The Ambition-cm Trial Newsletter (Issue 4: August 2017)

AMBITION-CM AMBISome Therapy Induction Optimization

In this issue:

- Ethical and regulatory updates
- PhD Opportunity at Institut Pasteur, Paris
- Health Economics and Mycology Training Courses
- Welcome to our colleagues from Gaborone and Harare!
- Map of study sites and recruitment targets

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Nabila and David (LSHTM, Gaborone)

Philippa (LSHTM, London)

Timothée (Institut Pasteur, Paris)

Greetings from Gaborone!

We continue to work hard behind the scenes and with each of our African collaborators to prepare for patient recruitment. Thank you especially to those who are working with Nabila to complete the documentation for ethical and regulatory submissions. We are excited also to embark upon other aspects of the project, including the planning of training courses and sub-studies, and the development of the African Meningitis Trials Network.



We also enjoyed a successful few days at the 9th IAS Conference on HIV Science in Paris, with some fruitful discussions about AMBITION and about cryptococcal disease. More information to follow in due course.

We introduce many colleagues in this issue—a very warm welcome to all!

Ethical and regulatory updates

We have received feedback from the LSHTM Ethics Committee, and have responded to the one small query that was raised. We anticipate receiving final, formal approval within the next few days.

We are also contacting our African partners to prepare regulatory submissions. As soon as you are able to, please let us know the name of the colleague at your site who will lead on these submissions. We look forward to working together to proceed with these.

AMBITION Phase III is now registered on the ISRCTN database: ISRCTN 72509687.

PhD Opportunity at Institut Pasteur, Paris

Following the emails already circulated, the AMBITION grant provides a fully funded PhD Studentship at the Institut Pasteur.

A reminder to please share this exciting opportunity widely with your network. The deadline for submitting the expression of interest application (CV, two references and a covering letter of two pages max.) is midnight on Friday 11 August. Skype interviews will follow, with the PhD commencing in Paris at the end October / early November. Details of the project are attached to the email which contains this newsletter.

The IP team would be delighted to answer queries from interested candidates. Please contact:

- Prof. Olivier Lortholary <u>olivier.lortholary@wanadoo.fr</u>
- Prof. Françoise Dromer <u>dromer@pasteur.fr</u>
- Dr. Alexandre Alanio <u>alexandre.alanio@gmail.com</u>
- Dr. Timothée Boyer-Chammard <u>timothee.boyer-chammard@pasteur.fr</u>



Health Economics and Mycology Training Courses

We are starting to plan the Health Economics and Mycology Training Courses, which we hope will take place in Blantyre and in Cape Town respectively. Full details will be circulated in the near future!











The Ambition-cm Trial Newsletter (Issue 4: August 2017)



The Botswana-Harvard AIDS Partnership

The Botswana Harvard AIDS Institute Partnership (BHP) was established in 1996 and was formed from a partnership between Botswana's Ministry of Health and Harvard School of Public Health. While the original partnership was structured to build HIV lab capacity and expertise, the current mission of BHP is to support Botswanan public health research, education prevention and the treatment services programme. BHP remains heavily involved in HIV research, but has expanded its public sphere presence to work on cardiovascular, oncology, birth outcomes and nutrition projects. BHP has over 300 staff members, including 23 at the doctoral level. Harvard maintains an agreement with the Ministry of Health in Botswana, initially signed in 1996 and renewed since then in 5-year terms.



The main headquarters of BHP, including the Botswana Harvard HIV Research Laboratory (BHHRL) are located in the grounds of the main public hospital in Botswana, Princess Marina Hospital. The laboratory area consists of 18 rooms with different functions. The team of laboratory staff includes a PhD laboratory director, a PhD deputy director, a MSc laboratory manager, 6 research assistants, 10 research technicians, and an average of 5 postdoctoral fellows and/or doctoral students at any one time. There are four clinical sites on the campus of Princess Marina that are fully occupied by BHP clinical research staff conducting randomized clinical trials and observational studies. The Grants Management and Finance Department is located a short distance away.

In addition, BHP maintains a Community Advisory Board (CAB) which is supported by a separate grant structure at BHP. The Board meets quarterly, or more frequently if needed, proposes research agendas for BHP and provides feedback on planned studies.

BHP celebrated its 20th birthday in January 2016.

Here is the BHP AMBITION team:

Dr. Mosepele Mosepele MD MSc (BHP Principal Investigator)

I am a Senior Lecturer & Acting Assistant Programme Director (Convener of Master of Medicine, Internal Medicine) here at the University of Botswana Faculty of Medicine. I am a Specialist Physician, Infectious Disease Consultant and Clinical Epidemiologist with experience in research focused on HIV-associated complications such as cardiovascular disease, immune dysregulation and HIV treatment and care. My most current end-organ work has focussed on predicting risk factors for CVD (atherosclerotic versus non-atherosclerotic), neurocognitive impairment among virally suppressed HIV-infected patients, and the role of gut dysbiosis in persistent inflammation despite viral suppression among HIV-infected patients in Botswana. Work on HIV treatment and care has focussed on (1) the link between HIV drug metabolism (including the role of host single nucleotide polymorphism) and clinical outcomes, and (2) the use of social network theory to identify HIV patient treatment partner (treatment buddy) characteristics that are associated with viral suppression.



Dr. Tshepo Leeme (Study Doctor)

I am the study doctor for the AMBITION Phase III trial. I have been working in clinical research since 2014, as a study doctor in the AMBITION Phase II trial (just completed) here in Botswana. Previously, I worked as a medical officer in the public health system in Botswana.

I hold a MBBS from Monash University, Australia. I also hold a postgraduate diploma in HIV management from Stellenbosch University and a Diploma in Tropical Medicine & Hygiene from LSTHM, attained in 2015. I will be pursing a MSc in Epidemiology at the London School in 2017-2018.













The Ambition-cm Trial Newsletter (Issue 4: August 2017)



Dr. Kaelo Seatla (Study Doctor)

I have an MBBS from the St Augustine Campus of the University of the West in Trinidad and an East African Diploma in Tropical Medicine & Hygiene from the London School of Hygiene & Tropical Medicine. I worked in various capacities as a Government Medical Officer before joining Botswana Harvard Partnership as a Study Physician/Co-Investigator in 2014. I am a PhD Research Fellow interrogating HIV drug resistance mutations and am working part-time as a Study Physician for the AMBITION Study trial. I am from Mochudi, Botswana, and my other passions outside Cryptococcal/HIV research are gardening, farming and German Shepherd dogs.



Nametso Lekapwe (Senior Study Nurse)

I am Nametso Dimpho Tlhako, and I will work as the Head Research Nurse for the AMBITION Gaborone site. I have been working with the AMBITION team since 2014, but have been involved in research since 2009. I hold a Diploma in General Nursing obtained in 2007 at Institute of Health Sciences, Gaborone, and I am currently studying for a Bachelor of Arts in Nursing Health Services Management and Education through the University of South Africa. My hobbies are watching soccer, cycling and acting.



Katlego Tsholo (Junior Research Nurse)

I have worked as a study nurse on the AMBITON trial since August 2015. Before this, I worked at Sekgoma Memorial Hospital and Princess Marina Hospital. I studied General Nursing at the Institute of Health Sciences, and am now studying for my BA (CUR) with UNISA.



Norah Mawoko (Study Pharmacist)

I am a Clinical Research Pharmacist with a Bachelor of Pharmacy (Honours) degree from the University of Zimbabwe, and a Master of Science in Clinical Research degree from the University of Liverpool, UK.

I started my research career with Botswana-Harvard AIDS Institute in 2005. I have worked on more than ten different protocols, mainly on anti-retroviral therapy and opportunistic infections in HIV-infected or exposed participants. I also enjoyed two years with the BHP PEPFAR funded Master Trainer program as a Clinical Pharmacy Master Trainer. This gave me an opportunity to utilise the knowledge I obtained from research to train nurses on ARV prescribing and dispensing.



I was involved in setting up four research pharmacies in Botswana as well as training and mentoring pharmacy staff and other health care professionals.

I am the Pharmacist of Record for the AMBITION trial at the Gaborone Site. I will also be assisting with the procurement and supply of the study drugs to all AMBITION Clinical Trial Sites.

I am also working on a TB treatment trial with the University of Botswana under the Faculty of Medicine Public Health department.











The Ambition-cm Trial Newsletter (Issue 4: August 2017)



Kwana Lechiile (Laboratory Technician)

I am a Laboratory Scientist and will be based at the Gaborone site. I started working on the AMBITION Phase II trial in 2015 and will continue working on Phase III. I hold a Bachelor of Science degree, double majoring in Biochemistry and Human Physiology, from the University of Cape Town (UCT). Since graduation, I have been primarily involved in paediatric gastroenteritis and rotavirus surveillance projects as a Laboratory Scientist. I have experience in manual and automated nucleic acid extractions, real-time PCR, Culturing, ELISA, and ELISpots.

I have also been accepted to the London School of Hygiene and Tropical Medicine where I aspire to study on the 2018-2019 MSc. Control of Infectious Diseases programme.



Winnie Sento (Networking Manager)

I hold a Master's Degree in Social Work, obtained from the University of Botswana in 2013. I have over fifteen years' experience with HIV and Health related projects in the areas of programme management, project implementation, monitoring and evaluation and research. I am currently employed by Botswana Harvard Partnership Institute as a Project/Operations Manager and the Meningitis Trials Network Coordinator for the AMBITION study. Amongst others, my responsibilities will include facilitating the establishment of the Meningitis Trials Network and ensuring ongoing regular communication and collaboration between trial sites.



My work experience has largely been with civil society organisations in Botswana, and I have worked for both local and international NGOs. My involvement has been in the areas of community development and health

education, more specifically with HIV and AIDS interventions. I have extensive experience in project planning and implementation, developing monitoring and evaluation frameworks, monitoring and evaluation of health programs, and conducting operations research aimed at improving programmes.

I have previously participated in a number of local and international stakeholder engagement for such as the Community Involvement Community of Practice hosted by the Global Campaign for Microbicides (2008-2012), Stakeholder Community of Practice (COP) established by AVAC, and Stakeholder Engagement Committee for the Botswana Combination Prevention Project.

Refilwe Mmipi (Administrative Assistant)

I am Refilwe Mmipi, an administration assistant by profession. I have an Advanced Diploma in Marketing Management and am currently pursuing my Bachelor degree in Marketing Management. I started working for Botswana Harvard AIDS Institute Partnership in 2013, and joined the AMBITION study team on 1 June 2017.













The Ambition-cm Trial Newsletter (Issue 4: August 2017)



The University of Zimbabwe, College of Health Sciences (UZCHS)

Until 2012, The University of Zimbabwe was the only medical school in Zimbabwe. Initially, training was undertaken in collaboration with Birmingham University, UK, and the first medical students graduated in 1964. The College is a recipient of several international grants from various funding agencies. UZCHS has laboratory capacity for teaching medical and postgraduate students to conduct basic scientific and clinical research.

The associated teaching hospitals are Parirenyatwa Hospital (2,000 beds) and Harare Central Hospital (1,200 beds). Parirenyatwa is the national referral hospital, which serves the whole country, whilst Harare Central Hospital serves the Harare outskirts community. Together, these two hospitals provide a broad range of health services, which address the major health needs of Harare and most of the country.



The UZCHS established a Research Support Centre (RSC) in 2010. The overall aim was to develop a centralised unit to provide coordination, oversight and administrative support to the College research enterprise. Support for the RSC comes from the Wellcome Trust, Southern African Consortium for Research Excellence, NIH (MEPI Zimbabwe program, NECTAR and ZiRIM), the Netherlands-African Partnership for Capacity Development and Clinical Interventions Against Poverty-Related Diseases (NACCAP), the Research Support and Training Centres Network (ARISE) project and the Eunice Kennedy Shriver NICHD support (BRAD G11 project). The RSC receives institutional support (infrastructure, management and human resources) from the UZCHS. In 2014 an RSC building was constructed which has seven offices, a training/seminar room, which can accommodate up to 100 participants, and a computer laboratory with 10 workstations.

The **Department of Medicine** aims to provide exemplary clinical service to all patients referred to medical wards and clinics at the central teaching hospitals in Harare, and to conduct relevant scientific research to the high standard required by national IRB committees. A five-year MBChB programme and a four-year postgraduate specialist programme are offered.

Here is the UoZ AMBITION Team:

Prof. Chiratidzo Ellen Ndhlovu (UoZ Principal Investigator)

I am the current Deputy Dean of the University of Zimbabwe College of Health Sciences as well as being an Associate Professor in the Department of Medicine. As a medical educator and clinician involved in Nephrology and HIV Medicine, I have vast experience in internal medicine, renal care as well as having vast experience in looking after HIV patients in a resource-limited setting. I am a Principal Investigator in various HIV related research activities, in particular studying outcomes in cryptococcal meningitis and HIV, and adherence to antiretroviral therapy in adolescents. I am the current Chairperson of the National Medicines and Therapeutics Policy Advisory Committee (NMTPAC) which advises the Secretary of Health & Child Welfare on all issues pertaining to pharmaceutical use including coordinating the review of the Zimbabwe Essential Medicines List as well as monitoring rational use of medicines in the country.



As the AMBITION Principal Investigator at the University of Zimbabwe site I will be responsible for overall study oversight here in Harare, and for supervising the rest of the study team.











The Ambition-cm Trial Newsletter (Issue 4: August 2017)



Dr. Admire Hlupeni (Study Doctor)

I hold a BSc in Human Physiology, an MBChB from the University of Zimbabwe, College of Health Sciences and I am a candidate for an MPhil degree that is looking into the Immunology of Cryptococcal infection reactivation in patients with advanced HIV infection. My interest is in Public Health and Translational Medicine in HIV-related Opportunistic infections, in particular Cryptococcus, with my main focus being the significant reduction in mortality and morbidity associated with Cryptococcal disease in Sub-Saharan Africa. I am currently involved in the CryptoART study as the Medical Study Officer in which we are evaluating the impact of screen and treat intervention for asymptomatic Cryptococcal disease in a cohort of HIV-infected participants with advanced immunosuppression. I have gained vast experience in the clinical inpatient management and follow-up of patients with HIV-associated Cryptococcal disease and other opportunistic infections.



In the AMBITION Clinical Trial, as the Medical Officer, I will be responsible for the clinical inpatient and outpatient management of the Zimbabwean cohort participants and for supervising, coordinating and supporting research nurses in all their clinical activities. I will be also reporting the study clinical activities to the PIs and adverse events to the relevant IRBs.

Mrs. Takudzwa Mtisi (Study Co-ordinator)

I am a Medical Research Scientist with 10 years' experience in laboratory diagnostics, laboratory quality management, HIV/AIDS research, project management and coordination. I studied for a BSc (Hons) Medical Laboratory Sciences (UZ) then later an MSc in Medical Microbiology (UZ) and a Masters in Public Health (Maseno), and am a Doctoral Fellow in the Department of Clinical Pharmacology, UZ. My work has focused on HIV and has transitioned through fulltime clinical laboratory practice, research and implementation science, culminating in my role as Project Coordinator within the University of Zimbabwe, Department of Medicine/Research Support Centre. I joined the UZRSC full time in February 2015 from the National Microbiology Reference Laboratory, Ministry of Health and Child Care, where I had worked since 2006. I have experience developing project protocols and implementation tools, and am coming in as the Coordinator for the AMBITION project in Zimbabwe. My main task is to provide overall day-to-day management, and ensure successful study implementation. I look forward to working with everyone to deliver a successful trial.









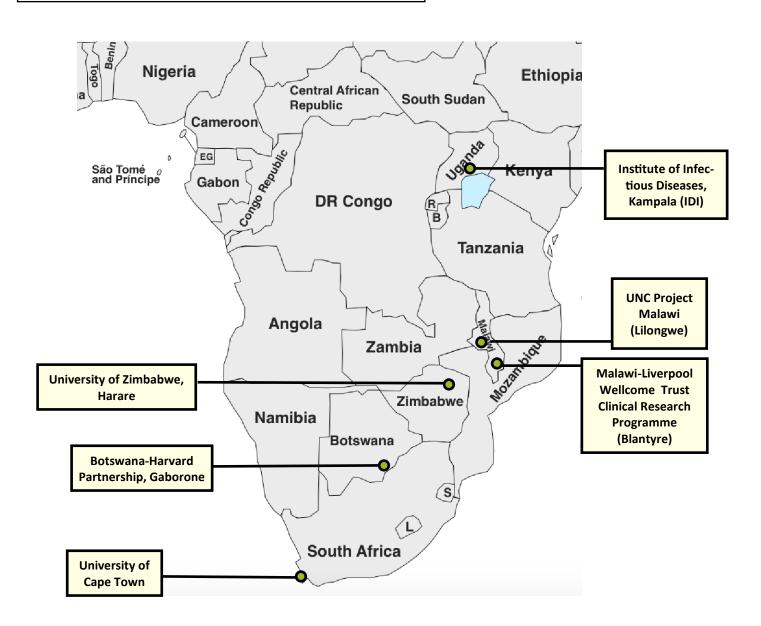




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Please see below a map showing the location of our study sites:



ANTICIPATED PATIENT RECRUITMENT	
Botswana-Harvard Partnership (Princess Marina Hospital, Gaborone)	90
University of Zimbabwe (Parirenyatwa General Hospital, Harare)	230
UNC Project Malawi (Kamzu Hospital, Lilongwe)	110
Malawi Liverpool Wellcome Trust Clinical Research Programme (Queen Elizabeth Hospital, Blantyre)	230
University of Cape Town (Mitchells Plain Hospital)	80
IDI Uganda (recruitment to start in early 2018) (Mulago and Mbarara Hospitals)	110
TOTAL	850