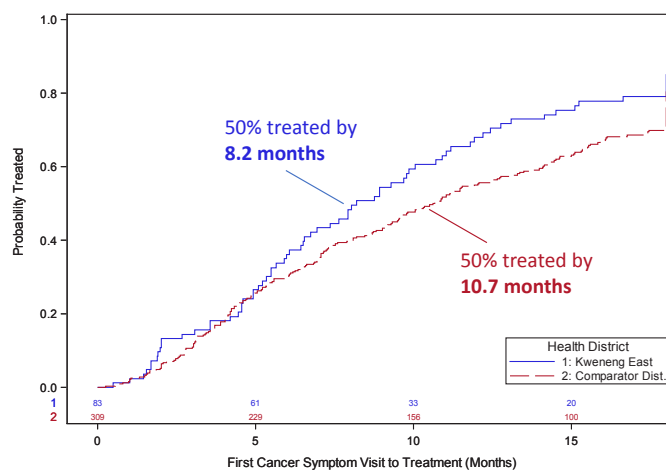
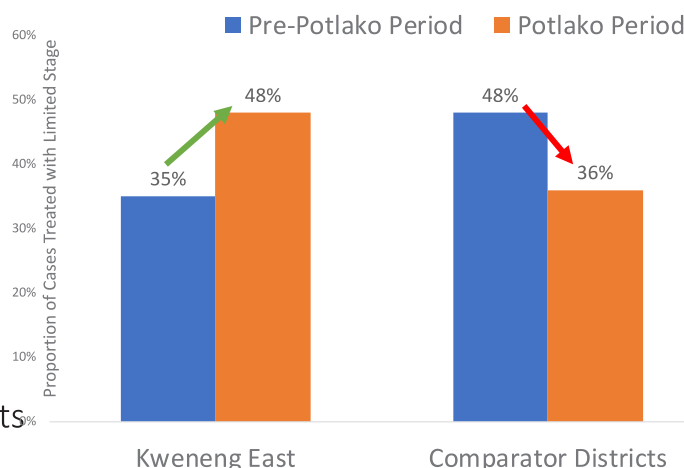


Figure 2: Effects of Potlako Intervention on stage at cancer diagnosis.

Compared with pre-Potlako and analogous districts:

Increase in % patients treated for limited stage (p=0.056)

Declining performance over time in other districts



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Meeting to disseminate Potlako Study findings to Kweneng-East District Health Management Team members in June 2019

Figure 3: Considerations for Policy and Practice from Potlako Study

Health System-Level

- Resource cancer early diagnosis **protocols and training**, as part of PHC guidelines
- In training, **target particular cancers** (e.g. esophageal, lymphoma) and targeted counseling for **males**
- Introduce “**chronic care coordinator**” role
- Include **standardized referral pathways** for cancer as part of cancer treatment guidelines that are being developed
- Include **biopsy turn-around-time** as performance indicator
- **Scheduling**: avoid Mondays/Fridays, institute defaulter tracing mechanisms

Patient/Population-Level

- Innovate around **social supports** needs (transport, childcare and work obligations)
- Institute **visit reminders** for patients
- Enhance **awareness**: target males, include messaging around religious in addition to traditional beliefs (similar to what was done in HIV campaigns)

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3) Hepatitis B Virus infection in pregnant women and 18 months old infants in Botswana

Hepatitis B Virus (HBV) chronically affects approximately 257 million people worldwide and is responsible for 887 000 deaths per annum. Despite wide availability of an efficacious HBV vaccine, vertical (in-utero, at delivery) and horizontal infections still occur. The majority of HBV infections acquired in early childhood lead to chronic hepatitis B virus (persistence of hepatitis B surface antigen (HBsAg) for more than 6 months). Routine screening for HBV is through detection of HBsAg. However, occult hepatitis B infections (HBsAg negative and HBV deoxyribonucleic acid (DNA) positive) are missed by this current standard approach. High HBV DNA levels and HBeAg positivity during pregnancy have been associated with higher transmission of HBV from the mother to the child during pregnancy. The study aimed to assess the prevalence of chronic and occult HBV infection in HIV-infected and -uninfected pregnant women in Botswana and also HBV DNA positivity in 18 months old infants.

The objectives of this study were to determine:

1. The prevalence of chronic and occult HBV infections (CHB and OBI) in pregnant women in Botswana;
2. HBV DNA positivity in 18 months old infants

Plasma samples from 752 pregnant women at delivery were tested for HBsAg and HBsAg-positive samples were then tested for hepatitis Be antigen (HBeAg). Maternal samples that were HBsAg negative were screened for occult hepatitis B infections. A total of 143 eighteen (18) months old infants were tested for HBV DNA levels.

Among the 752 (384 HIV positive and 368 HIV negative) women tested during pregnancy or early postpartum, 16 [(2.1%) (95% confidence interval (CI) 2.0–2.2)] were HBsAg-positive. The prevalence of Chronic Hepatitis B (CHB) infection was similar among HIV-infected [3.1% (95% CI: 3.0–3.2)] compared with HIV-uninfected women [1.1% (95% CI: 1.07–1.1, $p = 0.057$)]. However, there was no difference in occult HBV infection in HIV-negative women as compared to HIV-positive women (24 (7.4%) of 323 versus 17 (5.7%) of 299 women, respectively). Three of thirteen HBsAg-positive participants were HBeAg-positive had high HBV DNA levels ($>1.7 \times 10^8$ IU/ml) and all were HIV-negative. Of the 143 infants tested for HBV, 14 (9.8%) had detectable HBV DNA ($<2.0 \times 10^3$) IU/ml. There were two mother infant pairs with HBV infection, one infant was born to an occult infected mother while the other was born to a chronically infected mother who was HBeAg positive

and had very high HBV DNA levels ($>1.7 \times 10^8$ IU/ml).

Policy Implications

High HBV DNA level and HBeAg positivity in HIV negative pregnant women increases chances of mother to child transmissions and this was observed in HIV negative women. The presence of occult hepatitis B infections in Botswana might also lead to HBV transmissions through blood transfusion.

Recommendations:

- 1). Testing all pregnant women for HBsAg with further testing for HBeAg and HBV DNA levels in HBsAg positive women.
- 2). Use of antiretroviral therapy (TDF, 3TC containing regimens) as part of prevention of HBV mother to child transmissions in HIV negative HBsAg positive women.
- 3). Nucleic acid testing in blood transfusion based on the findings of the presence occult HBV infections (6.6%).

b. CLINICAL RESEARCH PROJECTS

BHP continues to provide quality research through its conduct of both network 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 Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) Networks.

NETWORK CLINICAL TRIALS**1) AIDS Clinical Trials Group (ACTG)**

The ACTG was established in 1987 and supports a large network of clinical and translational investigators and therapeutic clinical trials units in the world, including sites in resource-limited countries. Work by the ACTG has contributed significantly to optimizing ART, managing drug resistance, preventing and treating co-infections, evaluating acute and long-term toxicities, and demonstrating the importance of pharmacogenomics in predicting drug toxicities. The ACTG's mission is to cure HIV infection and reduce the burden of disease due to HIV infection and its complications, including TB and viral hepatitis.

Two ACTG trials were conducted at BHP during the reporting period.

i) PHOENIX (A5300B): Protecting of Households on Exposure to Newly Diagnosed Index MDR-TB patients.

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This is a Phase III, open-label, multicenter trial with a cluster-randomized superiority design (eligible contacts in the same HH are a cluster) to compare the efficacy and safety of 26 weeks of DLM versus 26 weeks of INH for preventing confirmed or probable active TB during 96 weeks of follow-up among HIV-infected and other high-risk HHCs of adults with MDR-TB (index case). High-risk HHCs are those with HIV or non-HIV immunosuppression, latent TB infection, and young children below the age of 5 years.

There are currently no standard therapy recommendations based on quality evidence for TB preventative therapy for high-risk contacts of MDR-TB patients. The PHOENIX study, which opened in June 2019, seeks to provide quality evidence to guide TB preventative therapy for high-risk household contacts of MDR-TB patients. The study envisions enrolling 5178 participants globally, with 300 to be enrolled from Botswana. At the time of reporting, the Botswana site had not enrolled any participant.

ii) REPRIEVE (A5332): A randomized trial to prevent vascular events in people living with HIV.

REPRIEVE is a prospective, double blind, randomized, placebo-controlled, multicenter phase III efficacy study that will examine the effects of 4 mg daily pitavastatin on cardiovascular-related events among HIV-1 infected adults who are currently on ART. HIV-infected persons face an increased risk of CVD morbidity and mortality, yet no preventive strategies for CVD risk reduction have been proven for this population. Statins may target the unique mechanisms of cardiovascular disease in HIV. REPRIEVE study opened in February 2017 and enrolled a total of 7557 participants globally of which 281 were enrolled from Botswana. The study is closed to accrual and currently on participant follow up.

2) International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT)

The IMPAACT Network was established in 2006 for the purpose of evaluating interventions to treat and prevent HIV infection and to decrease mortality and morbidity due to HIV and HIV-associated infections and co-morbidities in infants, children, adolescents and pregnant/postpartum women through the conduct of high quality clinical trials.

The Network's research agenda includes evaluation of: new and existing anti-HIV drugs and formulations; novel approaches for addressing tuberculosis in HIV-infected or at-risk populations; biomedical/behavioral interventions to prevent mother-to-child HIV transmission; immunogenicity, safety and efficacy of high priority vaccines; potential for HIV cure through therapeutic interventions; and methods to prevent and manage complications

and comorbidities of HIV infection and its treatment.

i) 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 HIV-1 infected infants initiating Combination antiretroviral therapy (cART) within 12 weeks of birth. The study opened in February 2019 and will enroll approximately 68 infants globally and 8 infants in Botswana.

ii) P1026s: Pharmacokinetic (PK) of Properties of Antiretroviral Therapy During Pregnancy. The study is designed to evaluate 1) the pharmacokinetics of antiretroviral medicines when used alone or core administered with TB medicines during pregnancy, 2) the pharmacokinetics parameters of lopinavir/ritonavir and atazanavir/ritonavir/tenofovir in women postpartum before and after starting hormonal contraceptives and 3) the concentrations of ethinyl estradiol, etonogestrel and other progestins in women using hormonal contraceptives and protease inhibitors. The study is currently ongoing.

iii) IMPAACT 2005: Phase I/II Open-label, Single-Arm Study to Evaluate PK, Safety, & Tolerability of Delamanid (DLM) in Combination with Optimized Multidrug Background Regimen (OBR) for MDR-TB in HIV-infected & HIV-uninfected Children with MDR-TB. The study is designed to characterize the pharmacokinetics of DLM, using model-based approach, and to evaluate safety and tolerability of DLM over 24 weeks of study treat. The study is currently ongoing.

iv) P1093: Phase I/II, Multi-Center, 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. The study's primary objectives are to select a DTG dose for chronic dosing; to determine the safety and tolerability of the dose; to evaluate the steady-state pharmacokinetics of DTG in combination with other ARVs and to determine the dose of DTG that achieves the targeted C24h and AUC0-24 PK parameters in the population.

v) 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 VESTED study (Virologic Efficacy and Safety of ART Combinations with TAF/TDF, EFV, and DTG) will compare the regimens with regard to safety and virologic efficacy during pregnancy and through 50 weeks of maternal and infant follow-up postpartum. A total of 643 mother-infant pairs were enrolled globally, 51 in Botswana. Participant follow up is ongoing.

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3) HIV Prevention Trials Network (HPTN)/ HIV Vaccine Trials Network (HVTN)

The HPTN 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 HVTN is the world’s largest publicly funded multi-disciplinary international collaboration facilitating the development of vaccines to prevent HIV/AIDS and conducts all phases of clinical trials, from evaluating experimental vaccines for safety and immunogenicity to testing vaccine efficacy.

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. Its main objective is to evaluate the safety and efficacy of the injectable agent, cabotegravir (CAB LA) compared to daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), for pre-exposure prophylaxis (PrEP) in HIV-uninfected women. The five-year PrEP study is being conducted at 20 sites across Sub-Saharan Africa and will enroll 3200 participants (200 from Botswana). The study is currently ongoing.

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. A total of 1924 participants were enrolled globally. The Botswana site successfully attained its target of 150 participants, within the stipulated time frame. The study accrual was attained in September 2018 and is currently in the follow up phase.

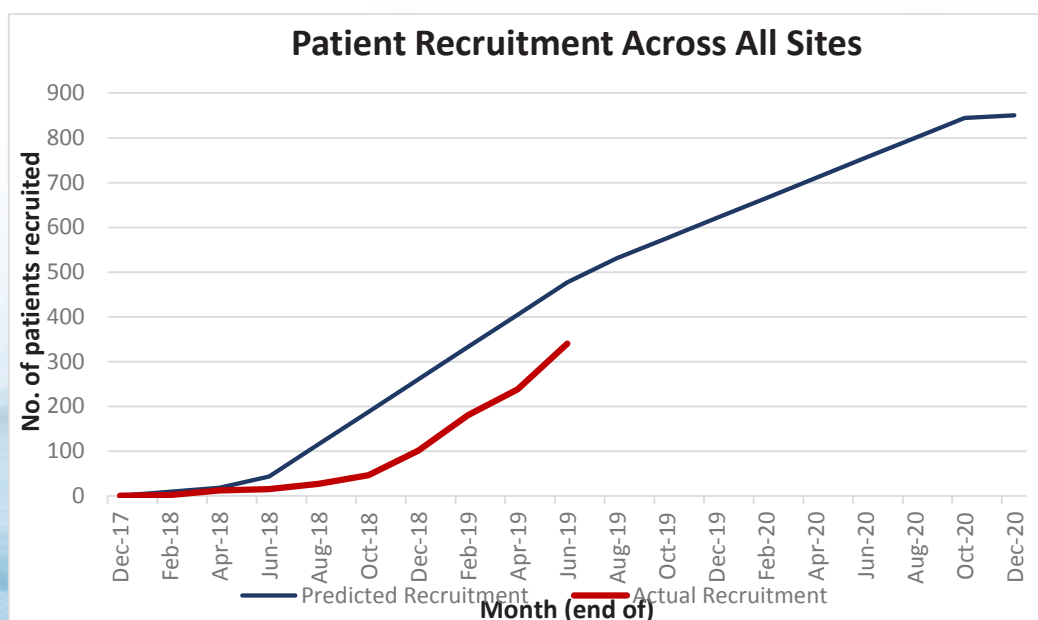
PRINCIPAL INVESTIGATORS INITIATED RESEARCH PROJECTS

Botswana Harvard AIDS Institute Partnership investigators, either individually, in collaboration with other local- or international-based PIs, continue to apply for and conduct non-network research projects. An encouraging number of Early Investigators (local) have successfully managed to be awarded small grants. Principal Investigator initiated research projects undertaken during this reporting period include:

i) The AMBITION-cm Study

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 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 EDCTP and is currently ongoing. As of 31/07/2019, there are 42 participants recruited from Princess Marina Hospital.

Figure 4: Ambition Study-Recruitment graph across all sites



RESEARCH EXCELLENCE

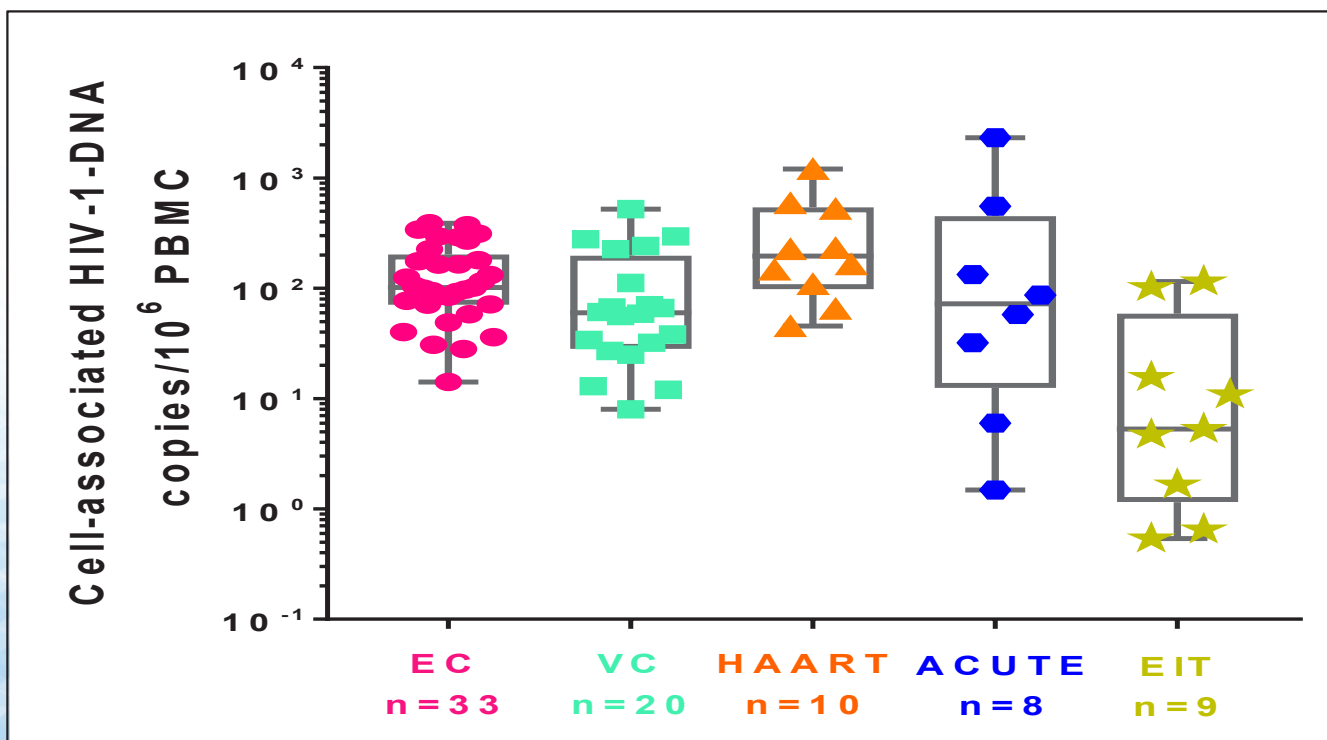
Studentships, Grants and Promotions

- Dr Tshepo Leeme (AMBITION-cm study doctor) won a studentship to pursue an MSc in Epidemiology at the London School of Hygiene and Tropical Medicine, which she completed earlier this year. Dr Leeme presented her findings at CROI last March in an oral presentation entitled 'Utility of CD4 cell count monitoring in Botswana: analysis of routine laboratory data, presented at CROI'.
- Charles Muthoga won a MSc studentship entitled 'Developing a costing tool for then management of cryptococcal meningitis in Bostwana' with the University of Liverpool (UK), expected completion date is 2019.
- Ms Tshepiso Mbangiwa won a studentship to pursue a PhD entitled 'Development of a novel qPCR for diagnosis of cryptococcosis' with the University of Cape Town (RSA) and Institut Pasteur (France), expected completion date is 2020.
- Dr Nabila Youssouf (AMBITION-cm Trial Manager) won a Public and Patient Engagement Small Grant Award from the London School of Hygiene and Tropical Medicine to deliver a workshop entitled 'Myth Bursting: Demystifying Lumbar Puncture), expected workshop date is late 2019.
- Dr Mosepele Mosepele (AMBITION-cm Principal Investigator and AMNET Chair) was appointed as Associate Professor of Internal Medicine and Infectious Diseases at the University of Botswana.

ii) Early Infant Treatment

Early Infant Treatment Study (EIT) is a single arm non-randomized clinical trial of early ART in antepartum and peripartum infected children. The study tests HIV-exposed infants for HIV at birth and offers immediate (within 3 days) antiretroviral therapy for those that are positive. The overall objective is to determine whether very early antiretroviral treatment (ART) initiation in HIV-infected infants limits the seeding of viral reservoirs and maintains immune responses. The study was activated in April 2015 and has since completed accrual and is now in the follow-up phase. Preliminary findings indicate that early infant treatment with ARVs leads to reduced viral particles in the infants' blood (Fig 1).

Figure 5: HIV DNA in PBMCs at 84 weeks was lower than other early treatment cohorts



RESEARCH EXCELLENCE

iii) Tatelo Study

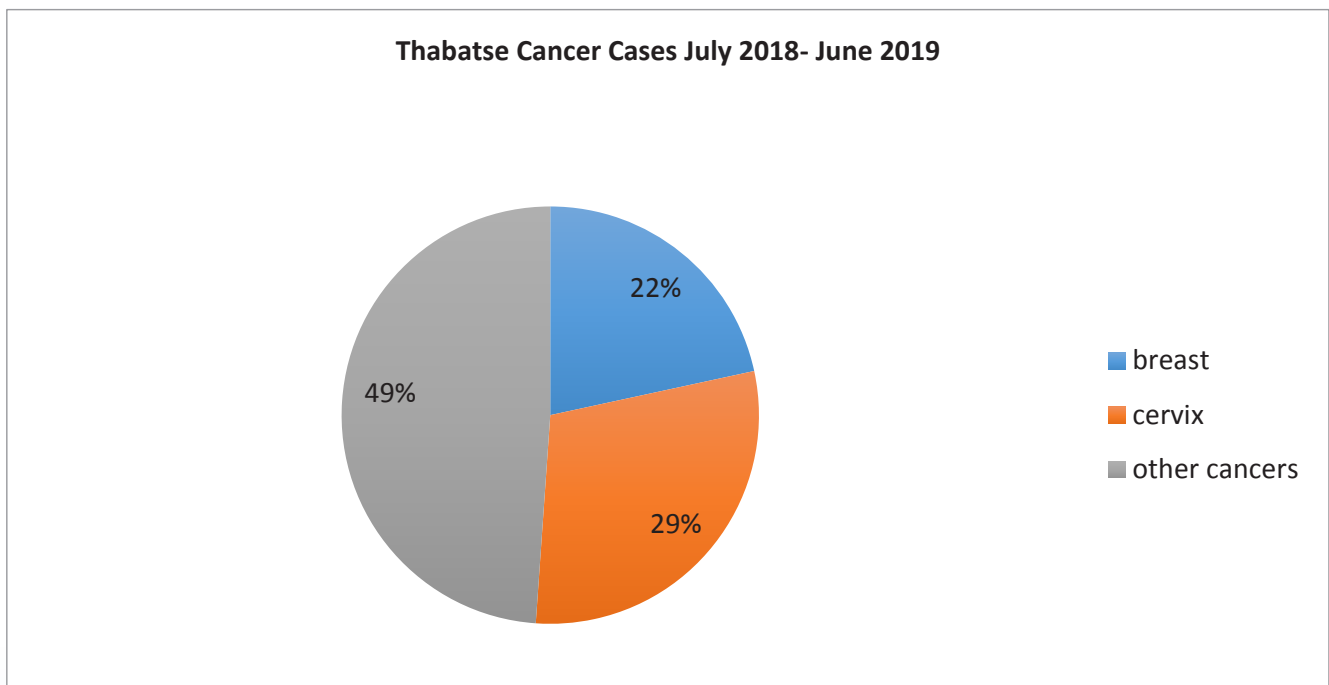
A Clinical Trial to Evaluate the Impact of Broad Neutralizing Antibodies VRCO1LS and 10-1074 on Maintenance of HIV Suppression in a Cohort of Early-Treatment Children in Botswana (Dual bNAb Treatment in Children).

The study aims to determine the safety, pharmacokinetics, dosing and antiviral efficacy of dual bNAbs immunotherapy in early-treated HIV-1 infected children, evaluate effects of treatment on the size and cellular composition of residual viral reservoirs and investigate the influence of treatment on the magnitude and quality of antiviral innate and adaptive immune responses. The study opened June 2019 and enrollment is ongoing.

iv) Thabatshe

Thabatse (meaning tap root in Sesotho) is a prospective cohort study that enrolls biopsy-confirmed cancer cases who present for specialized oncology care at the four-referral level oncology centres in Botswana. The primary aims are to evaluate the important risk factors for cancer in Botswana including HIV and to describe the response to treatment for patients without HIV, and those with HIV on HAART. During the reporting period, the study got IRB approval to increase the initial sample size of 4000 people by 2500. Thabatse study findings have been shared with clinicians at NRH and PMH. Multiple abstracts on HIV, smoking and the risk of head and neck cancers, solar exposure and melanoma, effects of HIV on survival in women with breast cancer, were accepted for oral presentation at the 2019 AORTIC International Conference on Cancer in Africa.

Figure 6: Habits Cancer Cases, July 2018 – June 2019



v) Feasibility and accuracy of nanosensor-based cancer diagnosis at the point-of-care (Chedza Study)

This is a prospective feasibility and validation study of a novel modality for diagnosis of malignancy among cancer suspects in Botswana. The study also known as Chedza (Kalanga word for light), is so called because of the novel technology used in the study; Contrast Enhanced Microholography (CEM), a system that takes images of diffraction patterns of light and analyzes them computationally. The study goals include a) Assessing if CEM can permit accurate, close to point of care diagnosis of Lymphoma and

Breast Cancer in Botswana, b) develop comprehensive training materials including training video, pamphlet, and written protocol and, c) test the effectiveness of training individuals of various education levels with or without in-person training on CEM.

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A total of 25 participants from BHP with a wide range of Laboratory experience were randomized to in-person practical or simulated practical training.

The study additionally provided Fine Needle Aspirations trainings at the National Health Laboratory (NHL) and Scottish Livingstone Hospital (SLH). Efforts are being made to get feedback from key stakeholders and preparations for the various clinical sites for enrollment. Lastly, one abstract titled “Assessing implementation and feasibility of a novel point of care diagnostic device for cancer” was accepted for oral presentation at the 2019 AORTIC International Conference on Cancer in Africa.

vi) The Tshilo Dikotla Study: Metabolic Outcomes of children HIV/ARV –Exposed Uninfected in Botswana

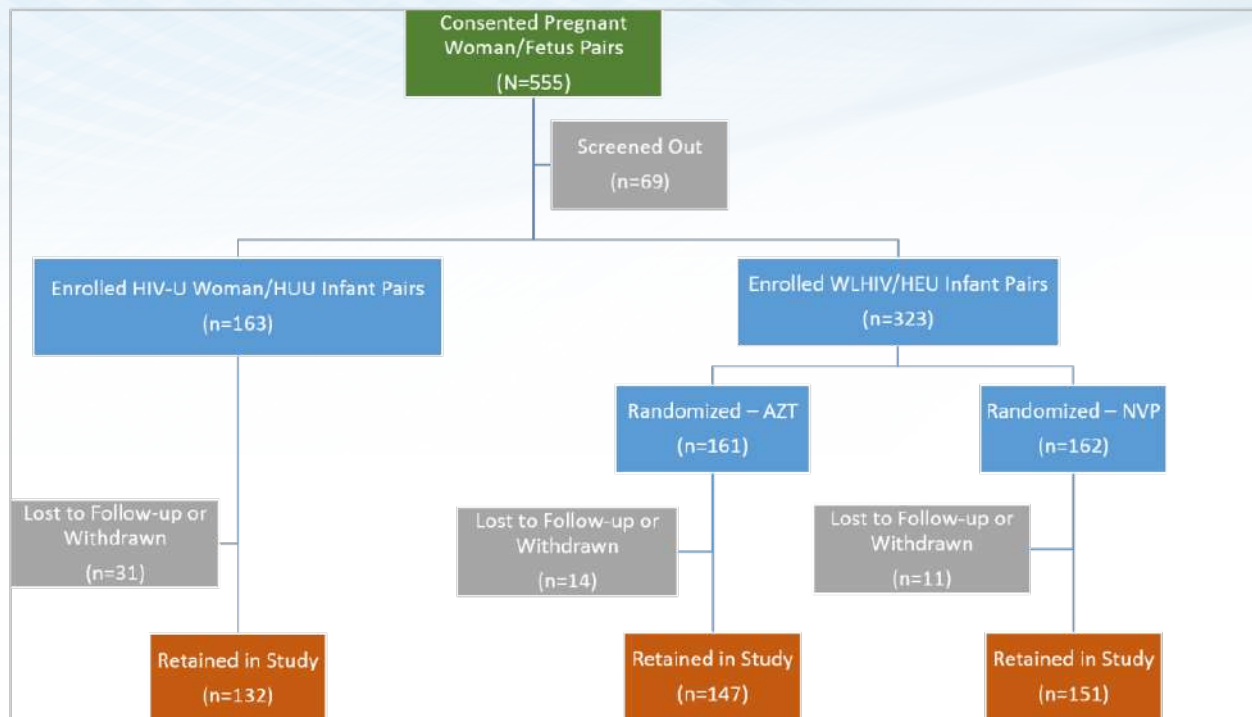
The Tshilo Dikotla study is a prospective cohort study of pregnant women living with HIV (WLHIV) and HIV-uninfected (HIV-U) pregnant

women and their children in Botswana, with a nested randomized component. HIV-exposed infants are randomized to receive a month of zidovudine versus nevirapine prophylaxis. The study is assessing whether in utero and neonatal HIV/ARV exposure is associated with changes in insulin sensitivity in HEU children from birth to 3 years of life using HIV-unexposed uninfected (HUU) infants as a comparator group. In addition, the study is evaluating whether zidovudine versus nevirapine neonatal prophylaxis regimens differ in metabolic effects amongst HEU children.

The accrual has been completed and the study is currently on participant follow up. Five abstracts have been presented at international conferences, 3 of which were from local early investigators.

RESEARCH EXCELLENCE

Figure 7: Tshilo Dikotla Study Enrolment Flowchart



vii) Ikitse Study: Acceptability and Uptake of HIV-Self Testing Among Female Sex Workers in Botswana

This is a Harvard University Center For AIDS Research (CFAR) funded mixed-methods study among 230 female sex workers and 5 non-governmental organization staff directly supporting FSW in Botswana, to assess the acceptability, feasibility and uptake of HIV self-testing in FSW in Gaborone and surrounding areas.

Specific Aims

- 1). Assess the acceptability of, obstacles to, and preferred approaches to HIV self-testing in FSW, using qualitative methods
- 2). Evaluate the uptake of HIV self-testing among FSW in Botswana, in a pilot study.
- 3) Determine “90-90-90” coverage in HIV-infected FSW in Botswana

First participant was enrolled into the qualitative study on 18 February 2019. Participants were fully enrolled (35 participants) into the qualitative study by March 2019. Qualitative data analysis is ongoing. Enrollment into the quantitative pilot study started 10 June 2019 and by end of June 32 participants had been enrolled.

viii) Pharmacy

The Pharmacy Department continues to be an integral part of the different drug related studies being conducted at BHP. It is mandated with ensuring adequate and safe receipt, handling, storage and dispensing of pharmaceutical products in compliance with applicable regulatory requirements. Other services offered by the department include but are not limited to; provision of medication adherence counseling to study participants. In an effort to increase its efficiency, the department has successfully relocated CTU pharmacy operations to the new Gaborone CTU site from, as well as upgraded the Francistown site pharmacy to a fully-fledged pharmacy with a fulltime pharmacist onsite.

The main objectives of the Pharmacy over the period 2018/19 were to grow and strengthen network/collaborations with stakeholders, deliver quality services, increase BHP advocacy awareness and to increase publications in high impact journals. To date, stakeholder engagement meetings have been undertaken with Princess Marina Referral Hospital, Scottish Livingstone Hospital, Nyangabgwe Referral Hospital dispensaries, Drug Regulatory Unit/Medicines Regulatory Authority and the Central Medical Stores (CMS).

ix) Community Engagement

Community Engagement is a process of building relationships that may be on-going or permanent. Community Engagement ensures

RESEARCH EXCELLENCE

that different stakeholders, particularly community stakeholders, know what BHP is, which specific research projects are conducted by BHP and what the outcomes of research studies BHP has conducted are. In addition, it ensures that BHP has a deep appreciation of various community stakeholders including what their health needs are and what their research priorities are. In ensuring that

engagement between investigators and community stakeholders is continuous, BHP has a Community Advisory Board (CAB), which interphases investigators with various community stakeholders. Continuous engagement with stakeholders is also achieved through various stakeholder engagements such as the Media Science Café, the journal club, and multiple stakeholder meetings.



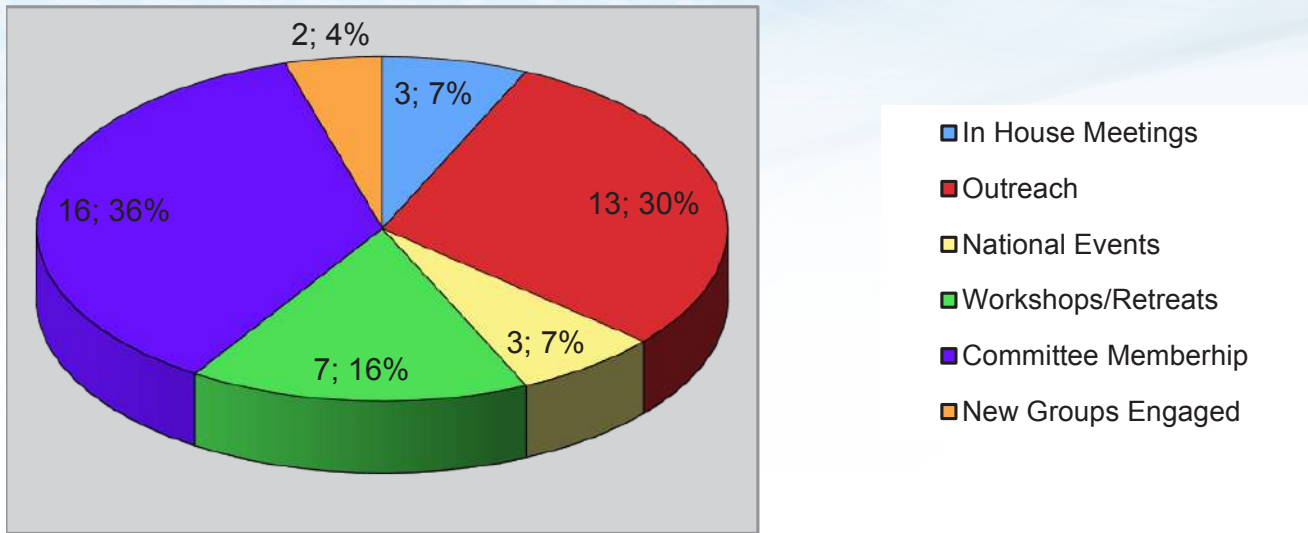
Lumbar Puncture Workshop with BHP CAB Members and members of the Media

Stakeholder engagement activities undertaken during the reporting period are depicted in the pie-chart below. Major achievements were the completion of results dissemination to all the 30 BCPP communities, their DHMTs, and to Ntlo Ya Dikgosi (House of Chiefs). Furthermore, two other study results were widely disseminated. The Tsepamo results on the birth outcomes associated with use of DTG in pregnancy were disseminated to all the 8 original sites where from data was collected. The Potlako study results that showed

that innovative interventions including basic one-day training of healthcare workers on cancer diagnosis and management, and patient navigation through healthcare system could improve patients' outcome by reducing time delay from symptom onset to cancer treatment initiation. The results were disseminated to the MoHW, Kweneng East DHMT, and to the 35 Kweneng East health facilities.

RESEARCH EXCELLENCE

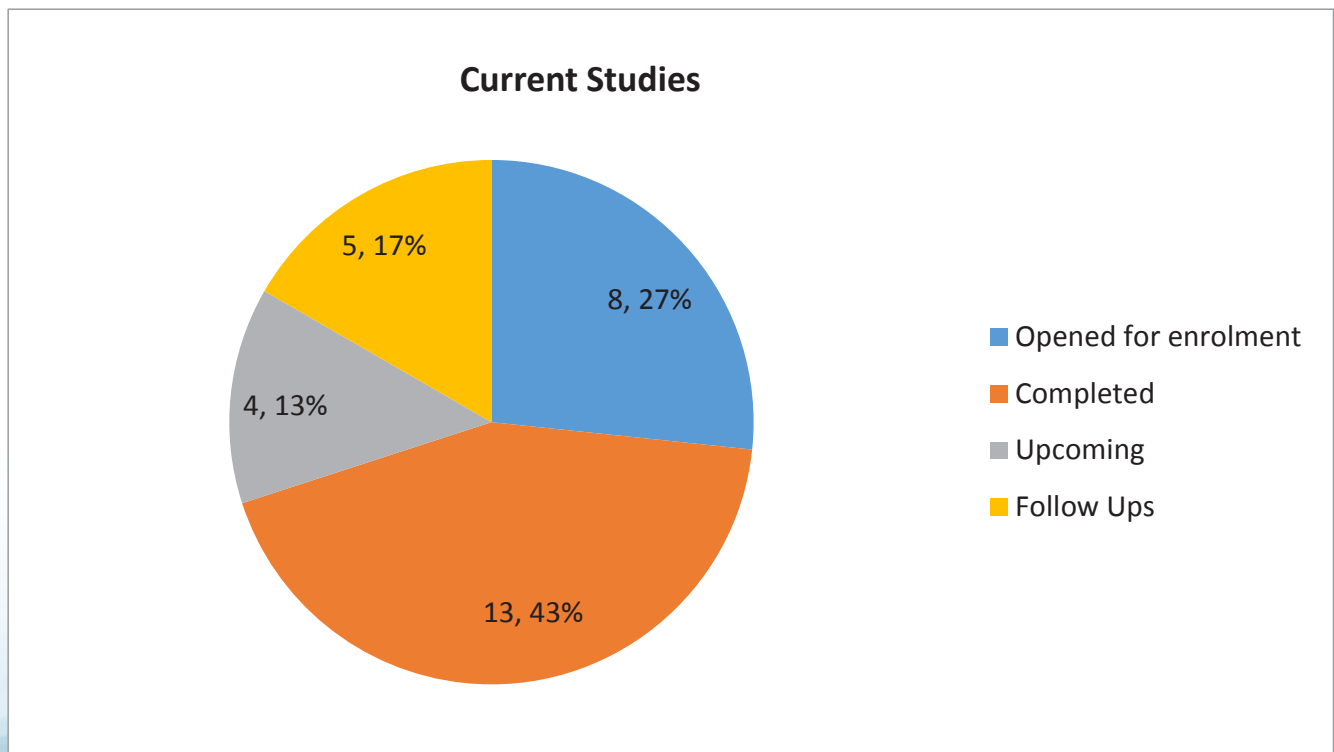
Figure 8: Community Engagement Activities by Category



x) Regulatory Office

Tasked with the oversight of research compliance, the department facilitates and maintains IRB approvals for all studies conducted at BHP. Fifteen (15) applications were made to the ethics committees for new studies and 14 were approved.

Figure 9: Number of current studies



RESEARCH EXCELLENCE

To ensure ongoing research excellence, the Regulatory office facilitates Responsible Conduct of Research (RCR), Research Ethics and Good Clinical Practice training. In the current reporting period, 18 BHP employees have been trained on Responsible Conduct of Research. Additionally, through collaborative Partnerships and support from Trials of Excellence for Southern Africa (TESA) program, a total of 35 people, 4 from BHP 28 from HRDC and 3 from other African countries were trained on Research Ethics.

xi) Software Engineering & Data Management Center

The Software Engineering and Data Management Center (SE & DMC) at BHP serves multiple clinical and research studies. SE & DMC continues to ensure a complete, accurate, compliant, auditable, confidential, secure and accessible research data. The department successfully upgraded the existing Electronic Data Capture system (EDC) for Potlako study and for Tshilo Dikotla study. The department successfully closed the Botswana Combination Prevention Project (BCPP), a study that was running systems deployed across 30 communities in Botswana.

During the year BHP's Laboratory Information System crashed and a new system, the Senaite LIMS, had to be developed and deployed. The project was successfully concluded This system is used to help manage all data around research participants' sample life cycle including result management. The team is currently undertaking training on software security and data management.

xii) Laboratory Lead Research/Activities

BHP's laboratory has three major functions; a) To support all clinical research protocols (Clinical laboratory), b) To oversee training of and to mentor young scientists at both undergraduate and post graduate levels and conduct research (Research Laboratory), and c) To ensure that the Botswana Harvard HIV Reference Laboratory (BHHRL), meets and maintains international quality standards and is accredited

Clinical Laboratory

The Botswana Harvard HIV Reference Laboratory (BHHRL) continues to support the clinical trials conducted by the BHP. It provides quality testing for key assays for enrollment and management of study patients.

BHHRL has maintained its approved status in conducting clinical trials supported by the US National Institutes of Health (NIH) and the Division of AIDS (DAIDS) through ACTG, IMPAACT and HPTN studies. BHHRL was granted 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. A total of 20 lab scientists have been trained on this (ISO) 15189) quality standard.



Laboratory Scientist, Seretlogelwa Moseki preparing samples for HIV-1 Qualitative testing in the Early Infant Diagnosis (EID) Laboratory.

RESEARCH EXCELLENCE

Activities of the Clinical Laboratory: 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 HIV ELISA, Hepatitis B profiles, Hepatitis C Antibody, Syphilis RPR and TPHA, HIV-1 Western Blot, Incidence Assays [Limiting Antigen, Avidity, Bio-rad Avidity and BED capture enzyme immunoassay], QuantiFERON TB Gold Plus assay , Cepheid Point of Care Viral load and Gene Expert TB.

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.



Laboratory Scientist, Corretah Boleo participating in training and validation of the Abbott Architect Immunoassay at the Serology Laboratory.

I I. CAPACITY BUILDING AND TRAINING

BHP has several grants that are specifically for capacity building and training. The major ones are the EDCTP grants (TESA II, SANTHE), Beth Israel Deaconess Medical Center (BIDMC) grant, Massachusetts General Hospital (BOTSOGO) grants, and several small grants from NIH, Forgary, and CFAR.

i) BHP Laboratory Capacity Building Projects.

The BHP research laboratory houses 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 the lab director Dr Simani Gaseitsiwe, the deputy lab director Dr Sikhukile Moyo and Dr Rosemary Musonda, PI and BHP Research Associate. The group also boasts of international collaborators who assist in the

CAPACITY BUILDING AND TRAINING

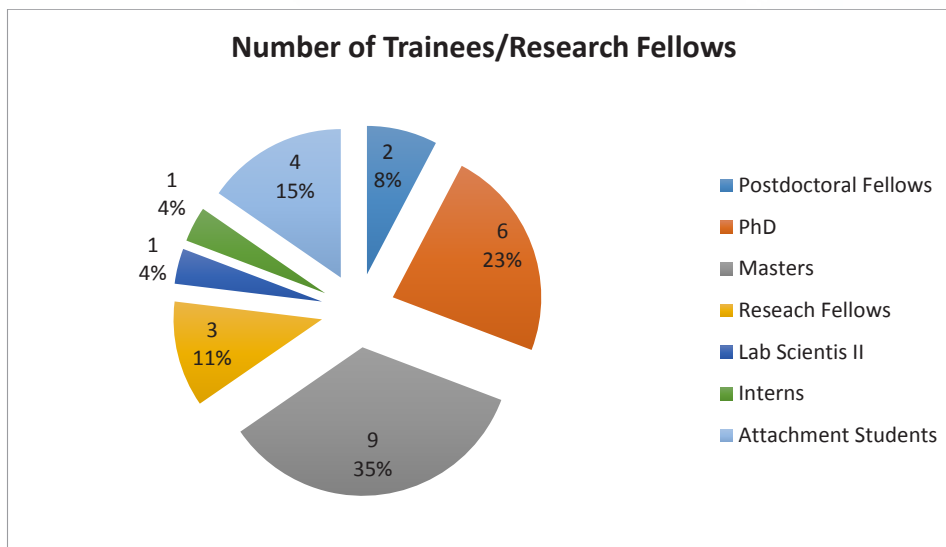
supervision of fellows working on areas where there is limited capacity at BHP. The fellows are registered with various academic institutions including University of Botswana (UB), Botswana International University of Science and Technology (BIUST), Stellenbosch University, University of Cape Town, University of Witwatersrand and University of Kwazulu Natal.

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.

The pie chart below summarizes the number of trainees by level of training/degrees. Over the reporting period BHP had in its training program; 2 PhD fellows, 6 PhD students, 10 Masters students, 1 intern, 1 Lab scientist II, and 3 research fellows.

Figure 10: Number of BHP Trainees/ Research Fellows



A number of the research lab staff attended local and international short term trainings (in total 11 trainings). In addition, five students from local universities (Botswana International University of Science and Technology (BIUST) and University of Botswana (UB)) were attached to the BHP lab for their projects. The research lab had 15 publications in total during the year.

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

BHP together with Beth Israel Deaconess Medical Center (BIDMC), Boston and Oregon Health & Science University (OHSU), Portland, fosters an initiative created to support healthcare capacity building clinical stewardship, medical education, quality improvement and research in Botswana.

The initiative is supported by Harvard clinical faculty in the area of Internal Medicine, Obstetrics & Gynaecology and Anaesthesia & Critical Care. They provide clinical training to University of Botswana medical students, interns and residents as well as local medical officers, nurses and other healthcare personnel.

The project has instituted a number of initiatives, mainly in the area of capacity building and training at both SLH and the Kweneng District. These include strengthening anaesthesia and critical care through training of nurses and doctors working at ICU and emergency departments of SLH, as well as assisting in developing a training of nurse anaesthetists at Institutes of Health Sciences (IHS). The other major development is that Dr Luckett who is a obstetrics and gynaecology (OBGYN) specialist and has since been given an adjunct position, is assisting in developing OBGYN training of residents at the University of Botswana (UB). At district level, both the specialist doctors and the residents from BIDMC and OHSU do out- reach to the district's clinics to offer both professional support to health care workers there through trainings, as well as too provide clinical care to the patients.

ii) Botswana Global Oncology Outreach (BOTSOGO)

BOTSOGO (Botswana Global Oncology Outreach) is a capacity building initiative that continues to support a monthly oncology tumor board. This is a continued medical education forum where healthcare providers at public referral hospitals in Botswana and

CAPACITY BUILDING AND TRAINING

oncology centers in Boston participate in bi-directional discussion of cancer cases through tele/video-conferencing. A total of 10 tumor board meetings were conducted between July 2018-June 2019, with approximately 60 clinicians attending per session.

In addition to the Tumor Board initiatives, the program has invited both public and private sector clinicians and cancer radiotherapy technicians to Boston for a week or two of clinical exposure and training sessions.



Health Professionals attending Tumor Board meeting at the BHP Conference room.

12. PUBLIC POLICY & ADVOCACY

Research results from BHP studies continues to positively impact on policies and treatment guidelines in Botswana and globally. Results from the Tsepamo study impacted major policy on the use of DTG in Botswana and Globally. Based on recent findings from the Tsepamo Study WHO updated its recommendations on antiretroviral therapy, incorporating DTG in Treatment Guidelines for use by women of child bearing potential. BHP presented about 33 abstracts at different international conferences and published 53 research papers in various scientific journals, a substantial number of abstracts and publications that signify BHP's commitment and resolve to continue producing quality research work aimed at improving public health policies.

A number of BHP investigators continue to be active members of both international and several MOHW technical teams where

they give expert advise on different health matters. Below are some (but not all) of the technical committees/organizations where BHP staff is involved.

1. Cryptococcal Group (CryptoMAG)
2. African Meningitis Trials Network (AMNET)
3. 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
4. Board for Biomedical Research Training Institute, Zimbabwe,
5. University of Botswana IRB

PUBLIC POLICY & ADVOCACY

6. HPTN Community Group Steering Committee –Executive Committee of the CWG
7. HPTN075 Protocol Team
8. HPTN Ethics Working Group
9. HIV/AIDS Network Coordination (HANC)
10. ACTG Performance Evaluation Committee
11. TB/HIV Surveillance (NAHPA)
12. Strategic Information Working Group, Estimates and Projections
13. National Working Group on Laboratory Reference Ranges
14. 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.



BHP Community Engagement Coordinator interacting with members of the public at World AIDS Day commemoration in Maun.

13. OPERATIONAL EXCELLENCE

i) Human Resources

The Human Resource (HR) Department plays an important role in strategic planning and company growth through various HR initiatives. It facilitates recruitment and retention of qualified personnel and provide conducive conditions of service to achieve operational excellence.

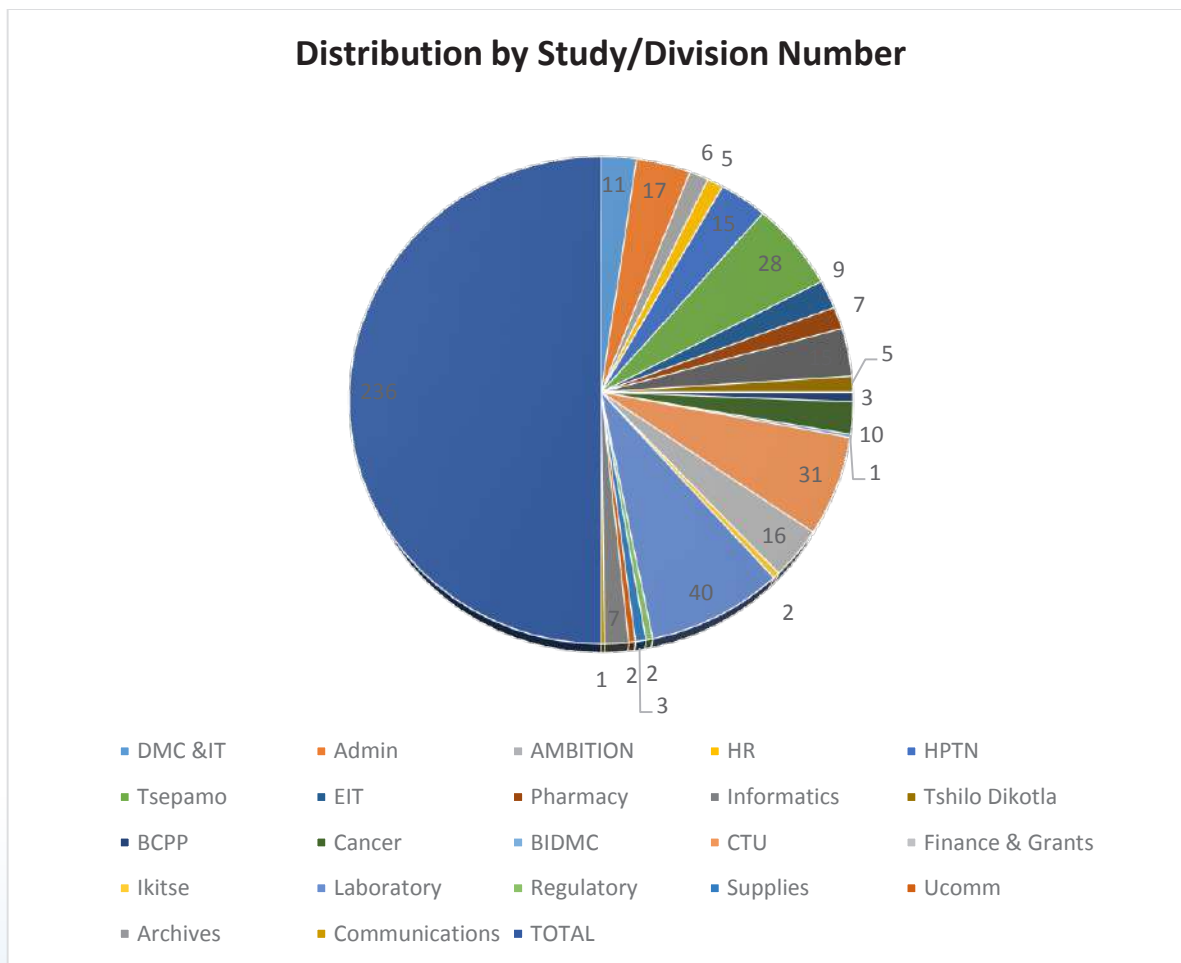
The department is currently reviewing all HR Policies and Procedures to enhance efficiency and to effectively deliver HR services to staff. One of the interventions to improve efficiency is the introduction of Employee Self Service (ESS) system. This is an employee self

support system that allows staff to connect with HR remotely to perform specific HR services by themselves. The system provides employees access to their personal records and details and allows for administrative tasks such as applying for leave, reviewing timesheets, requesting overtime, etc.

Staff complement

As of June 2019 the staff complement at BHP was 236 distributed across 22 division/projects. There is excellent staff diversity as indicated by the fact that seven (7) nationalities are represented in BHP staff complement.

Figure 11: Distribution of BHP staff by study or departments



BHP is made up of different Studies and the pie chart above represents the number of employees per each project/department. Laboratory has the highest number of employees at 40, followed by CTU with 31 employees.

Figure 12: Distribution of BHP Staff by Gender

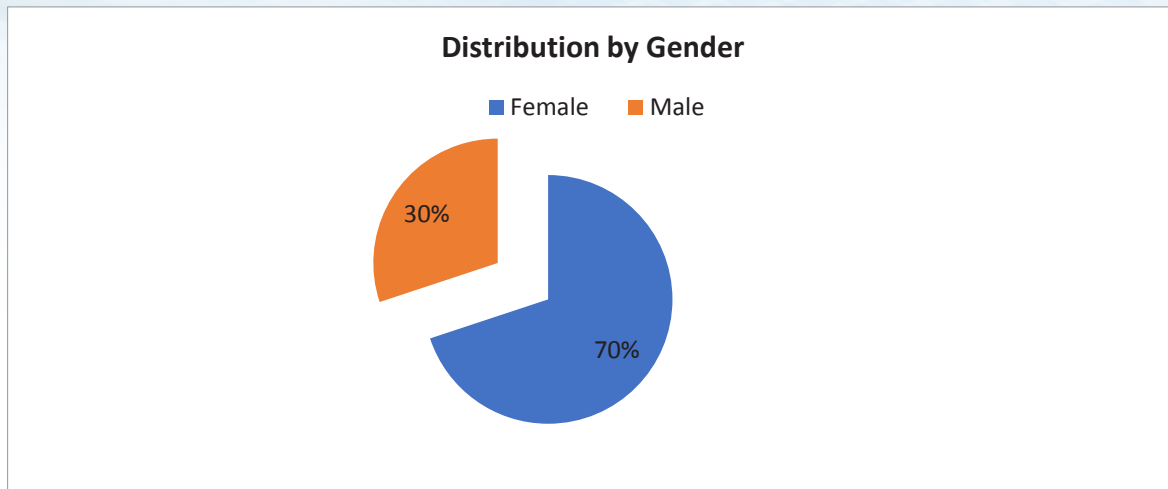
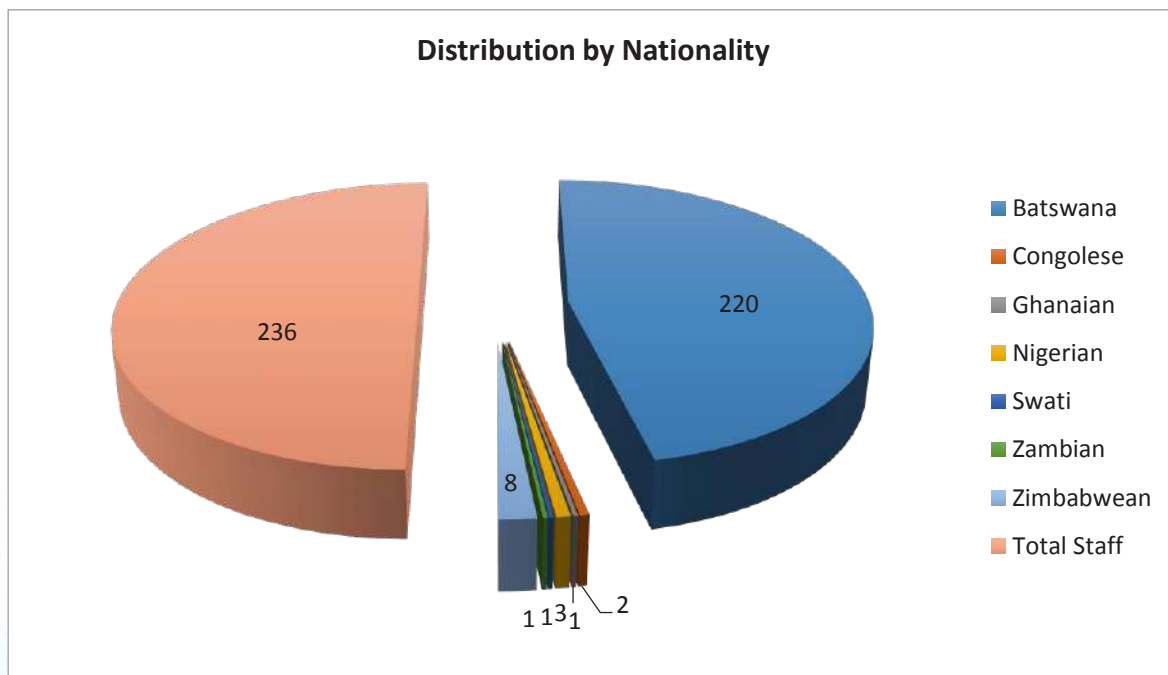


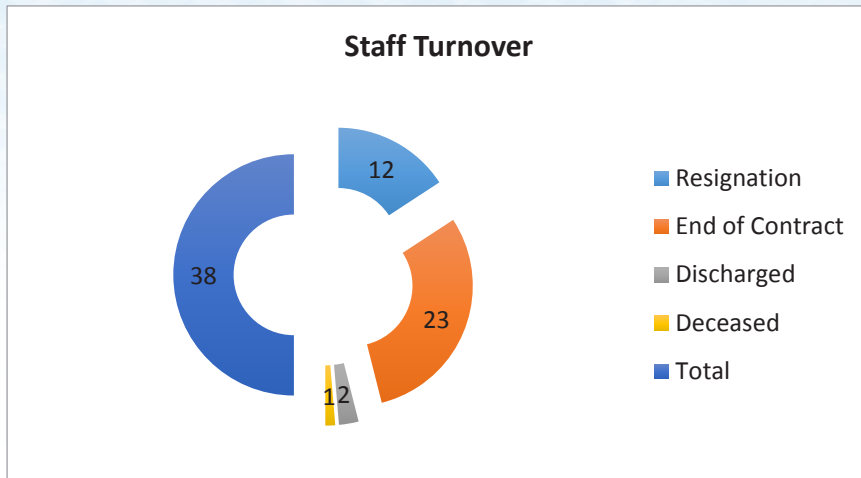
Figure 13: Distribution of BHP Staff by Nationality



Staff Turnover

BHP recorded 38 separations of which 23 were due to end of contracts and 12 were resignations. The table below summarises separations under the current financial year.

Figure 14: BHP Staff turnover



Training & Development

BHP HR Department, as well as individual PIs and projects, continues to provide support employees to undergo training. A total of 36 staff members attended various mandatory /compliance trainings, Protocol specific meetings and conferences locally, regionally and internationally to increase productivity and effectiveness. (Other trainings are reported elsewhere under relevant projects in this report).



Group Breakaway session at the Good Clinical Practice (GCP) and Clinical Trials Training

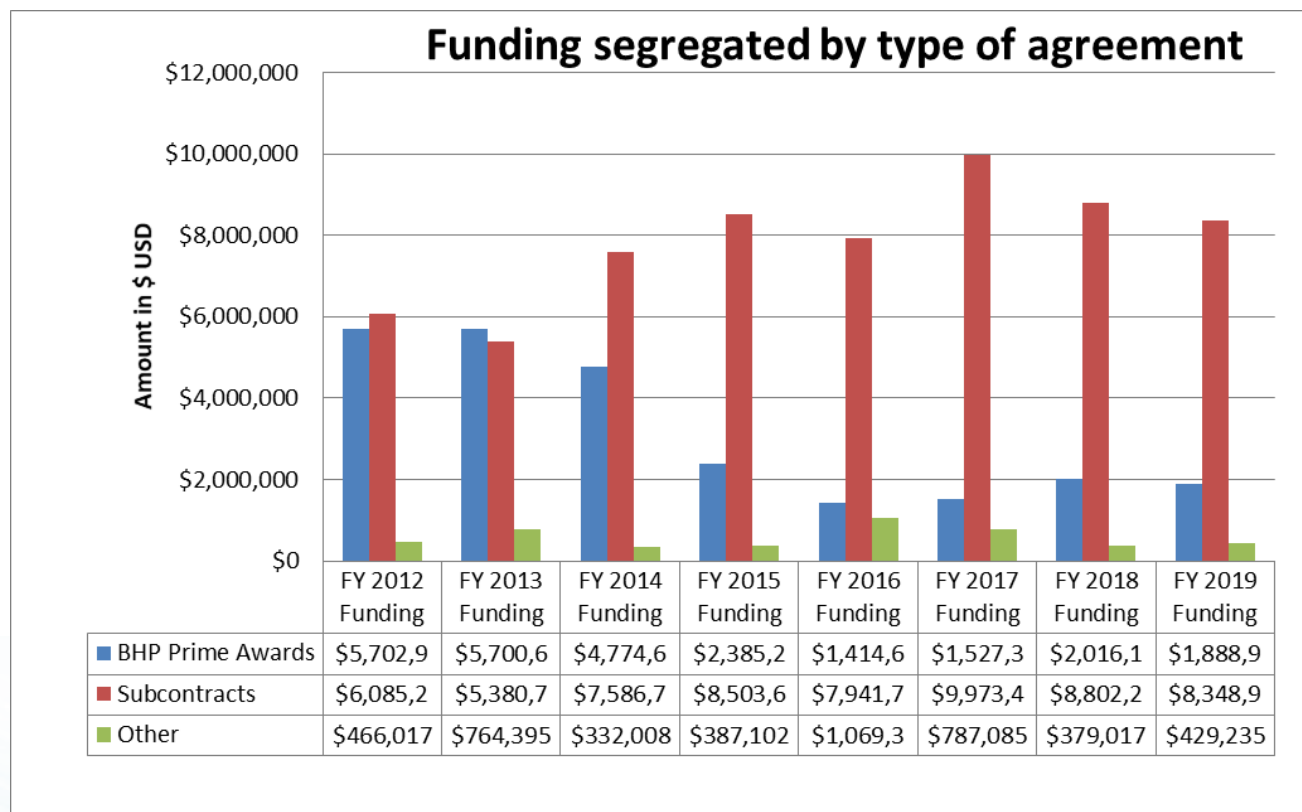
ii) Finance & Grants

Finance and Grants Department continues to play an important role in prudent management of BHP funds. The department is currently managing about 45 grants from 12 different sponsors.

One unqualified external audit was conducted and there has been a decline in the BHP's liquidity ratio since 2017. Liquidity ratio for 2019 is currently at 0.76. Major contributors are:

- Winding down of BHP's major grant – BCPP in 2018 to completely close in June 2019.
- The cyclical nature of grants receipts versus expenditure, including BHP's internal reporting and invoicing procedures. Most grants are on a reimbursable cost model, leading to delayed reimbursements.

Figure 15: Funding cascade by type of agreement for the past eight years



The above table indicates that BHP's grant management has mostly been on subcontracts. Subcontracts continue to surpass prime award due to BHP's established collaborative and networking strengths. Prime awards have declined since 2014 due to loss of some BHP's PEPFAR programs during re-competition.

	Year 2019	USD	Year 2019	USD	
Small	4	190,059	Small	6	328,570
Medium			Medium	6	680,493
Large	7	9,986,552	Large	0	0
Total Grants Applied for	11	10,176,611	Total Grants Awarded	12	1,009,063

s= <\$100k m= \$100k-500k l=>500k s= <\$100k m= \$100k-500k l=>500k

NB: All awarded grants were applied for in the 2017/18 reporting and were awarded in the current reporting period (2018/19).

There were 12 grants awarded in the year 2018/2019 against a target of 15 grants. The 2019 grant application was targeted at 8 grants. 11 grants as indicated in table above were applied for in 2019. This reflects 38% above the year’s target.

14. SUSTAINABILITY

Sesikalla Investments (Pty) Ltd is a BHP Business Enterprise being established to ensure the long-term viability and sustainability of the BHP and its research. It is aimed at generating additional and alternative revenue streams for BHP to augment its funding for capacity building and research.

A business plan for one of the key business areas (Clinical Services) under Sesikalla Investments (Pty) Ltd is at an advanced costing stage. A Lease agreement and memorandum of agreement has been signed for the sub-lease of space at Marymont & Springfield Clinic, an existing clinic in Extension 9, Gaborone.



Plot next to Princess Marina Hospital secured for Clinical, laboratory and Research expansion of the BHP

14. PUBLICATIONS & ABSTRACTS

a) Publications

i) 2018 Publications

1. Bailey, H., R. Zash, V. Rasi and C. Thorne (2018). "HIV treatment in pregnancy." *Lancet HIV* 5(8): e457-e467. Aug 2018
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