



ANNUAL REPORT

2021

Botswana Harvard AIDS Institute Partnership
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Institute Partnership

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2021 - Annual Report

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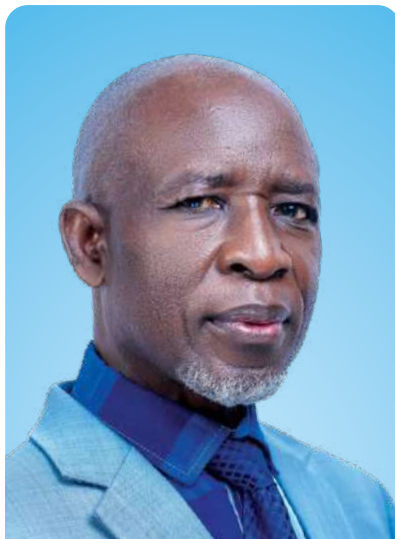
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C. EXECUTIVE MANAGEMENT



Joseph Moeketsi Makhema
MB.ChB, FRCP (UK)

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



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

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



Ria Madison

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

D. SENIOR MANAGEMENT



Sikhulile Moyo
MSc, MPH, PhD

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



Cornelius Gaetsaloe
BCom, AHMP

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



Gaerolwe R. Masheto
MD, PGDip FamMed

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



Ayotunde Omoz-Oarhe
MBBS, MPH

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



Coulson Kgathi
BSc

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



Dineo Tumagole
BAcc

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



Thuso Mokane
BSc

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



Beauty Malumbela
Dip. HRM, BSc, MBA

Beauty Mphonyana Malumbela is a Human Resources Specialist with demonstrated experience in the whole HR value chain, with emphasis in Cultural Transformation, Organizational Development and Performance Improvement. Ms. Malumbela holds a Bachelors of Science Degree, Diploma in Human Resource Management, and Master's in Business Administration. She has HR experience across multiple industries; Private, Governmental and NGOs. Ms Malumbela has broadened her knowledge in delivering powerful Human Capital Strategic Solutions for the Business, and understanding in the HR business partnering model.



Tshenolo Ntsipe
BSc, MPH

Tshenolo Ntsipe is the Laboratory Quality Assurance Manager at BHP and her role is to implement the quality management systems, GCLP/GCP requirements and maintenance of laboratory accreditation. She has a BSc Biomedical Sciences degree from the University of KwaZulu Natal (UKZN), South Africa and completed Master's in Public Health at the University of Limpopo (UL), South Africa (Medunsa Campus). She is a National Quality Management Systems mentor, a Certified Auditor for the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and a Trainer of Trainers for Strengthening Laboratory Management Towards Accreditation (SLMTA). Ntsipe started working for BHP in June 2005 as Laboratory Master Trainer. She has held various positions including Deputy Head, Viral Load Department and Section Head, DNA PCR section. Ntsipe also worked as Quality Officer. She has also worked at the Ministry of Health and Wellness as Medical Laboratory Scientist.

E. PRINCIPAL INVESTIGATORS



Roger L. Shapiro
MD, MPH

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



Shahin Lockman
MD, MPH

Dr. Lockman is an infectious disease- and internal medicine trained clinician and has conducted collaborative epidemiologic, implementation science, and clinical trials investigation related to HIV-1 in Botswana since 1996. Much of her research has focused on preventing vertical transmission of HIV, optimizing the treatment of pregnant and postpartum women living with HIV, and the health and neurodevelopment of children who are born to mothers living with HIV. She established and serves as co-PI (with Dr. Makhema) of the Botswana Clinical Trials Unit the Botswana Harvard AIDS Institute Partnership, which conducts adult (ACTG), pediatric and perinatal (IMPAACT) treatment, HIV prevention (HPTN), and COVID-19 (CoVPN) network trials, and she has led two multi-country ACTG and IMPAACT trials. Dr. Lockman was also co-PI of the Botswana Combination Prevention Project. She now spends most of her time on mentoring early-career investigators from Botswana and the region (and from the US) on a range of clinical research projects related to HIV and more recently COVID-19.



Kathleen M. Powis
MD, MPH, MBA

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



Bruce Chabner
MD

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



Jennifer Jao
MD, MPH

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



Scott Dryden-Peterson
MD, MSc (epi)

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



Vladimir Novitsky
MD, PhD

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



Laura Bogart
PhD

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



Mosepele Mosepele
MD, MSc

Professor Mosepele Mosepele is a Research Associate with BHP since 2014. As an Infectious Disease Consultant and Clinical Epidemiologist, his research focuses on HIV-associated complications such as cardiovascular disease and immune dysregulation. Professor Mosepele is the Botswana site Principal Investigator on several protocols funded by partners in Europe and the US, including the AMBITION-cm trial (High Dose AMBISOME on a Fluconazole and Flucytosine Backbone for Cryptococcal Meningitis Induction Therapy in sub-Saharan Africa: A Randomised Controlled Non-Inferiority Trial), the REPRIEVE trial (Randomized Controlled Trial of Prevention of Vascular Events in HIV) at BHP and also acts as Co- PI on a pilot study focusing on social network-level factors associated with viral suppression among HIV-infected patients at a Gaborone HIV Clinic, also at BHP. He was awarded a prestigious NIH implementation science grant in 2020, to integrate cardiovascular care cascade within existing HIV services in Botswana (InterCARE), a collaborative trial with stakeholders in the US, UK, Botswana and other countries in the SSA region. He is a committed educator with faculty position at the University of Botswana (UB) where he lectures medical students and mentors several early career researchers, both at UB and the BHP. Professor Mosepele has been working as the Deputy Coordinator for the Botswana Presidential COVID-19 Taskforce since March 2020



Neo M. Tapela
MD, MPH

Dr. Tapela is an internal medicine physician, epidemiologist and healthcare innovator who is currently Chief Scientific Officer and VP (Outcomes Research) at the international non-profit, ICHOM. She has been a research associate at BHP since 2015. Her research specializes in understanding the determinants and patient-centered outcomes of chronic non-communicable diseases (NCDs), and designing innovative equity-driven interventions addressing these conditions in resource-limited settings. Dr Tapela has over a decade's experience leading research in the sub-Saharan African region, including co-leading the Potlako+ study: a cluster-randomized trial evaluating a multicomponent intervention for early diagnosis of cancer. Her research and consultancy work are informed by experience in health policy, NCD strategic planning and program evaluation (she is former Head of Botswana's National NCDs Program). Dr Tapela holds an MD and MPH from Harvard University; she is Associate Physician at Brigham and Women's Hospital (Division of Global Health Equity) and Visiting Fellow at the University of Oxford (Nuffield Department of Population Health).



Jason A. Efstathiou
MD, DPhil

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



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

Professor Joe Jarvis is a Professor at the London School of Hygiene and Tropical Medicine, and Research Associate at the Botswana Harvard AIDS Institute Partnership, based between the UK and Gaborone, Botswana. His main research interests are advanced HIV disease, opportunistic infections, in particular cryptococcal meningitis, and strategies to rapidly and safely initiate ART in individuals with low CD4 counts. Prof Jarvis is the Chief Investigator for the Ambition Study, a multi-centre phase 3 trial investigating novel treatments for HIV-associated cryptococcal meningitis, and lead CDC and NIHR funded projects aimed at improving the management of HIV-associated opportunistic infections. He has served as Research Director for the CDC Implementation Protocol of the Botswana Combination Prevention Project (BCPP), 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.



Ava Avalos
MD

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



Sara Schwanke Khilji
MD, MPH, FACP

Dr. Sara Schwanke Khilji is an Associate Professor of Medicine at Oregon Health & Science University (OHSU). She currently serves as the Internal Medicine Site Director for the Botswana Harvard Partnership’s Clinical Capacity Building Program in Kweneng District. In this role, she supports clinical stewardship, health professional education, quality improvement, and related research initiatives at Scottish Livingstone Hospital and the surrounding district. Dr. Schwanke Khilji completed her MD and MPH at Mount Sinai School of Medicine, followed by residency in Internal Medicine and Primary Care at Massachusetts General Hospital and an Overseas Research Fellowship in Thailand with the London School of Hygiene & Tropical Medicine (LSHTM). She is actively involved in medical, inter-professional, and public health education in Botswana and at OHSU, while continuing to serve as a distance learning tutor for LSHTM. Her research interests include women’s health, health policy, and non-communicable diseases (NCDs).



Chelsea Morroni
MBChB, DFRSH, MPH, PhD

Dr. Chelsea Morroni a research associate at the Botswana-Harvard AIDS Institutewhere she directs the Botswana Sexual and Reproductive Health Research Initiative (BSRHI). She is an epidemiologist and medical doctor with over 20 years of experience in Southern Africa. She has an undergraduate degree from Harvard, an MPH and medical degree fromtheUniversity of Cape Town, and a PhD from Columbia University. She has lived with her family in Botswana for 8years. Here, 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 a Chancellor’s Fellow and a Reader in GlobalSRHat the University of Edinburgh Centre for Reproductive Health, an honorary Professor ofWomen’s Health at University of Cape Town, and Co-Director of the UK Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit.



Rebecca Zash
MD

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



Lisa Butler
MA, MPH, PhD

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



Rosemary Musonda
PhD

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



Simani Gaseitsiwe
BSc, PhD

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



Tendani Gaolathe
BS, MD

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



Rebecca Lockett
MD, MPH

Rebecca Lockett is an Obstetrician Gynecologist at Beth Israel Deaconess Medical Center in Boston and at Princess Marina Hospital in Botswana. She is an Associate Professor in Obstetrics and Gynecology at Harvard Medical School and the Assistant Programme Director of OBGYN at the University of Botswana. She completed her Medical Degree and Masters in Public Health at Mount Sinai School of Medicine before pursuing her residency at the Brigham and Women's and Massachusetts General Hospitals integrated program, where she also served as Administrative Chief Resident. Dr. Lockett's research focuses on the intersection of cervical cancer, human papillomavirus and human immunodeficiency virus. An active educator, Dr. Lockett facilitated the development the first OBGYN residency training program at the University of Botswana and participates in resident and undergraduate medical education.



Emily Shava
MBChB, MSc

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



Ponego Ponatshego
MD, DTMH

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



Motswedi Anderson
BSc, PhD

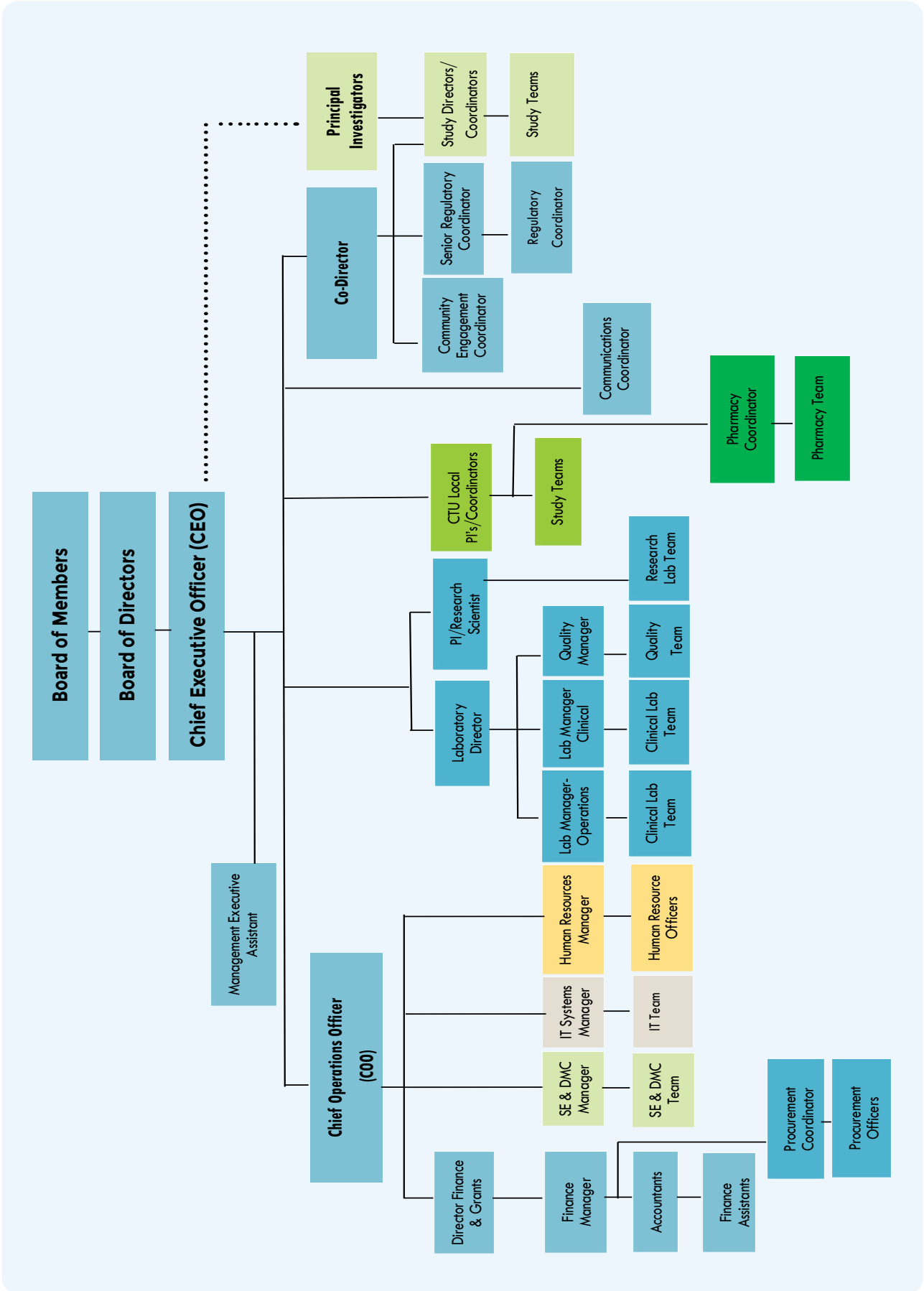
Dr. Motswedi Anderson is a Wellcome International Training Fellow /BHP Research Associate. She has been with Botswana Harvard AIDS Institute Partnership since 2006. Her research interests are in viral hepatitis (B, C, D and E) and human immunodeficiency virus. She completed her PhD in Biological Sciences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



Lucy Mupfumi
PhD

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

4. ORGANISATIONAL STRUCTURE



5. ACRONYMS

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

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

7. CHIEF EXECUTIVE OFFICER'S REMARKS

The past year continued to witness steady progress despite the unprecedented global health crisis. Because of the disruptions to normal business operations caused by COVID-19 restrictions, we developed and instituted new strategies that enabled us to continue our mandate. These resulted in the continued attainment of significant BHP strategic objectives.

While we experienced a steep decline in the number of abstracts presented to different local and International Conferences, 16 down from 35 from the previous period, we have however increased the number of publications in international scientific journals. In this reporting period, BHP published 91 manuscripts, exceeding last year tally of 80 publications.

The number of active Principal Investigator (PI) initiated research projects increased from 16 to 24. Network Clinical Trials increased from 9 to 11, which include CoVPN 5001 from the newly established COVID-19 Prevention Network which was formulated for quick response to COVID-19 pandemic. Even though unwelcome and disruptive, COVID-19 challenges called for forces of change that have enhanced our research enterprise and ways of business operations. COVID-19 studies at BHP saw an increase from one study in the previous year to four studies this year.

Apart from conducting research, BHP also has a unique role to play in shaping public policy and advocacy. BHP staff continue to make invaluable contribution in this respect by taking part in different Ministry of Health and Wellness committees, IRBs and network trials' committees to give expert advice on different health matters thereby contributing to translating research into policy. The number of committees and technical/reference groups in which BHP staff serve increased from 15 in the previous year to 22 this year.

Our achievements rely on efficient stewardship of the limited resources that has been entrusted to us by research funders and donors. Oncemore, this year, BHP's Annual Financial and Generally Acceptable Government Auditing Standards audits (GAGAS) audit remained unqualified, which reflect BHP's effective financial resources management and compliance to best practices in finance and grants management. In this cycle BHP has a portfolio of over 60 grants, while grant revenue increased by \$1. 3M in 2021, an increase of 16% from 2020. Grant applications during the period totaled thirty (30), an increase of 53% from the previous year. There was a significant increase in the number of funding applications for medium sized



DR JOSEPH MAKHEMA
BHP CHIEF EXECUTIVE OFFICER

grants, (nineteen (19) medium grants applied for compared to seven (7) in the previous period) which reflects the investment in, and the development of BHP's local early investigators.

We continue to strive to make BHP self-sufficient and self-sustaining by nurturing and maintaining a pipeline of early career investigators and trainees who can independently apply for research grants and are ever ready to take up various roles and positions in the organization. Plans are underway to develop a robust fund-raising strategy that will help augment BHP finances to enable the execution of transformative changes that will propel and protect our institution's reputation as the leading research institute in the field of public health in country and globally well into the future.

I extend my profound gratitude to the BHP Board of Directors for their relentless support and wise counsel and commend BHP investigators, Research Associates, Scientists, Staff and Collaborators who continue to serve with great self application to ensure that we produce quality research outputs that save lives.

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



8. EXECUTIVE SUMMARY

The Botswana Harvard AIDS Institute Partnership (BHP) is presenting its 2020-2021 annual report. The reporting period is from July 1, 2020 to June 30, 2021. This has been a period characterized by the still on-going SARS-CoV-2 spread and the resultant COVID-19 pandemic. The effect of this pandemic has led to severe disruptions in health systems, economic activities, academic and research activities. Governments and organizations the world over, including BHP, has had to come up with strategies geared towards surviving these disruptions. The organization has proven its resilience once more, emerging with growth across majority of its 5 strategic themes, which are: Research Excellence, Capacity Building & Training, Operational Excellence, Policy & Advocacy, and Sustainability.

BHP's performance results for this reporting period have, despite all the challenges brought about by the COVID-19 pandemic, once again shown that the institute is making considerable strides in growing its research profile. In this reporting period, BHP published 91 manuscripts in peer-reviewed journals, an increase of 13.75% from the previous year's publications achievement of 80 manuscripts. However, our performance with regards to presentations at national and international conferences was unsatisfactory, having presented only 16 compared to last year's 34 abstracts presentations. This was mainly due to travel restrictions to conferences as well as restrictions on gatherings, both locally and internationally.

Exceptional performance was recorded in the area of Capacity building and Training, thanks to excellent mentoring in proposal writing, manuscript writing, and research supervision by our dedicated principal investigators (PIs) and laboratory leadership. This year BHP had a total of 73 research projects (an increase from 60 last year), 13 of which were new projects. There were 30 funding applications that were submitted and 16 of them were awarded. This is a remarkable success rate of 53%.

BHP, in collaboration with institutes of higher learning regionally and further afield, continues to supervise and mentor up-coming scientists at post-graduate level all the way to PhD degrees. A total of 15 scientists had enrolled into different degree programs at several universities, conducted their research projects at BHP under the supervision and mentorship of BHP's scientists. Of these 2 graduated with MPhil/MSc, and 2 graduated with PhD. Our laboratory where many of these research projects are conducted, maintained its accreditation to ISO 15189 through the Southern African Development Community Accreditation Service (SADCAS). This represents international recognition of quality and competency in all aspects of our medical laboratory services. The lab successfully added SARS-COV-2 to the accreditation scope and has also received certification from the African Society for Laboratory Medicine (ASLM) for COVID testing under the COVID-19 Laboratory Testing Certification Program (CoLTeP).

Despite the negative economic impact experienced world over, BHP registered funding growth of USD1.3m which is a 16% growth from the 2019/2020 period. This remarkable growth is mainly attributable to the increase in grant funding applications, 15 as prime and 15 as subcontracts, experienced in the year. Effort is being made to supplement the grants funding revenue stream with third stream income through a subsidiary investment vehicle retailing in pharmaceuticals, and donor/philanthropy targeted resource mobilization, which is spearheaded by the Board of Directors. BHP once more achieved unqualified audits both the Annual Financial and the Generally Acceptable Government Auditing Standards (GAGAS) audits.

The performance of any organization is driven by its employees above all. BHP had a human capital compliment of 240 (70% being females), a growth of 27 employees from the previous period. Staff separation due to resignation or being discharged stood at 6%. The HR strategy strives to improve human capital by enhancing the productivity of the workforce and fostering a well-engaged staff. A number of trainings were offered to different cadres of employee with financial literacy being a favourite among staff.



9. INTRODUCTION

BHP is a not-for-profit, health research and capacity building organization in existence since 1996. Its mission is to fight HIV/AIDS and other emerging public health challenges through research, education, capacity building that impacts policy and practice.

BHP has continued to deliver on its mandate as seen by the wide range of projects it works on. The organizations research portfolio includes clinical trials (both network trials and Principal Investigators initiated trials), implementation science studies, and laboratory-based studies.

In the area of education and capacity building, BHP, being a partnership between the Government of Botswana and Harvard University, and through its collaborative nature, has a wealth of scientists locally and internationally from Harvard affiliated institutions and other US and European institutions, who provide mentoring and training of upcoming scientists in research and publications. Furthermore, BHP collaborates with local and regional universities who are able to offer degree qualifications for mentored and supervised MSc/ MPhil and PhD candidates.

BHP plays a noticeable role in the area of systems strengthening with several BHP scientists providing technical expertise in some of the Ministry of Health and Wellness's committees and technical working groups.



10. RESEARCH EXCELLENCE

The year 2020/2021 has been a uniquely challenging one due to the continuing SARS-CoV-2 pandemic. This notwithstanding, BHP continued to excel on the delivery of its mandate of both clinical (network and PI initiated) and laboratory research. More research grants were applied for and awarded, the number of on-going research projects grew from 60 in the past reporting period to 73 by the end of Financial Year 2021. The number of publications grew from 80 in 2020 to 91 in 2021.

CLINICAL RESEARCH PROJECTS



BHP Clinical Trials Unit (CTU) Gaborone Site

sensitive viruses, which represented only 30% of isolates, the protective efficacy of the single monoclonal antibody was 75%. In contrast, for viruses in the intermediate and resistant categories, there was no significant effect” (Walker, 2021).

The finding also indicated that participants were able to take VRC01 with little or no discomfort. When participants had side effects, they were usually mild to moderate and they lasted a few hours to a few days after the IV infusion. Participants had headaches, tiredness, feeling unwell, body aches, nausea, fever, chills, and pain or tenderness where they got the infusion. Less than 1% of participants had symptoms that were severe enough to interfere with their normal daily activities. 3.5% of participants had a reaction like itching, a rash, or shortness of breath during or immediately after the infusion. These immediate reactions to the infusion did not last long and the participants who had them recovered without ongoing problems.

“The results from the AMP trials will be instrumental in the development of future trials testing combinations of the highly potent long acting bnAbs, under clinical development ” (Myron Cohen, AMP Protocol Chair).

iii) HVTN805/HPTN093: Antiretroviral analytical treatment interruption (ATI) to assess immunologic and virologic responses in participants who initiated ART in early HIV infection after having received VRC01 or placebo in HVTN 703/HPTN 081

This is an exploratory study of participants living with HIV undergoing an analytical treatment interruption after early initiation of antiretroviral therapy (ART) following HIV acquisition in the HVTN 703/HPTN 081 study, where they received VRC01 or placebo infusions. One participant has been enrolled to date on 09 June 2021. Majority of the seroconversion participants, which for the Botswana site totalled 6, are not eligible to enrol in the study due to timing of HIV diagnosis and the last infusion received whilst in the parent study (HVTN 703/HPTN 081). A total of 4 participants of the 61 expected have been enrolled globally. Follow-up visits are on-going.

B. ACTG STUDIES

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

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

REPRIEVE, which has been on going in Botswana since 2017, seeks to investigate if the use of a cholesterol lowering medicine (Pitavastatin) may reduce the risk of heart attack or stroke in HIV infected individuals. The study which has enrolled 7560 participants globally and 281 in Botswana, is currently in participant follow up phase and is expected to close in March 2023.

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

This study seeks to assess the efficacy and safety of Delamanid (a novel anti-TB drug) compared with Isoniazid (standard of care) for protection of high-risk Household Contacts (HHCs) against acquiring TB. The study aims to enrol 5160 participants globally over 3 years (MDR-TB index cases and their household contacts).

Since the study opened in 2019, Botswana has enrolled 11 participants out of its target of 300. Accrual has been challenged by a temporary pause in enrolment of households with children <18 years of age from Nov 2020 to April 2021. This was as a result of the occurrence neuropsychiatric adverse events in some children enrolled at other participating sites which led to a temporary pause in enrolments to allow for analysis of all Pharmacokinetic data and review of delamanid dosing options.

safety and tolerability of DLM over 24 weeks of study treatment. A total of 48 participants are to be enrolled globally, 10 in Botswana. To date 4 participants have been enrolled globally. No participants have been enrolled in Botswana to date. It has proven challenging to identify participants for this study due to low pediatric MDR-TB numbers in the country.

iv) IMPAACT 2017 - Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents.

The study seeks to confirm the dose and evaluate the safety, tolerability, acceptability, and PK of oral CAB, long-acting injectable CAB (CAB LA), and long-acting injectable RPV (RPV LA) among virologically suppressed HIV 1 infected children and adolescents aged 12 to <18 years.

The study envisions to enroll a total of 155 participants globally, 25 in Botswana and is expected to run for approximately 7 years. A total of 41 participants have been enrolled to date. Botswana has recently received IRB approvals and is yet to enroll into the study.

D. COVPN STUDIES

PI: Dr Joseph Moeketsi Makhema-MB.ChB, FRCP

i) CoVPN 5001: A prospective study of acute immune responses to SARS-CoV-2 infection

The study seeks to generate standardized datasets characterizing the quality, magnitude, and kinetics of humoral immune responses to SARS-CoV-2 infection in asymptomatic participants and symptomatic participants (both hospitalized and non-hospitalized). It also included characterizing

the innate and cellular immune responses to SARS-CoV-2 infection during infection with SARS-CoV-2 in asymptomatic and acutely symptomatic participants (both hospitalized and non-hospitalized). The Gaborone site enrolled the assigned 20 participants of the 806 globally enrolled from 54 sites across different continents. The first participant enrolled at site was on 17 February 2021. Recruitment sites included the different isolation centres in Greater Gaborone including Sir Ketumile Masire Teaching Hospital. The site achieved 100% retention of participants. The study is awaiting final results.



BHP Stakeholder Engagement Meeting to introduce CoVPN 5001 Study

PRINCIPAL INVESTIGATOR INITIATED RESEARCH PROJECTS

i) Birth Outcomes Surveillance Study (Tsepamo Study)

PI: Professor Roger L. Shapiro, MD, MPH

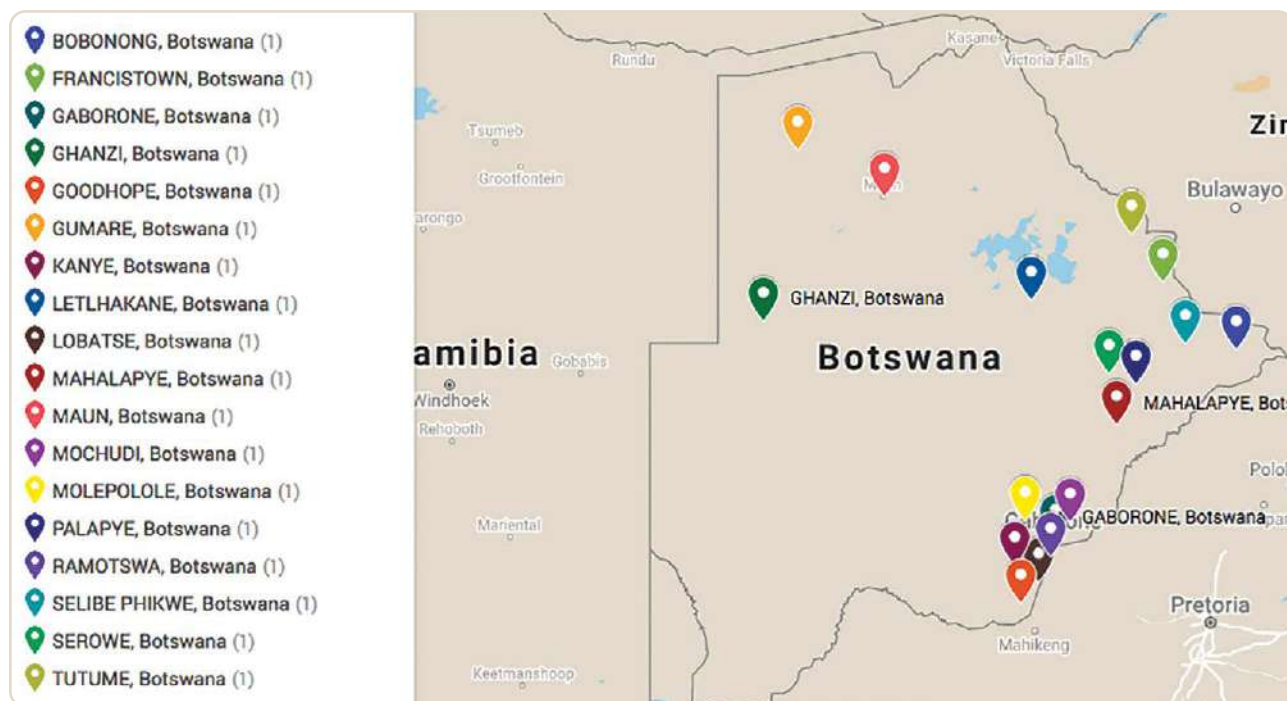
Tsepamo study is an observational surveillance of birth outcomes in maternity wards of 16 public hospitals scattered throughout Botswana. The primary objectives of the study include; comparing birth outcomes (stillbirth, preterm delivery, small for gestational age (SGA), congenital abnormalities and in-hospital neonatal deaths) among HIV-infected women and HIV-uninfected women, and initially, to determine whether there is increased neural tube defects among children born to women on TDF/FTC/EFV (Atripla). However, Dolutegravir was rolled out in mid-2016, allowing for its inclusion in comparative analyses. Data is extracted prospectively from obstetric records delivering mothers and where indicated, there is capturing of anonymous

photos of infants with congenital abnormalities. To date, 206 102 records have been captured out of a target of 250 000.

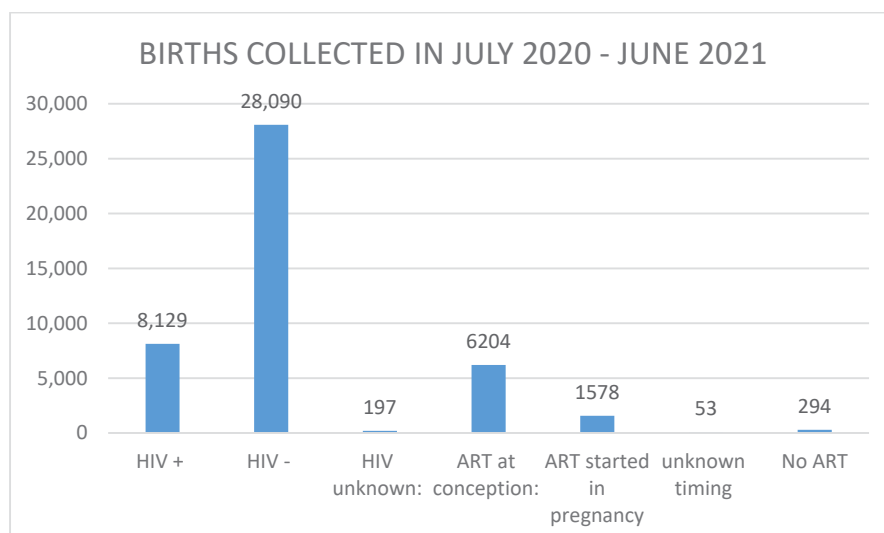
Geographical Distribution of the Tsepamo Sites

The map below shows all the 18 study sites that the study was in in the previous reporting period. However, due to the low birth rate at two sites, namely Bobonong and Goodhope, the number of sites captured in this reporting period is 16, representing about 70% of all annual deliveries in the county.

A total of 36 416 deliveries were abstracted in this reporting period and data analysis is ongoing. Two scientists presented at international conferences, 2 abstracts were accepted at international conferences, and 2 manuscripts were published. A further 2 manuscripts from junior local authors have been submitted and are pending publication.



Births collected from July 2020 to June 2021



ii) The AMBIsome Therapy Induction Optimisation (AMBITION-cm)

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



The AMBIsome Therapy Induction Optimisation (AMBITION-cm) trial investigated whether a single high dose of liposomal amphotericin-B (L-AmB, Ambisome) paired with two oral antifungals, fluconazole and flucytosine, was as effective as 7-day amphotericin-B based therapy in reducing deaths.

The trial recruited individuals from hospitals in five countries in Southern and Eastern Africa (Botswana, Zimbabwe, South Africa, Malawi, Uganda). Botswana site at Princess Marina Hospital contributed 85 study participants of the global enrollment of 844 adult patients with a first episode of HIV-associated cryptococcal meningitis. No participants were lost to follow up.

Study Findings

Trial results were announced at the 11th International AIDS Society (IAS) Conference on HIV Science on Wednesday 21, July 2021. The trial found that a single, high-dose of liposomal amphotericin B was as good as (“non-inferior”)

to the current WHO recommended standard of care for HIV-associated cryptococcal meningitis was much easier to administer, requiring just one intravenous infusion compared to 7 days with standard therapy. The liposomal amphotericin B regimen was also associated with significantly fewer drug related side effects such as anaemia, electrolyte abnormalities and intravenous line site infections. This regimen offers a practical, easier-to-administer and better-tolerated treatment for HIV-associated cryptococcal meningitis in Africa with the potential to reduce the length and cost of hospital admissions.

In line with the BHP’s mandate of capacity building, two early career researchers, with assistance from their mentors, received some awards from different funders.

- Nabila Youssouf was awarded a public engagement grant from the London School of Hygiene and Tropical Medicine to produce a biographical theatre play retracing an AMBITION-cm trial participant’s battle against cryptococcal meningitis (CM). The play, performed by a local dance group, will tackle HIV stigma, challenge enduring local beliefs that lumbar punctures kill with scientific facts, illustrate how cryptococcal fungus is handled in the lab, the working mechanisms of the medications used to treat the fungus and exemplify the potential recovery if medical attention is quickly sought, as was the case for our patient advocate. The play will be recorded by students in Media and Creative Arts at a local university, once COVID-19 protocol allow, to be screened

at various health-related events in schools, communities and stakeholder meetings around Botswana and the Southern African region.

- Charles Muthoga received a fellowship to attend the IAS 2021 virtual conference. Charles also completed an advanced course in ‘Decision modeling for health economic evaluation’ at the York Centre for Health Economics

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

PI: Professor Roger L. Shapiro, MD, MPH

Early Infant Treatment Study (EIT) is a single arm non-randomized clinical trial of early Antiretroviral Therapy (ART) in antepartum and peripartum infected children. In this study, HIV-exposed infants are tested at birth and, if HIV positive, they are offered antiretroviral therapy within 72 hours of birth.

The study seeks to determine whether very early ART initiation in HIV-infected infants limits the

seeding of viral reservoirs and maintains immune responses. The rationale for doing this study follows published literature that clearly shows that early infant HIV diagnosis and early initiation of antiretroviral therapy (ART) are critical in the global fight against HIV in children, as high mortality and rapid disease progression occur in untreated HIV-infected infants. The study is currently in extended follow-up phase until 2024.

The study findings have shown that a pediatric HIV treatment strategy starting NVP, ZDV, and 3TC in the first week of life and then transitioning to LPV-r, ZDV, and 3TC resulted in lower viral reservoir (Fig 2). The study findings also showed that negative serostatus and qualitative DNA were useful markers of sustained viral suppression from 24–84 weeks.

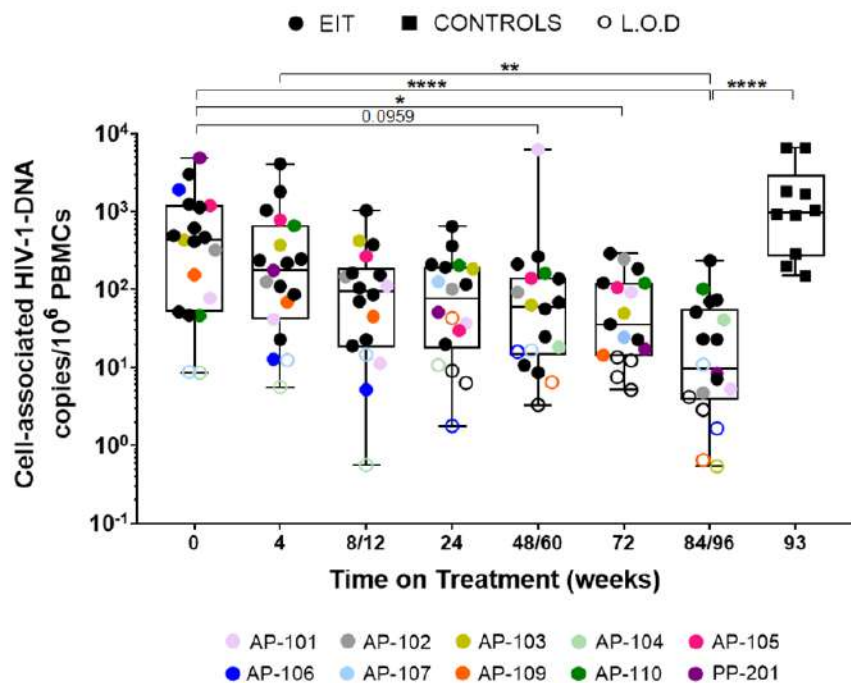


Figure 2

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

PI: Professor Roger Shapiro, MD, MPH

The Tatelo Study is an interventional clinical trial of dual treatment with two broadly neutralizing monoclonal antibodies (bNAbs), VRC01LS and 10-1074, in HIV-1 infected virally suppressed children. Non-Antiretroviral Therapy (ART) viral suppression strategies are a priority for children because of several factors including adherence issues with long-term ART use and accumulated toxicities to ART over time. Early-treated HIV+ children may be the ideal candidates for use of broadly neutralizing monoclonal antibodies (bNAbs) as an alternative to antiretroviral treatment (ART) because of their low HIV viral reservoir at enrolment and after 84 weeks of ART. The study enrolled HIV-infected children who were enrolled in the Early Infant Treatment (EIT) Study.

Primary Objectives:

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

Out of a total of 38 children enrolled into EIT, 29 (76%) of them met eligibility criteria and were successfully enrolled into Tatelo Study.

The study has maintained excellent retention (100%) over 2 years. Safety and Pharmacokinetics of Intravenous VRC01LS and 10-1074 in Young Children show that the two bNABs being studied were safe and well tolerated among children with HIV receiving ART. Further analysis aimed at responding to the study objectives is ongoing.

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

PI: Dr Jennifer Jao, MD, MPH.

Tshilo Dikotla study is a prospective observational study which enrolled pregnant women living with HIV (WLHIV) and HIV-uninfected (HIV-U) pregnant women, together with their infants. The study evaluates the metabolic effects of *in utero* and neonatal exposure to HIV medications in the first three years of life in HIV-exposed uninfected (HEU) children in Botswana.

The study is also investigating whether a specific signature of metabolites is predictive of adverse metabolic health such as insulin resistance or mitochondrial dysfunction using innovative

metabolomics techniques. The results of this study could impact current diabetes treatment and prevention strategies in HEU children and argue for further research to identify HIV medication regimens with superior efficacy in this group.

A total of 495 women were enrolled (Table 1). From these women, 466 infants were registered into the study after birth. The study has fully accrued and follow-up is expected to be completed by March 2022.

out of the study and 168 mothers provided informed consent for their participation and the participation of their 168 children for a total of 336 participants. As of 9-Apr-21, all follow-up visits have been completed with a 98% retention rate (Figure 1).

During this reporting period the international collaborators held some meetings to discuss preliminary results of the project and further analysis is ongoing. Two study clinicians received the IAS Educational Fund scholarship - 11th IAS Conference on HIV Science (IAS 2021).

vii) FLOURISH: Following Longitudinal Outcomes to Understand, Report, Intervene and Sustain Health for Infants, Children, Adolescents who are HIV Exposed Uninfected

PI: Kathleen M. Powis MD, MPH, MBA; Jennifer Jao, MD, MPH; Joseph Makhema, MB.ChB, FRCP

Started in December 2020, the FLOURISH study is evaluating short- and long-term health and development outcomes of children and adolescents with fetal exposure to HIV who have remained HIV-uninfected. The study is structured to identify possible biological, social and structural mechanisms for identified differences between children who are HIV-exposed uninfected (HEU) and those born HIV-unexposed uninfected (HUU). It also seeks to explore differences in outcomes among children who are HEU by the class of antiretroviral drug to which the child was exposed in utero.

Study Aims

- Establish a cohort of infants/children/adolescents who are HEU from birth through 17 years of age and a comparison cohort who are HUU.
- Evaluate differences in rates of infectious morbidity and all-cause mortality between children who are HEU and HUU up to 5 years of age.
- Assess whether HIV/antiretroviral (ARV) fetal exposure is associated with differences in neurobehavioral functioning among school aged (6-10 years) children who are HEU compared to those who are HUU.
- Assess for associations between HIV/ARV fetal exposure and cardiometabolic risk factors (central obesity, dyslipidemia, elevated blood pressure, and insulin resistance or impaired fasting glucose) in adolescents \geq age 10 using age, sex, and body mass index frequency matched individuals who are HUU as a comparator.

Figure 1 displays recruitment and cohort assignment breakdown for FLOURISH participants.

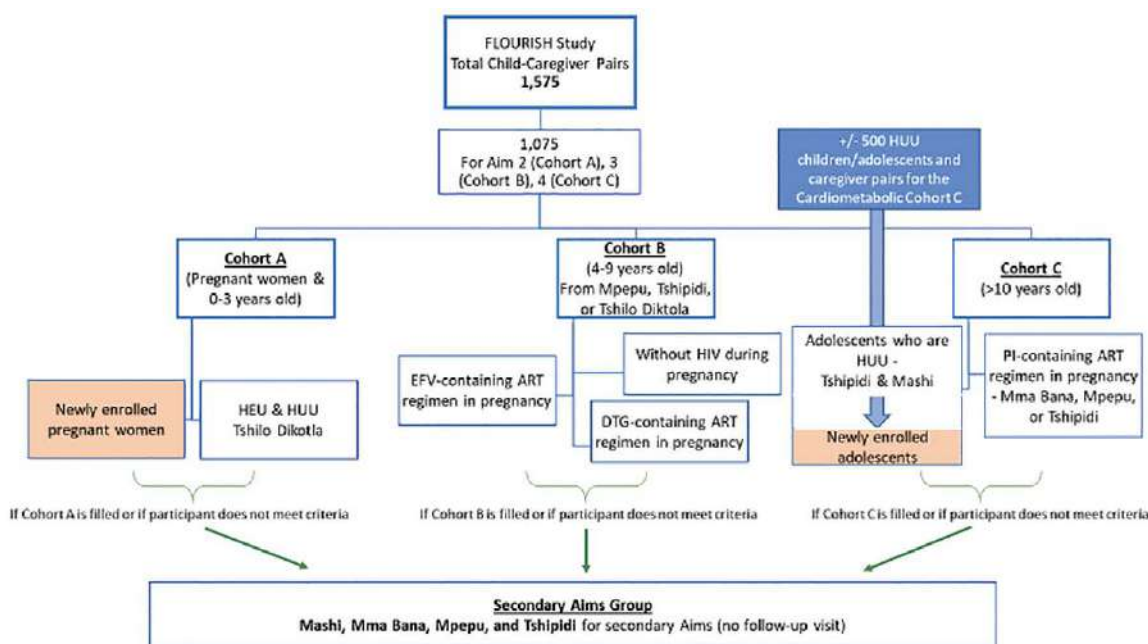
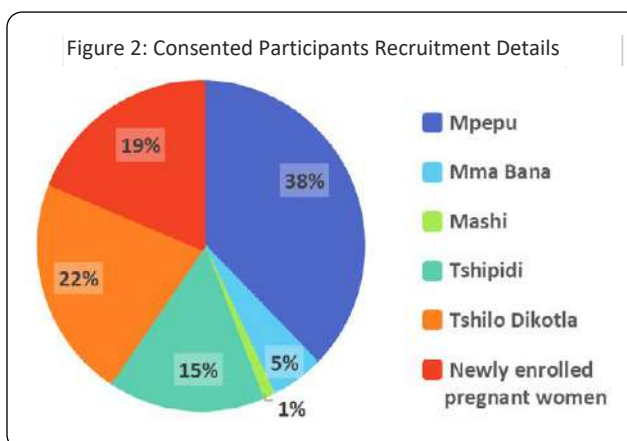


Figure 1: FLOURISH Cohorts

The study has leveraged on the BHP Maternal-Child Database and Document Archival System to identify mother-child/adolescent pairs and retrieve prior participant locator data to contact past study participants eligible for enrollment.

Study Recruitment and Retention

The first Caregiver-child dyad was consented on 30-Apr-21. As of 16-Feb-22, the FLOURISH study has consented 1,329 participants into the study, including 657 caregivers and 672 (accounting for siblings and twins). Consented participants breakdown is shown in Figure 2.



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

PI: Dr Scott Dryden-Peterson, MD, MSc

Chedza Study, which is in its second year of implementation, is a prospective, observational, implementation and effectiveness study which aims to assess if Contrast Enhanced Microholography (CEM) can be used for point-of-care diagnosis of Lymphoma and Breast Cancer in Botswana. The study goals include a) Assessing if CEM can permit accurate, near 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. Accrual has been completed with a total of 270 participants enrolled in the study since it opened in July 2019. The study is currently conducting follow up of participants and awaiting data analysis.

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

PI: Dr Scott Dryden-Peterson, MD, MSc

The Breast Cancer Magnetic Resonance Imaging (MRI) Study was opened in 2019 to evaluate the

effect of high-dose anthracyclines in patients with or without HIV that are being treated for breast cancer. Anthracyclines are cardio toxic and therefore patients undergo MRI at baseline prior to anthracycline-based chemotherapy and at 12 months after chemotherapy to evaluate for possible differences in cardiac changes following treatment by HIV status. The Gaborone site has enrolled a total of 25 participants from Gaborone Private Hospital and Princess Marina Hospital (13 HIV infected and 12 HIV non-infected). Seven (28%) participants have completed their MRI scans, two participants died before their second MRI scan while 16 participants have not had their second MRI as a result of delays in supplies of MRI electrodes due to COVID-19 restrictions. There have been no results published as yet.

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

PI: Dr Scott Dryden-Peterson, MD, MSc

Thabatse is a prospective cohort study that enrolls biopsy-confirmed cancer cases who present for specialized oncology care to evaluate the risk factors for cancer and describe the response to treatment for patients who are HIV positive and not on Antiretroviral Therapy (ART) and those on ART. Out of a target of 6500 participants, the study has enrolled 5197 participants from four Oncology Centres (Princess Marina Hospital, Nyangabwe Referral Hospital, Bokamoso Hospital and Gaborone Private Hospital).

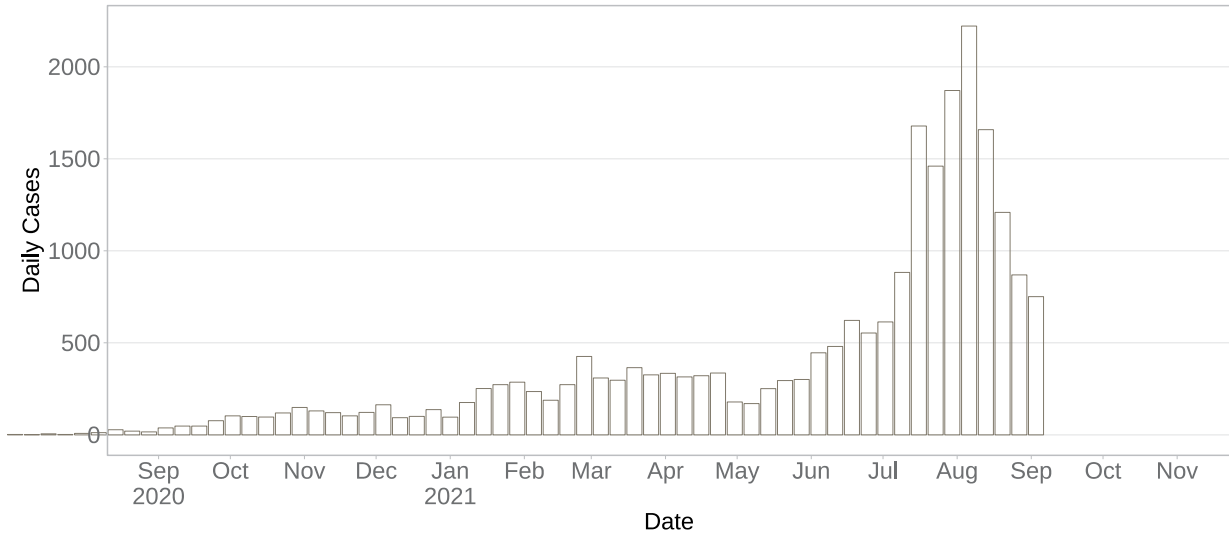
Households with Covid-Like Illness, Botswana

Last household call: 2021-09-06 | 3-week running average, 90% confidence limits



Daily Covid-19 Diagnoses, Botswana only

Last data release: 2021-09-03



Source: Weekly data through Fridays as released by Covid-19 Task Force
 Note: Delayed reported cases on 23 April 2021 distributed to preceding 3 weeks for interpretability

The Thabatsse team, in response to the emergence of SARS-CoV-2 in Botswana March 2020, decided to conduct weekly Covid-19-like illness surveillance on the study participants and their household members to assess for the presence of COVID-19 symptoms, and provide counseling and linkage to care for testing. To date, total of 7107 calls have been made to 2207 participant households. Of these households, 232 (10.5%) reported active COVID-19-like symptoms during at least one phone call and 319 (14.5%) households had a confirmed COVID-19 case during the follow-up period. This COVID-19-like illness surveillance can be used to augment understanding of regional epidemic intensity and guide decisions.

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

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

Potlako + is a cluster randomized study that evaluates the impact of a multicomponent intervention in achieving earlier diagnosis and treatment initiation of cancer in 20 communities in Botswana. The study works with the community leadership, (dikgosi, community associations, clubs and Village Development Committees

(VDCs), District Health Management Teams (DHMT's) and health facilities in the 20 study communities to:

- a) Support patients in navigating the health system by providing transport support and clinic appointment reminders
- b) Support health system through better coordinated and algorithm-based referrals, bookings and follow up of pathology results and
- c) Produce patient based educational materials and conduct campaigns to sensitize communities about signs and symptoms of targeted cancers.

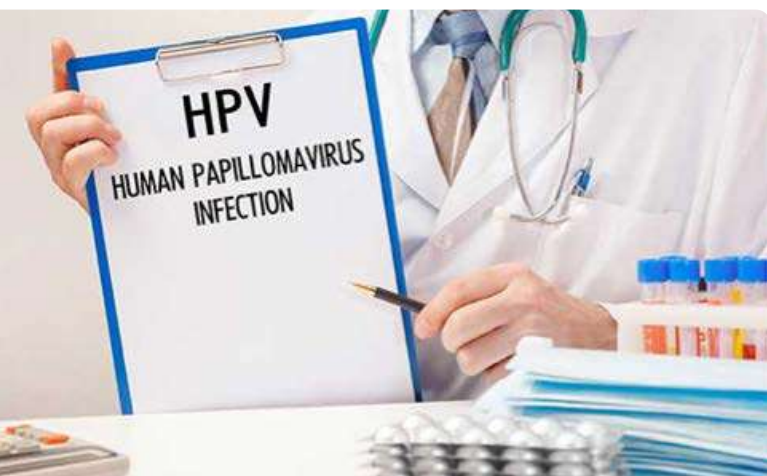
In November 2020, the project trained 179 health care workers; both nurses and doctors, from facilities in study communities and their immediate referral points on early cancer diagnosis. The study aims to recruit 1500 cancer suspects and 400 confirmed cancers. A total of 169 cancer suspects have been enrolled and recruitment is ongoing. The enrollment is rather slow mainly due to travel and gathering restrictions due to covid-19. Facility support and community education activities have been negatively impacted by these restrictions. There is no data analysis at this stage.



Nata Community Leadership at the BHP Cancer Awareness Campaign

xii) Human Papillomavirus (HPV) Cervical cancer screening study

PI: Dr Rebecca Luckett, MD, MPH



The HPV cervical cancer screening study was started in 2018 with the aim of improving cervical cancer screening by evaluating cancer screening algorithms using primary high-risk HPV testing followed by acetic acid and colposcopy in women living with HIV in Botswana. The study recruited 300 women from Princess Marina Hospital in 2018.

Findings from the initial cohort of 300 women paved the way for expansion of the study to include a larger cohort of 3000 women with or without HIV in South East District, over a period of 3 years (October 2019 – September 2022). The expanded study will evaluate new technologies for triaging women who are HPV positive and identify an optimal screening strategy for all women in Botswana. The new triage strategy called automated visual evaluation is designed

to be used at the point-of-care and is easy to use in low-resources settings as it requires little infrastructure and may be a suitable alternative to either colposcopy or visual inspection with acetic acid.

Recruitment into the expanded study began in February 2021, due to delays caused by COVID-19 pandemic. A total of 1007 women have been enrolled into the study to date.

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

PI: Dr Chelsea Moroni, MD, MPH, PhD

The STI study is a cohort study among antenatal patients to determine the burden of gonorrhoea and chlamydia among asymptomatic pregnant women in Botswana. The study seeks to investigate the impact of gonorrhoea and chlamydia testing to prevent vertical transmission and associated adverse neonatal health outcomes.

Most countries, including Botswana, utilize the syndromic approach to classify symptoms into STI syndromes and provide standardized treatment. Syndromic management lacks specificity and sensitivity which can result in pregnant women being unnecessarily exposed to antibiotics and asymptomatic infections are often missed, putting neonates at risk. This study could inform policy changes to improve management of STIs during antenatal care and improve maternal and neonatal outcomes.



Research Assistant, Kehumile Ramontshonyana, using the Gene Xpert Platform to test a specimen for Chlamydia trachomatis and Neisseria gonorrhoea.

Recruitment began in March 2021 and 98 out the target of 500 participants have been enrolled. Recruitment of more participants is ongoing.

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

PI: Dr Chelsea Moroni, MD, MPH, PhD

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

Provision of contraception is complicated in high HIV prevalence settings due to proven drug-

drug interactions between some anti-retroviral therapy (ART) agents and hormonal methods. Dolutegravir (DTG) is highly effective in managing HIV and is a WHO recommended first-line agent. However, thus far, there is little data on the effect of DTG on hormonal contraception. Rigorous and complete evidence on the risk of drug-drug interactions between hormonal contraceptives and DTG is urgently needed to inform local and international guidance. The CODA Study is funded by ViiV Healthcare, and is preparing for enrolment.



COVID-19 testing

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

PI: Professor Mosepele Mosepele, MD, MSc

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

The study's objectives are:

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

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

PI: Professor Mosepele Mosepele, MD, MSc

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

1. Describe the prevalence and longitudinal changes in albuminuria over a 12-month period among treated HIV-infected adults overall, and in relation to the use of ACEI/ARB
2. Describe the association between albuminuria and inflammation among treated HIV-infected adults overall and in relation to the use of ACEI/ARB

3. Create a human bio-repository and HIV-CVD outcomes clinical registry for the study of long-term clinical outcomes of albuminuria.

The EDCTP-sponsored study commenced enrolment in January 2020 and accrual was completed in January 2021. A total of 1537 participants were enrolled. Data analysis is ongoing.



Urine Albumin testing

xvii) Mopati: A Pilot HIV Treatment Partner Intervention in Botswana

PIs: Professor Mosepele Mosepele, MD, MSc & Laura Bogart PhD

Botswana has one of the highest HIV prevalence in the world. As a result, low-cost, scalable interventions are essential to support people living with HIV to adhere to antiretroviral treatment (ART) and remain in care. One such intervention is the use of treatment partners, which are recommended by HIV treatment guidelines in at least 20 countries worldwide. Specifically, national HIV policies of several countries, including Botswana, recommend that healthcare providers encourage patients initiating ART to identify an individual who can provide support, accompany patients to appointments, and provide medication reminders.

Mopati Study is implementing a multi-level intervention that guides healthcare providers and patients about treatment partner selection and trains treatment partners on provision of effective support. It presents a unique opportunity to examine ways to improve ART use in practice and has relevance for both HIV- care as well as healthcare for other conditions (e.g., diabetes, tuberculosis) that require strict adherence.

Mopati Study is recruiting 160 treatment partner pairs (80 intervention and 80 control). To date, 35 pairs have been enrolled (13 intervention and 25 control). A total of 9 treatment partner training sessions have been conducted for the intervention group.

xviii) Acceptability and Feasibility of COVID-19 Screening and Testing Among Workers and Businesses in Gaborone, Botswana

PIs: Dr Nabila Youssouf PhD; Laura Bogart PhD and Mosepele Mosepele, MD, MSc

The general objective of the study is to explore the acceptability and feasibility of COVID-19 testing among workers and businesses in Gaborone, Botswana and to acquire feedback about potential interventions to further respond to this evolving crisis in the workplace. The study aims to conduct qualitative work to explore

the knowledge, experiences and attitudes on COVID-19 testing.

100 workers from various industries around Gaborone were asked questions on their understanding of the virus, their knowledge on transmission and prevention methods, their opinions on the government measures and responses to the virus and the impact of such measures on their industries. The study also



BHP staff geared up for Covid-19 testing.

explored their thoughts on what can be done to improve the screening and testing approaches that are currently in place.

The study started in September 2020 and conducted 30 face-to-face interviews with workers and two focus group interviews of 8 workers and 7 workers respectively. Data collection has been completed and data analysis is ongoing.

This project will help to understand the impact of the pandemic on workplace dynamics and provide insights on the contextual factors such as underlying values, beliefs and assumptions, to guide actions and future policies.

xix) Exploring the Acceptability and Feasibility of COVID19 Testing among Truck Drivers in Botswana

PIs: Nabila Youssouf PhD; Laura Bogart PhD and Mosepele Mosepele MD, MSc

Truck drivers have been regarded as the major vector for COVID-19 transmission as border testing in most countries has shown a high number of cases among this population. Truck drivers in Botswana show relatively high levels of COVID-19 prevalence and grievances on COVID-19 testing. The study was conducted in partnership with health officials at the borders to understand the acceptability of COVID-19 testing among truck drivers in Botswana. The

study used a qualitative data collection strategy, using survey and interviews to explore COVID-19 testing knowledge, perceptions and attitudes among truck drivers entering Botswana. Findings from the study could help inform the response to the COVID-19 testing approach and be scaled up across other sectors of the population.

The study started in September 2020 and has conducted 30 face-to-face interviews with truck drivers and one focus group interview consisting of 8 truck drivers. Data collection has been completed and data analysis is ongoing.



Many Border Gates experienced long queues of trucks transporting essential supplies during lockdowns as truck drivers were being tested for COVID-19 before entry.

xx) Innovative HIV Testing Strategy for Middle-to-Upper Income Men in a Resource-Limited Setting

PIs: Prof. Mosepele Mosepele MD, MSc, Laura Bogart PhD

In Botswana, men over age 40 show relatively high levels of HIV prevalence and risk behavior, and low levels of HIV testing. Moreover, higher income is associated with increased risk of being HIV-positive in sub-Saharan Africa. It is essential to develop differentiated, tailored approaches for risk groups, such as men of relatively higher socio-economic status (SES), that are untouched by existing prevention and testing frameworks in countries of high HIV prevalence.

The research utilizes a mixed methods approach to develop an intervention that de-stigmatizes and encourages HIV testing among men of middle-to-higher socio-economic status in Gaborone, Botswana. It focuses on increasing HIV testing among men of higher socio-economic status.

Study Objectives

1. To initially conduct formative qualitative work to explore the role of stigma on low HIV testing uptake among 20 men via face-to-face interviews, and then to obtain feedback about potential interventions using asynchronous online focus group discussion among 40 men all with relatively high socio-economic status (SES) in Botswana.
2. To develop and conduct a small pilot test of a local, culturally appropriate HIV testing strategy targeting 100 men in the higher-SES in Botswana.
3. To build capacity for HIV stigma and related behavioral research by conducting focused workshops in Botswana.

The study started in January 2020 and has enrolled 32 participants from local banks.

xxi) Integrating Hypertension and Cardiovascular Diseases Care into Existing HIV Services Package in Botswana (InterCARE Study)

PIs: Prof. Mosepele Mosepele MD, MSc, Tendani Gaolathe BS, MD, Kathleen Wirth Hurwitz

People living with HIV (PLWHIV) are twice as likely to develop cardiovascular (CVD) disease. Almost 1 in 4 PLWHIV in Botswana have hypertension (HTN), making it one of the leading CVD risk factors in this population. In a recent hypertension study nested within the Botswana HIV Combination Prevention Project (BCPP, a study of 30 matched-pair villages indicating that a combination of HIV prevention measures significantly reduces HIV incidence), only 46.0% of PLWHIV were aware of their hypertension, and 42.0% of those aware were on treatment—with 44.0% of those on medication attaining blood pressure control, resulting in only 19.0% of all hypertensive PLWHIV having attained blood pressure control.

The InterCARE study proposes the adaptation and testing of strategies to effectively integrate evidence-based interventions (EBI) into HIV care to improve the hypertension cascade of care (awareness, diagnosis, treatment, control) and

general cardiovascular disease (CVD) risk factor knowledge, diagnosis and treatment using a late-stage T4 implementation research hybrid type 2 study design.



The InterCARE study is divided into 2 stages:

1. The pilot is being implemented in 2 clinics to check whether the proposed interventions are feasible and if they improve

cardiovascular outcomes for participants. The pilot started in March 2020 and is due to end in December 2022.

2. A larger randomized trial where the InterCARE protocol and procedures will be rolled out to 10 clinics around Botswana from January 2023 to end of 2025.

Achievements:

- An Implementation Research Workshop was held in March 2021 with Professor Lisa Ruth Hirschhorn (NWU) delivering online training to the InterCARE team and stakeholders to ensure a common understanding of this relatively new field.

- The InterCARE team has completed pre-implementation surveys of patients, their treatment partners and healthcare workers. This work will feed into the next phase of the pilot, as the interventions are being rolled out.
- Ponego Ponatshego has been elected Chair of the Capacity Building Committee.
- Nabila Youssouf has been elected Chair of the Project Operations Committee and Vice-Chair of the Risk Management Committee.
- Ernest Moseki has been elected Chair of the Community Engagement Committee.

xxii) Prevalence and outcomes of the usage of lumbar puncture in patients who presented with central nervous system symptoms at Princess Marina Hospital during the period 01/01/2014 to 31/03/2021

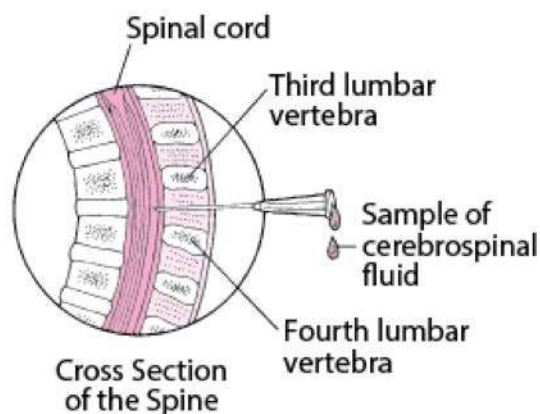
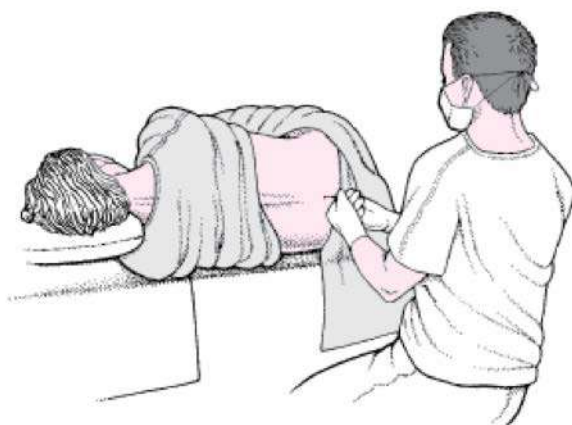
PIs: Nabila Youssouf PhD, Mosepele Mosepele MD, MSc, Sara Schwanke Khilji MD, MPH, FACP

Diagnostic evaluation for Central nervous system aetiologies should include a lumbar puncture in order to verify the diagnosis. Meningitis, most commonly cryptococcal meningitis, is a major cause for mortality in Sub-Saharan Africa. The survival rate for patients with meningitis drastically increases with appropriate treatment.

This study is a retrospective review of all patients who presented to princess Marina Hospital with

central nervous system aetiologies from January 2014 to March 2021. The objective of the study is to determine the prevalence of the usage of lumbar puncture and compare outcomes in patients who present with neurological symptoms of the patients who received a lumbar puncture against those who did not.

The study started in June 2021 and is reviewing all the records for patients admitted with central nervous symptoms in Princess Marina Hospital from January 2014 to March 2021. Data from 14 records have been reviewed and collected for study data. Data collection is ongoing.



xxiii) Neurodevelopment In HEU Children Exposed In Utero To Dolutegravir or Efavirenz and HIV-Unexposed Children (Motheo Study)

PIs: Shahin Lockman MD, MPH & Dr Adam Cassidy

This is a longitudinal observational cohort study that will, over a 1-2 year period, prospectively enroll three new cohorts of children (aged 2 years at enrollment and followed till they are 5 years old) and their mothers in Botswana and follow children’s neurodevelopmental and social-emotional outcomes and mothers’ mental health and sleep status in 560 mother-child pairs consisting of :

- 200 HEU children previously exposed in utero to EFV/TDF/XTC and their mothers (XTC indicates either 3TC or FTC);
- 200 HEU children previously exposed in utero to DTG/TDF/XTC and their mothers;
- 160 HUU children and their mothers.

The primary objectives of the study are:

1. To assess developmental outcomes (neurodevelopment, psychosocial) at 2 years of age in HEU children exposed in utero to DTG/TDF/XTC (N=200); EFV/TDF/XTC (N=200); and community controls without HIV or ARV exposure (N=160), and compare outcomes between groups.
2. To assess and compare developmental

outcomes in the same children at 5 years of age. Further deterioration of 2-year deficits would be expected at 5 years; and, evaluation of children during the early childhood period will allow us to more comprehensively examine a range of cognitive and self-regulatory capacities, including emerging core executive function skills (i.e., inhibitory control, working memory, and shifting/flexibility) that are recognized as critical for future achievement, independence, and resilience.

3. To assess the presence/severity of depressive symptoms, anxiety symptoms, and sleep problems in the mothers of participating children. Results of this aim are relevant to millions of women on ART globally, and are also important for analyses of child outcomes, as maternal mental health affects child development.

The study opened to accrual on the 12th March 2021 and by the end of June 2021 the study had enrolled 14 mother-child pairs. There have been significant delays in starting the study mainly due to delays in HRDC approving the project. To add on this, Covid-19 related study interruptions are negatively impacting on the rate of recruitment and enrollment.

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

PI: Lisa Butler, MA, MPH, PhD

Monana Ke Isago Study is an intervention development study. Its aim is to develop, and pilot test a novel multi-component community-based adolescent-friendly intervention for mental health care designed with and for pregnant adolescents and new mothers aged 15-19 years old in Botswana. Participant enrollment started on 11th November 2020 and was completed on 4th March 2021 with 34 participants enrolled.

This study, just like others, faced serious challenges due to the Covid-19 gathering restrictions. The study procedures centered on group interviews and these had to be delayed



or cancelled on several occasions hence the low enrollment achieved.

xxv) Mitigating the COVID-19 effects on adolescent sexual and reproductive health through self-testing: a mixed methods pilot study (ICHECKE!)

PI: Lucy Mupfumi, PhD

Young people in sub-Saharan Africa face considerable barriers to access to sexual and reproductive health (SRH) services that have been exacerbated by the COVID-19 pandemic, resulting in reduced screening rates for HIV/STIs and access to contraceptives since the start of the pandemic. The ICHECKE! study aims to mitigate against these barriers in the short- medium term through the introduction of a self-care model for SRH care among young adults in Botswana. Specifically, the study will pilot self-testing for HIV/Syphilis/HBsAg/HCV enabling young people to conduct the test from a single finger prick with results available within 10 minutes. The study will recruit 200 young people aged 18-24 years. In-depth interviews will be conducted with 20 young people and 5 healthcare providers to understand the current barriers to SRH access and the acceptability of self-testing for HIV and STIs by young people. This proposed pilot is nested within a larger planned trial on improving access and uptake of SRH services among young people in Botswana. The study is conducted in collaboration with the Botswana Family Welfare Association (BOFWA),



London School of Hygiene & Tropical Medicine (LSHTM) and Bielefeld University, Germany. Enrolment started in July 2021 and it is ongoing.

The study's objectives are:

- To determine the effectiveness of a self-testing approach to HIV and STIs by young people in Gaborone, Botswana.
- To determine the barriers to SRH services by young people in Gaborone, Botswana.
- To determine the acceptability of self-testing by young people in Gaborone, Botswana.

RESEARCH SUPPORT

i) Clinical Laboratory

The Botswana Harvard HIV Reference Laboratory (BHHRL) supports the clinical trials conducted by the Botswana Harvard AIDS Institute Partnership (BHP). There is a Clinical Trials Unit that provides a vital interface between Clinical Trials and entire BHHRL. In 2020-2021, BHHRL continued to provide the needed coverage for all the clinical trials at BHP. BHHRL continued to maintain its approved status in conducting clinical trials supported by the US National Institutes of Health. The laboratory also maintained its accreditation to ISO 15189 through the Southern African Development Community Accreditation Service (SADCAS). This represents international recognition of quality and competency in all aspects of our medical laboratory services. The lab successfully added SARS-COV-2 to the accreditation scope and also received certification from the African



Laboratory Scientists at the COVID-19 lab section

Society for Laboratory Medicine (ASLM) for covid testing under the COVID-19 Laboratory Testing Certification Program (CoLTep).

BHHRL has the competencies and capacity, through the in-house expertise available, to do numerous clinical tests and procedures. These



Laboratory Scientists busy at the Lab

include: Processing and Accessioning, Inventory and Archiving; Clinical Chemistry, Hematology, CD4, Viral load, Diagnostic DNA PCR, HPV PCR, Chlamydia and Gonorrhoea, HIV Drug Resistance; Serological Assays including fourth generation HIV ELISA, Hepatitis B profiles, Hepatitis C Antibody, Syphilis RPR and TPHA, HIV-1 confirmatory assays (Geenius), Incidence Assays [Limiting Antigen, Avidity, Bio-rad Avidity and BED capture enzyme immunoassay], QuantiFERON TB Gold Plus assay, Cepheid Point of Care Viral load, Gene Expert TB and SARS-CoV-2 testing. Several research assays in-house or through referral laboratories are available including TB (AFB, Molecular, culture and Drug Sensitivity), Cytology/Histology, and inflammatory cytokines. The laboratory has registered all assays in External Quality Assurance (EQA) programs and the EQA performance has been satisfactory in all tests during the past year. Specimen volumes received in the laboratory were fairly stable over the year. However, the nature and type of visits were increasing in processing intensity and complexity, for instance, the lab has seen an increase in pharmacokinetics sampling and PBMC isolation.

The BHHRL has been crucial in fight against the SARS-CoV-2 pandemic which has been a highlight achievement for the laboratory. The lab added a number of new assays to its test menu including the acquisition and validation

of the automated serological assays for HIV, Hepatitis, Syphilis and SARS-COV-2. The lab also developed capacity to do SARS CoV-2 testing for which on average of up to 800 tests are run per shift. BHHRL has contributed approximately 30% of the 1.9 million tests so far conducted in Botswana.

The HIV confirmatory testing was transitioned from the western blot assay to Geenius assay, that is differentiate between HIV-1 and HIV-2 as well provide confirmatory testing for HIV.

The laboratory's success in providing support to both clinical research projects and the national programs does not come without challenges. At the top of the list is the infrastructure of the lab building itself. There is inadequate space for the current workload. Additionally, the building is over 20 years old and it is now showing multiple structural defects that will need major repairs. The same applies to equipment, more especially the long-term sample storage freezers. The SARS-CoV-2 pandemic has resulted in delays in transportation of goods, both locally and internationally, and this has lead to frequent stock-outs of reagents and other supplies.

ii) Regulatory Office

Regulatory Office remains integral for the conduct of research studies at BHP. The office is mandated to support studies in continuous quality assurance activities and monitor compliance. This was fulfilled through Study activations, ensuring that studies meet all the regulatory requirements before start-up and continuous internal monitoring activities.

In the current reporting year, there were about 73 studies, 48 (66%) of which are ongoing 20 new (27%) and 5 (7%) closed out with Institutional Review Board (IRB) after satisfying requirements for closure (figure 1).

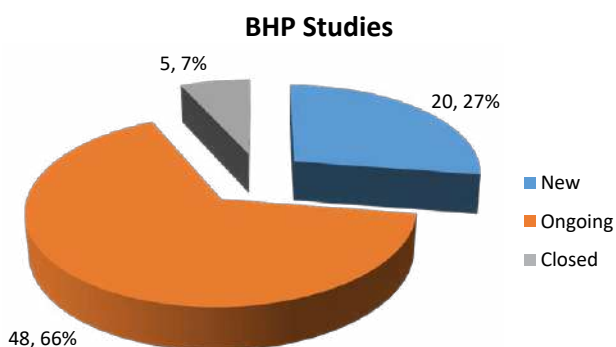


Figure 1: BHP Studies

During this reporting period, a total of 7 new protocols under Clinical Trials Unit (CTU) were approved; (IMPAACT 2017, IMPAACT 2026, IMPAACT 2028, A5375, A5401, A5356, HVTN 805/HPTN 093, CoVPN 3008).

iii) Community Engagement

Community Stakeholder Engagement ensures transparency, respect and builds trust between researchers and communities and other stakeholders. During this reporting period Community engagement has had to utilize alternative engagement strategies such as online meetings and/or larger venues to adhere to social distancing requirements due to COVID-19 pandemic. Additional resources such as laptops and monthly Internet allowance to members of the Community Scientific Sub-Committee (CSS) were provided by the ACTG to facilitate this.

New CTU Protocols

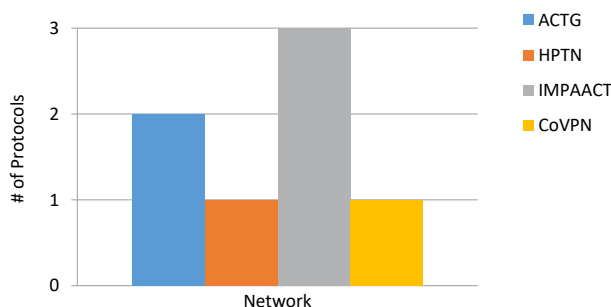


Figure 2: New CTU Protocols

Non-Network COVID-19 Submissions

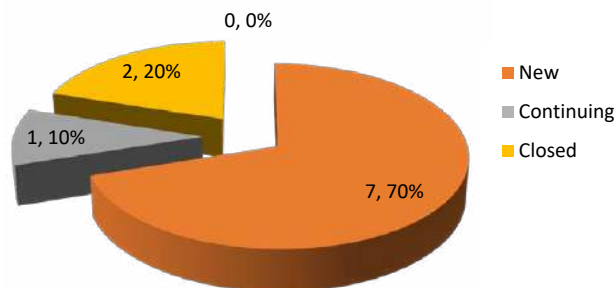


Figure 3: Non-Network COVID-19 submissions

Capacity Building

In terms of building capacity, with support from TESA, one of the staff members was trained on Basic Clinical Research Monitoring Course on the 24th-28th August 2020.

In-Person Outreach Activities/Meetings

Town/Village	Number of Meetings	Project
Gaborone	3	COVID-19 Surveillance
Jwaneng	4	COVID-19 Surveillance
Hukuntsi/Kang	3	COVID-19 Surveillance
Tsabong	4	COVID-19 Surveillance
Greater Palapye	2	COVID-19 Surveillance
Kasane	2	WHO COVID-19 Case Finding
Francistown	3	WHO COVID-19 Case Finding
Gaborone	1	CoVPN 3008
CAB Meetings	8	Various projects
Potlako + Communities	20	Potlako + project

Committee Membership

There have been seven new appointments to different committees, which included the BHP Community Engagement coordinator and five members of the BHP Community Advisory Board (CAB).

Manuscripts in development

1. COVID-19 personal experience - Stigma
2. HPTN084 Community Engagement in the Midst of COVI-19 Pandemic

iv) Pharmacy

BHP Pharmacy department has two units being the clinical trials pharmacy and the retail pharmacy. Over the reporting period this units have expanded their services. The clinical trials pharmacy unit is a multiple protocol and multiple site support unit.

The BHP clinical trials pharmacy unit has clinical trial standard pharmacies set up in Gaborone, Molepolole and Francistown. It serves multiple protocols mostly from the CTU trials and also from BHP investigator-initiated trials that have investigational product. The unit serves close to 500 study participants on a monthly basis across the different studies. For this reporting period the BHP pharmacy has grown to handle regulatory and investigational products for BHP collaboration studies with external partners like WHO Solidarity trial where collaboration was between BHP and World Health Organization through the Sir Ketumile Masire Teaching Hospital (SKMTH). Also, due the COVID-19 pandemic the department is working with a lot of complex molecules as investigational products that demand specialized processes and intense storage condition requirements that has lead to improvements in the pharmacies.



BHP Pharmacy Coordinator, Tshepo Frank Klass checking study product for IMPAACT 2008 protocol. The medication is kept in temperature-monitored fridges.

The BHP retail pharmacy unit, which is a BHP subsidiary trading as Sesikalla Investments (Pty) Ltd, has seen growth also in this reporting period. Sales have progressively grown from month to month due to the great working relationship of

in question. For example, the development of an electronic data capture (EDC) system that is synchronized centrally in real or near real-time for upcoming AZD 1222, Astra Zeneca Vaccine Efficacy study which is a multi-site study. Connectivity in some of the sites is poor and the department will ensure that data can be captured off-line and pushed to the central server at the end of each day. The other introduction was the development and implementation of the short message service (SMS) module for sending reminders to study participants. Also new is the addition of an archiving functionality to the EDC allowing for study data to be archived electronically as the study is still running, thereby

avoiding retrospective document archiving after the end of the project, a process that has proven to be both time consuming and costly.

The SE & DMC department continues to host REDCAP and with this, a number of small studies are being supported. Finally, in order to support operations, the department developed a 'utility system' with the goal of allowing office automation of some of the processes within the organization. These include management of time sheets for employees, contract management, and procurement, Grants management, and departmental staff budget management are still in development.

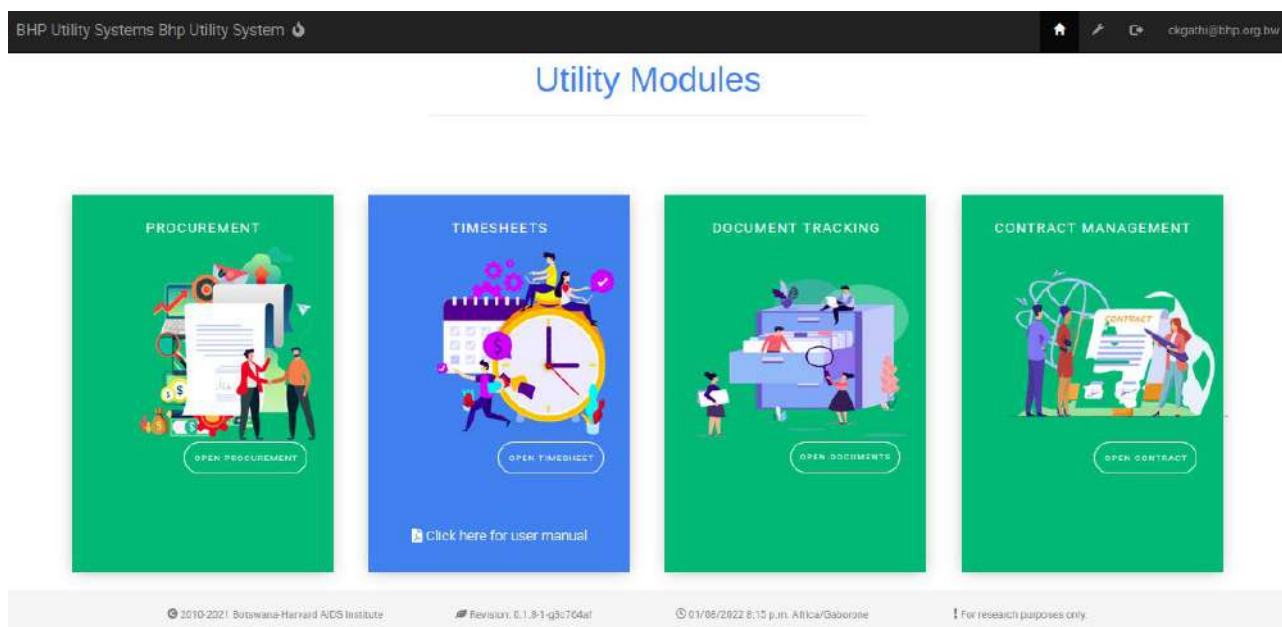


Figure 1: Utility system landing page

One of the major challenges of the department is loss of key staff who have requisite experience in the specialized work that we do. This leads to lots of time spent in training newly recruited replacement staff, ultimately leading to loss of man-hours in the actual programming work. It

has been the intension of the department to setup a graduate trainee program in software development so that newly graduated individuals could get exposed to working in a research environment.

vi) Information Technology (IT)

The IT department is responsible for hardware support, managing BHP systems, network management and computer support for end users across the entire organization. The overall goal is to provide a stable and secure computing environment that's aligned with industry best practices. IT support is, more than ever, very critical to BHP at these times of covid-19 pandemic

where electronic communication is order of the day. Unfortunately, hackers have identified this as an opportunity for them to disrupt organizations' information systems. The department has built a data centre that runs on virtualized infrastructure and it aims to keep up with emerging technologies that are aligned with keeping the computing environment of BHP secure.



11. CAPACITY BUILDING AND TRAINING

I) RESEARCH LABORATORY

The BHP research laboratory is a vibrant group of research fellows at various stages of training working on projects that are of public health importance in Botswana, the region and globally. The group works under the supervision of Dr Simani Gaseitsiwe, Dr Sikhukile Moyo and Dr Rosemary Musonda. Dr Motswedi Anderson who recently received a couple of grants, one from Wellcome Trust and another from Africa Research Excellence Fund (AREF) as Principal investigator takes a central role in pushing the viral hepatitis research agenda at BHP. The group also boasts of international collaborators who assist in the supervision of fellows working on areas where there is limited capacity at BHP. The fellows are registered with various academic institutions including University of Botswana (UB), Botswana International University of Science and Technology (BIUST), Stellenbosch University, 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, Noroviruses and Sapoviruses, and HPV molecular epidemiology. The fellows are supported by various grants including, SANTHE, Fogarty, H3ABioNet and TESA II.

Active Capacity Building Grants

TESA II
SANTHE
H3BIO
Welcome Trust
Fogarty D43
Fogarty HBNU

TESA II

The overall aim of TESAII is to develop, strengthen and expand clinical research capacities in the southern African region through the consolidation of the TESA nodes of excellence for conducting clinical trials. The consortium focuses on conducting high quality research on infectious diseases with the most severe morbidity and mortality in the region. TESAII has identified a framework of core capacity development activities which will take place within the larger context of the clinical trials in TB, HIV and malaria to be managed by the network. TESAII established three referral laboratories (TB, HIV and Malaria) to serve as training platforms for the less experienced members of the network. BHP is recognized as a reference lab for HIV and will offer training in HIV drug resistance and other related techniques. Through the TESAII grant, 3 staff members were supported for postgraduate studies at University of Botswana

and Stellenbosch University in South Africa while others were supported to attend short-term trainings such as Good Clinical Laboratory Practice, Biostatistics, HIV drug resistance and bioinformatics. TESAII grant came to an end on 31st August 2020 and had a no cost extension which ended on 28th February 2021.

Highlights of Projects in the Reporting Period

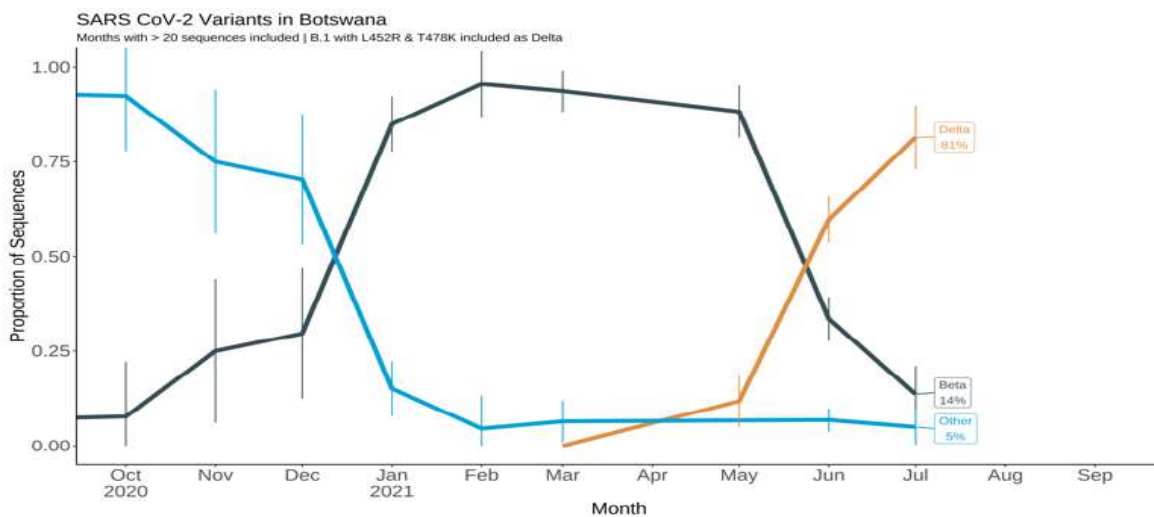
- Genomic Surveillance of SARS-COV-2
- Analysis of Drug Resistance in Low-level viremia
- Compartmentalization of HIV
- Pediatric Drug Resistance
- Prevalence of Hepatitis B virus the population-based household surveys
- Drug Resistance among Highly Treatment experience individuals
- HPV diversity

Genomic Surveillance of SARS-COV-2

BHP through the Botswana Harvard HIV Reference Laboratory played an important role in Botswana’s COVID-19 response and the genomic surveillance of SARS-CoV-2 in Botswana. BHP initiated genomic surveillance of SARS-CoV-2 in support of the Ministry of Health and Wellness (MOHW) and the Botswana Presidential Taskforce on COVID-19’s efforts. As of June 30, 2021 BHP had completed 254 SARS CoV-2 whole genome sequences and 141 were deposited in GISAID.



Laboratory Scientists working on Genomic Sequencing of the SARS-CoV-2



BHP was able to track proportion of variants of concern in circulation in the country. By the end of June 2021, the Beta variant (B.1.1.351 or 501Y.V2 first detected in South Africa) was at 82% of new genomes sequenced. As of 13 May 2021, the BHP laboratory detected the first case of B.1.617.2 (Delta) in Botswana, from a traveler from India. This was part of cluster investigation with immediate public health implications. The Delta variant has spread rapidly and now accounts for 81% of our recent sequences. This highlighted the need to increase capacity for local and global health response and was crucial in applying for subsequent funding.

BHP laboratory has generated over 2200 whole genome Sequences of SARS-COV-2 and was the first to sequence the Omicron variant of concern. The Laboratory is now focused on increasing sequencing throughput and build capacity for a country pathogen genomics in Botswana. The broad specific research and capacity building aims to:

Aim 1: To identify circulating SARS-CoV-2 viral lineages in Botswana (entry and spread) to inform public health response. We aim to perform ongoing genomic surveillance, understanding penetration and geographical spread (spatio-temporal spread using phylogenetics and

phylogeography) in support of national surveillance and outbreak investigations. We will identify known variants of concern/interest. We will investigate the extent of inter-and intra-host viral evolution; we will track the diversity and accumulation of mutations over time, and space to track the spread of the pathogen and support an enhanced understanding of potential transmission routes and dynamics.

Aim 2: To identify any associations of viral variants with disease severity and with HIV infection. We hypothesize that individuals living with advanced HIV (low CD4) have higher SARS-CoV-2 viral diversity or will be more likely to select for novel variants due to suboptimal immune pressure. We will compare viral characteristics (diversity and accumulation of mutations) between individuals with HIV, fast disease progression or death and appropriate controls.

Aim 3: To characterize SARS-CoV-2 mutations in vaccinated people with breakthrough infections and compare the mutations with those from contemporaneous infections occurring in unvaccinated people. We will investigate if new infections from previously vaccinated individuals are associated with mutations or genetically distinct from baseline infections.



Members of the Media Interviewing BHP Laboratory Director, Dr Sikhulile Moyo

Trainings

BHP through H3ABioNet grant hosted a course on Next Generation Sequencing Bioinformatics Training Course in collaboration with the University of Cape Town & H3ABioNet consortium. Next generation sequencing (NGS) has become an essential tool in genetic and genomic analysis. It is increasingly important for experimental scientists to gain the bioinformatics skills required to analyze the large volumes of data produced by next generation sequencers. This course intended to equip participants with the essential informatics skills required to begin analyzing NGS data and apply some of the most commonly used tools and resources for sequence data analysis. The course covered the prominent sequencing technologies, algorithmic theory, and principles of bioinformatics, with a strong focus on practical computational sessions using sequence analysis techniques and tools applicable to any species or genome size. A variety of applications covered included post-sequencing analysis – QC, alignment, assembly, variant calling, RNA-Seq and CHIP-Seq.

Research Fellows graduating over the reporting period

PhDs:

Lucy Mupfumi -University of Botswana
Prisca Thami -University of Cape Town

MSc:

Wonderful Choga – University of Cape Town
Tuelo Mogashoa – University of Botswana

Ongoing graduate studies

PhDs:

Bonolo Phinius-University of Botswana
Nametso Kelentse -University of Botswana
Dorcas Maruapula -University of Botswana
Kesaobaka Molebatsi -University of Botswana

MSc/MPHils:

Baitshepi Mokaleng -University of Botswana
Doreen Ditshwanelo -BIUST
Ontlametse Bareng -University of Botswana
Nokuthula Ndlovu -BIUST
Monkgomotsi Maseng -University of Botswana
Patrick Mokgethi -University of Botswana

II) THE BHP CLINICAL CAPACITY BUILDING INITIATIVE AT SCOTTISH LIVINGSTONE HOSPITAL

L launched in 2011, the BHP Clinical Capacity Building Initiative is a collaboration between the Botswana Harvard AIDS Institute Partnership (BHP), Beth Israel Deaconess Medical Center (BIDMC), Boston, and Oregon Health & Science University (OHSU), Portland. The initiative was created to support healthcare capacity building through clinical stewardship, medical education, quality improvement, and research in Botswana. The initiative is supported by three clinical faculty from BIDMC and OHSU who work full-time in Botswana in their respective programs in Obstetrics & Gynaecology, Anaesthesia & Critical Care, and Internal Medicine.

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

During the COVID-19 pandemic, on-site clinical faculty have focused on supporting local clinical capacity through COVID-19 trainings; providing direct clinical care for patients with COVID-19 at



12. PUBLIC POLICY AND ADVOCACY

BHP has continued to raise awareness of HIV/AIDS and other public health challenges through forums such as the Journal Club, Tumor Board, Kgotla Meetings, Community Advisory Board meetings, Community Stakeholder Engagement meetings and national commemorative events. The Community Engagement Department also visits local health facilities to give health talks and build important working relationships with them in order to share information on different studies and refer potential study participants to BHP.

Key research findings have been shared with the public through media briefings and press releases as well as media interviews. BHP continues to produce high quality research that gets accepted and published in different reputable peer-reviewed scientific journals. In this reporting period, BHP published 91 manuscripts in different peer-reviewed journals for wide spread of the research findings. Publishing in research in scientific journals is an important process of propagating research findings, a means upon which public policy is drawn. 16 abstracts have been presented at different international conferences to provide BHP with an opportunity to communicate its

research to a wide international audience, get feedback on its work, and learn from other presenters, thereby broadening its professional network of experts in different public health areas.

BHP has also presented a number of research findings to the Ministry of Health and Wellness as well as introducing different new studies to different stakeholders to get feedback and build rapport with public policy implementers on how best to plan and execute the various projects in order to yield positive results that will impact on policy and practice. In line with its core values, BHP is committed to collaborative research and it emphasizes

on the importance of teamwork by collaborating with international based investigators and partners as well as being active members of both international and several MOHW technical teams where they give expert advice on different health challenges.

BHP staff together with CAB Members serves in 22 Committees and Teams. The number of committees has increased from 15 in the last reporting period to 22 in the year ending June 2021. The committees and teams in which BHP staff serves are the following:

1. Presidential Task Force on COVID-19.
2. Cryptococcal Group (CryptoMAG)
3. African Meningitis Trials Network (AMNET)
4. Scientific Advisory Board for the African Cohort Study (AFRICOS)- Henry M Jackson foundation for US Military HIV Research Program/Water Reed Army Institute for Research
5. Board for Biomedical Research Training Institute, Zimbabwe,
6. University of Botswana IRB
7. HPTN Community Group Steering Committee – Executive Committee of the CWG
8. HPTN075 Protocol Team
9. HPTN Ethics Working Group
10. HIV/AIDS Network Coordination (HANC)
11. ACTG Performance Evaluation Committee
12. TB/HIV Surveillance (NAHPA)
13. Strategic Information Working Group, Estimates and Projections
14. National Working Group on Laboratory Reference Ranges
15. National HIV Treatment Guidelines Committee
16. Scientific Working Group (SWG) - Division of AIDS at the National Institutes of Health
17. Community Partners- HIV/AIDS Network Coordination (HANC)
18. HLB-S Community Engagement Subcommittee - Inter-CARE
19. IMPAACT CAB Leadership Group (ILG) – IMPAACT
20. Community Scientific Subcommittee- ACTG
21. Global CAB- ACTG
22. Good Participatory Think Tank- HPTN/AVAC
13. OPERATIONAL EXCELLENCE



13. OPERATIONAL EXCELLENCE

i) Human Resources

The delivery of excellent supportive professional HR services is designed to positively impact organizations results. This includes bringing HR’s knowledge of human capital trends to support Strategy and to provide access to the skills required.

Diversity and Manpower Strength

Botswana Harvard Partnership is committed to an inclusive culture that respects and embraces the diversity of employees. The organization aims to attract, develop and retain the most capable employees from all cultures, and ethnicities.

As at June 2021, the staff complement was 240 of which 27 were new recruits. The graph below indicates the number of staff per month for the period under review.

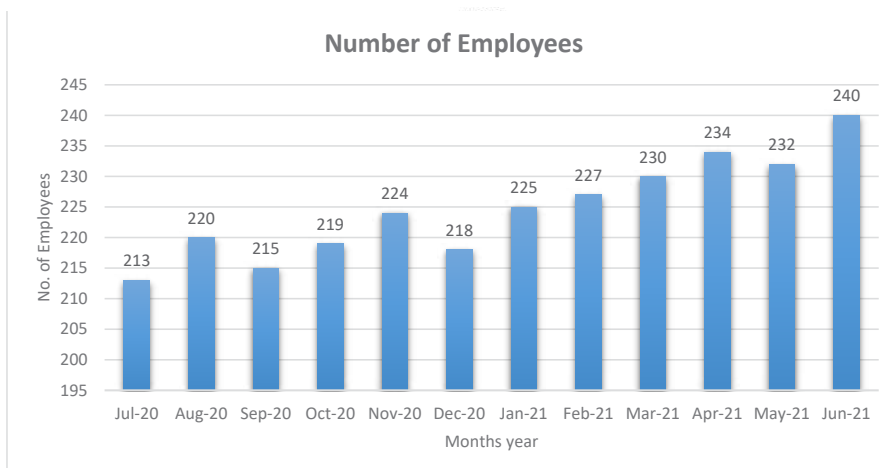


Fig 1: Staff Compliment trend per month

Nationality Distribution

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

Nationality	Number
Citizens	223
Non-Citizens	17

Below is the distribution of positions for Non-Citizens within BHP.

Distributions of Positions for Non-Citizens

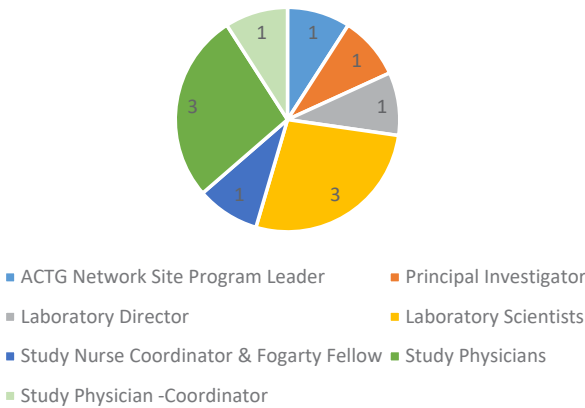


Fig 2: Distribution of Positions for Non-Citizens

Gender Distribution

BHP aims to achieve gender diversity throughout all cadres with a keen interest of promoting women in Science and the Medical field. The below graph indicates the distribution of gender in the organization, as well as, women in senior positions, as at June 2021.

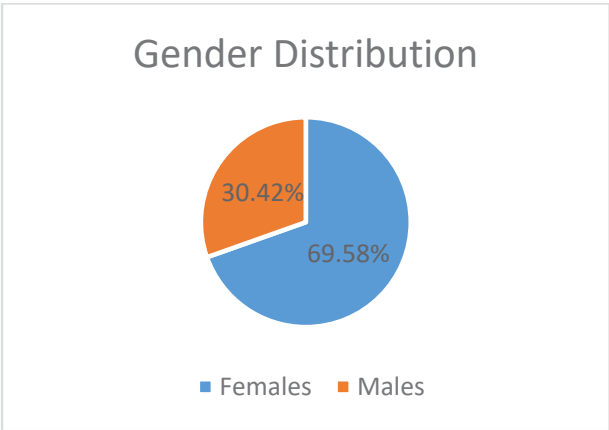


Fig 3: Gender Distribution

Staff Turnover

The previous HR report for 2020 recorded a total of 51 separations, which were mostly due to contract non renewals. For the period under review, we have a slight decrease of 41 terminated employees. The chart below indicates separations between professional and non-professional staff for the period under review.

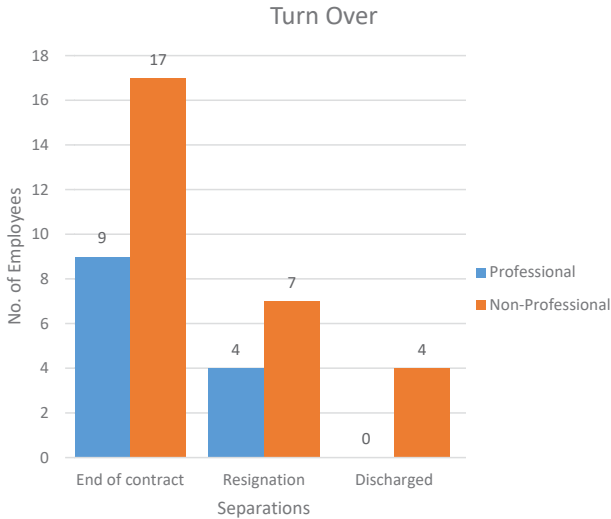


Fig 5: Staff Turn Over

Wellness

In an effort to curb the spread of COVID-19, Botswana Harvard Partnership has implemented guidelines to facilitate effective management of the pandemic. BHP provides employees with disposable masks and PPE. BHP has also provided temperature screening points and installed automatic sanitizer dispensers in all buildings.

With the increased COVID-19 infections in the past couple of months, the organisation introduced Work from Home Guidelines and Virtual Office Arrangements to curb the spread of the virus.

Human Resources Strategy

The Botswana Harvard Partnership Strategy has 5 Objectives with the Organizational Capacity Objective as the main focus for Human Resources Department, as outlined below.



Fig 6: Proposed HR Strategy

The HR strategy proposes to Improve Human Capital by enhancing the productivity of the workforce and fostering a well-engaged staff by implementing the following.

- Staff Engagement:

Roll out employee engagement surveys

- Develop Employee Value Proposition: A set of Financial and non-financial benefits provided by the organization to its employees in return for the skills, capabilities and experience they bring and contribution they make to the organization.
- Compensation and Rewards: In reviewing the remuneration structure, the following will be implemented;
 - o Determining the organizations pay philosophy
 - o Grade all jobs
 - o Conduct market research
 - o Develop pay ranges based on grades and market research
- Performance Management: In an effort to promote a productive workforce, the HR Department will introduce an online Performance Management System in the month of January 2022.

Implemented Human Resources Projects

a. HR Monthly News Letter

In an effort to increase communication and cultivate organisation culture, the Human Resource Department introduced a monthly internal newsletter called the “HR Monthly Catch Up”. The platform will provide updates on new employee engagements and any HR Projects.

b. Timesheets Automated System

The Human Resources Department together with Data Management Centre introduced online “Timesheet System” in June 2021. The initiative was designed to reduce the use of paper, improve process efficiency, save space and enhance data management and security.

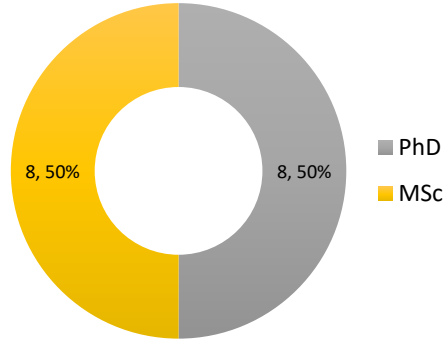
c. Gratuity Encashment

The Partnership provides a gratuity at the end of contract to promote completion of contract. However as at January 2021, staff members on 2-year contracts have the opportunity to encash 100% of the Gratuity accrued in the first year of the contract, upon successful completion of the first year, and 100% Gratuity for the second year will be paid upon successful completion of the second year.

Training and Development

Manpower training remains a key strategic mandate for the institution. BHP houses 8 PhD students and 8 Masters students. Over the years, the institute has also hosted a number of undergraduate students, visiting scholars and interns.

Though the COVID-19 may have disrupted training and conferences, compliance/Protocol specific trainings are still mandatory. Below is record of all trainings that took during the period under review.



Course/Training	Date	Number of Employees Attending/Study
First Aid Training	5-6 November 2020	10
GCLP Training	12 April 2021	2
Petty Cash Training	12 April 2021	2
Biosafety Cabinet operation training	30 June 2021	1

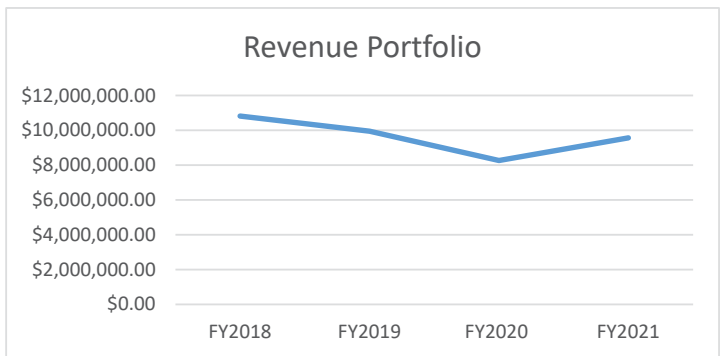
Fig 1: BHP PhD and MSc Training

ii) Finance & Grants

The Finance and Grants department provides effective management of financial resources, as well as the provision of grant management and compliance support to the organization. Currently BHP has a portfolio of over 70 grants. Since 2014, which marked the inception of BHP’s first yellow book audit (an audit of USG Federal Funding), the department has achieved unqualified statutory and yellow book audits which is testament to the BHP’s commitment to upholding the highest standards of financial management and grants administration.

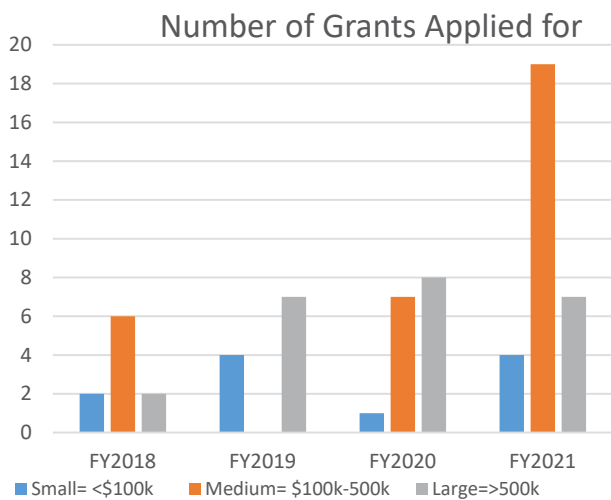
Revenue

In FY2021, grant revenue increased by \$1. 3M, an increase of 16% from FY2020. The linear graph below indicates revenue recorded since 2018.

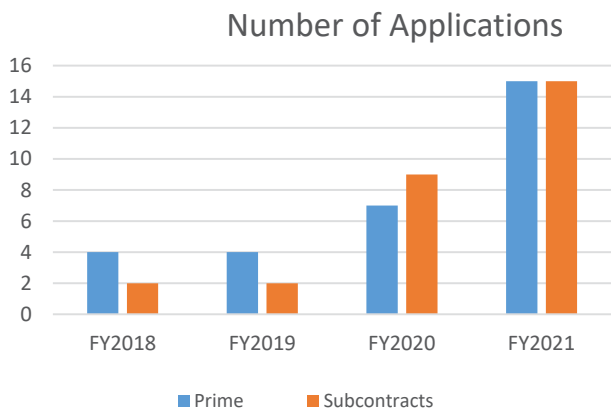


Funding Applications

Grant applications during the period under review totaled thirty (30), an increase of 53% from FY2020. A significant increase in the number of funding applications for medium sized grants, nineteen (19) medium grants applied for compared to seven (7) in the previous period) reflects the investment in, and the development of, BHP's local early investigators.

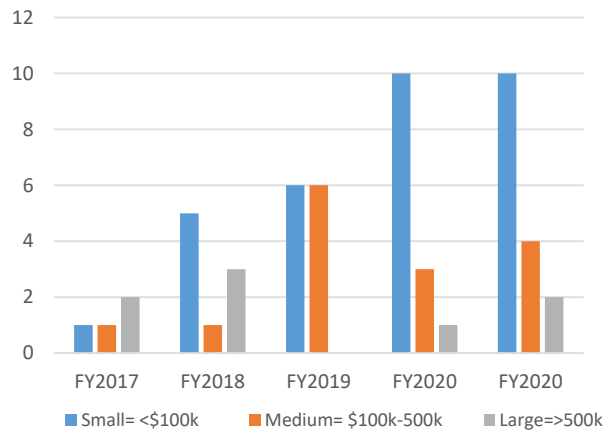


The table below classifies the number of applications as Prime and Subcontracts. In FY2021, 15 prime and 15 subcontracts were applied for. The increase in Prime awards reflects BHP's enhanced ability to independently source and attract funding.



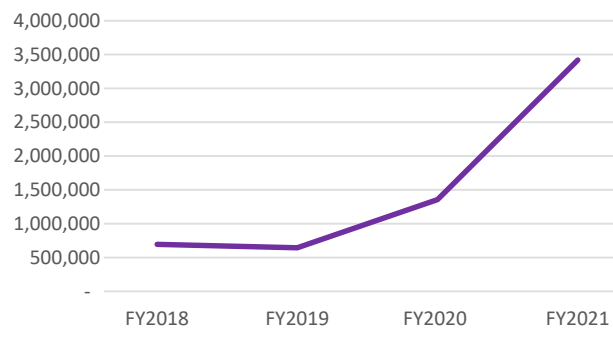
Of the 30 funding applications made, 16 were successfully awarded reflecting a funding application success rate of 53%, and highlighting the increasing capabilities of BHP's local investigators.

Number of Grants Awarded



Revenue from new grants has been increasing since FY2018, with FY2021 reflecting a sharp increase to \$3.4M from \$1.3M in FY2020.

Revenue from New Grants



BHP also achieved Unqualified Audit for Financial Year 2020. The audit for Financial Year 2021 is ongoing.



14. SUSTAINABILITY

BHP is actively pursuing diversified revenue sources, to help sustain and grow its critical missions of training, capacity building, and research. BHP and affiliated supporters are embarking upon initiatives to raise additional funds, including philanthropic, and continue to invest in supporting and developing the careers, including grant applications, of early career investigators from Africa.



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b) ABSTRACTS

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