The Mighty Women OF MU-JHU

*A few of the many mighty women at MU-JHU who have played important roles in MTN studies over the years — **(from left to right) Brenda Gati, Juliane Etima, Carolyne Akello and Doreen Kemigisha** attend MTN's DELIVER and B-PROETECTED stakeholder consultation in Kampala, Uganda in 2019.*

Mighty: Possessing great and impressive power or strength. *(Oxford Dictionary)*

For more than three decades, the Makerere University-Johns Hopkins University Research Collaboration (MU-JHU) in Kampala, Uganda, has excelled in conducting perinatal HIV prevention research, and has flourished into a diverse community of talented and dedicated clinical investigators, scientific researchers and study participants. Part of MU-JHU's rich history includes a cherished and long-lasting relationship with the Microbicide Trials Network (MTN) – a story that can't be told without one of its main characters, Clemensia Nakabiito, MBChB, MMed, a vocal and passionate advocate for women's health. Dr. Clemensia (as she is affectionately known by staff) has been involved with the MTN since 2006 when MU-JHU was selected as a site for the network's very first study. A hands-on mentor to many young researchers who have worked on MTN studies over the years, Clemensia has fostered a team of strong and independent Ugandan investigators – most of them women – who represent a future generation of leaders in HIV prevention.

***Clemensia** takes the podium at the 2020 MTN Annual Meeting in the greater Washington, DC area.*

In 1990, Clemensia, now site leader of MU-JHU, was working as an obstetrician-gynecologist at Mulago National Referral Hospital in Kampala. Known for her strong work ethic, she was asked by the late Professor Francis A. Mmiro to join his team at MU-JHU as a liaison officer between the site and hospital. MU-JHU gained a first-rate reputation for enrolling and retaining study participants through its work on the 1999 landmark HIVNET 012 trial, which evaluated the antiretroviral drug nevirapine for preventing the perinatal transmission of HIV. Several years later, when the call came for sites to join the newly formed MTN, MU-JHU's principal investigator at the time, Laura Guay, MD, a professor at George Washington University, pitched the site to the MTN. MU-JHU was invited to present at MTN's Regional Meeting in Cape Town in 2007, with Clemensia making the case on the site's behalf.

Clemensia recalls that meeting well. "That's when I met the whole MTN team for the first time. I presented on the capacity for MU-JHU to do microbicide research. I remember it was 2 p.m., after food, when people usually doze. I amused them, and I think I made an impression," she says with her signature deep chuckle. After that meeting, in fact, MU-JHU was selected to be part of the MTN-001 study – MTN's first as a network – looking at how tenofovir is absorbed in the body as either an oral tablet or a vaginal gel, as well as women's preferences and adherence to each approach. Clemensia and other leaders at MU-JHU, including Mary Glenn Fowler, MD, PhD, principal investigator of the JHU-Kampala Clinical Trials Unit (CTU), and Philippa Musoke, MBChB, MMed, PhD, executive director of MU-JHU, began to build capacity for the microbicide team in Uganda.

Principal investigator of the MTN, Sharon Hillier, PhD, also fondly remembers trips to Uganda to meet with Clemensia and the MU-JHU team. "When you walk around Kampala at the hospital or meet people from the ministry of health, everyone who has had training in obstetrics and gynecology trained with Clemensia. She is like a mother and role model for physicians in women's health." From those connections, she says, Clemensia was especially good at identifying up-and-coming investigators who similarly had demonstrable energy and passion for microbicide research.

"Clemensia is just amazing," agrees Mary Glenn. "She's so high energy. Aside from doing an outstanding job generally, I really give her credit for raising a group of independent and extremely capable investigators who are becoming stars in their own right."

Coming on strong

Among the up-and-coming researchers mentored by Clemensia are Brenda Gati Mirembe, MBChB, MSc, Flavia Matovu Kiweewa, MBChB, MSc, PhD fellow, and Carolyne Agwau Akello, MBChB, MSc. Like Clemensia, each have played key roles in several MTN studies throughout the years, sharing a desire to improve the health of women in Uganda and beyond.

Brenda Gati Mirembe

Along with Dr. Flavia Matovu Kiweewa, one of the first to join Clemensia's microbicide research team at MU-JHU was Dr. Brenda Gati Mirembe, who had been part of an

***Brenda Gati** is all smiles at the 2019 MTN Regional Meeting in Cape Town, South Africa.*

early cellulose sulfate microbicide study at Makerere University, and went on to work on MTN-001. Brenda continued to advance in her career, becoming associate coordinator of the VOICE study, testing two different ARV approaches for HIV prevention – daily tablets and gel – and then was promoted to coordinator for both the VOICE B sub-study (measuring the effect of the oral products used in VOICE on bone health) and for the ASPIRE study of the dapivirine vaginal ring. Through her exceptional work on these studies, she was appointed as investigator of record for HOPE, the open label follow-on study to ASPIRE, and now continues to focus on studies evaluating the dapivirine vaginal ring among different populations of women through REACH (adolescents), DELIVER (pregnant women) and B-PROTECTED (breastfeeding women), for which she is also the investigator of record.

"I think what keeps us going at MU-JHU is togetherness and the fact that we have maintained the same staff over time, right from MTN-001," says Brenda. "There's this sisterhood we have built as a team at MU-JHU working on MTN studies." Part of this includes team building activities, she says, to keep staff motivated, such as the creation of a work board that they have contributed to over the years to showcase their research journeys.

"Dr. Clemensia knows what it means to invest in a person, when they can actually contribute more. You start off as a medical officer and before you know it, you are a coordinator. There's this hope that I can get somewhere, that I can move a step further."

Flavia Matovu Kiweewa

***Flavia Matovu Kiweewa** attends the 2013 MTN Regional Meeting in Cape Town, South Africa.*

It's easy for Dr. Flavia Matovu Kiweewa to remember when she joined MU-JHU. It was 2005 and she was pregnant with her daughter who is now 15. Initially, she worked on an observational HIV-focused study, but was soon tapped by Clemensia to coordinate the MTN-001 and VOICE studies. Thanks to her dedication and expertise, she rose through the ranks to become investigator of record for the ASPIRE study. Leading the ASPIRE trial was a turning point, she says, because she learned about all aspects of conducting HIV clinical trials from protocol design to results dissemination, as well as managing inspections by international regulatory authorities.

Through her work on MTN studies, particularly the VOICE B sub-study, Flavia became drawn to bone health research. In 2015, she parlayed her enthusiasm into a successful highly competitive R01 grant from the National Institutes of Health looking at bone health in HIV-infected women. She was subsequently awarded an investigator-sponsored grant from Gilead Sciences, Inc.

Photo courtesy of Flavia Matovu Kiweewa.

Sharon Hillier and Flavia Matovu Kiweewa after co-moderating a session at CROI 2019 in Seattle, Washington.

to lead the first Phase IV trial of Biktarvy – a newer tenofovir-based HIV treatment regimen with bone and kidney sparing properties – in HIV-positive women from low- and middle-income countries.

As a testament to her passion and drive, Flavia, who will receive her PhD in bone health from the University of Witwatersrand in Johannesburg, South Africa, in December 2020, will be leading the Gilead Women's PrEP study in Uganda. Gilead is currently planning a trial of Descovy in African women, the first F/TAF PrEP trial among csigender women in sub-Saharan Africa. "From the MTN, I learned that when you start as an investigator, you don't wait for a study to end, you have to look ahead," says Flavia, also a tutor and lecturer at the London School of Hygiene and Tropical Medicine and Makerere University

School of Public Health. “You have to be like the African women – you have an older child, you have a baby, you are pregnant and also planning to conceive. When I had my baby, the R01, I didn’t wait for it to end before conceiving another concept. It’s because of these studies that I am now collaborating with mentors within Gilead Sciences, as well as renown international bone health experts. It’s been a long journey. I have maximized my networks and now it’s my duty to play it forward and share the lessons learned.”

Carolyne Akello

When Dr. Carolyne Akello started working on MTN’s VOICE study at MU-JHU in 2010, she had experience conducting research studies in malaria. She took note of the stark contrast between malaria and microbicide studies – protocols at the MTN were implemented with stakeholder and community consultation. “When I started working with the MTN, the idea of consulting with different stakeholders – the end users – seemed like a great idea and something that was different from what I had done previously. I liked that the MTN really considered stakeholder engagement as key.”

About six months after joining VOICE, Carolyne was assigned to be study coordinator for MTN-015 – an observational study of the women who acquire HIV while taking part in an MTN “parent” study – and then, later, for the HOPE study. In 2012, she received a competitive MTN Scholar’s Award to attend the Principles of STI/HIV Research course at the University of Washington in Seattle, and worked with Jennifer Balkus, PhD, MPH, associate director, Statistical Center for HIV/AIDS Research & Prevention at the Fred Hutchinson Cancer Center, on drafting her first scientific manuscript.

Through her work within the network, Carolyne became particularly interested in research on female-controlled methods for HIV prevention. In 2017, she was selected by Clemensia to be the investigator of record for the REACH study, further igniting her enthusiasm for research with adolescents and young women.

“Working on the REACH study with MTN has really been a clicking of passions,” says Carolyne. “I like studies where you really delve deeper into how you can help someone, not just because you want answers to your research questions. I am grateful to the MTN for giving me an opportunity to be able to do something I really love.”

Other women key to MTN’s research program at MU-JHU – by no means, an exhaustive list – include Juliane Etima Ongom, BSc, Betty Kamira, MBChB, Rita Nakalega, MBChB, MPH, and Maxensia (Maxie) Owor, MBChB, MMed. Juliane, a scientist who heads up the behavioral team at MU-JHU, has been crucial to many MTN protocols, especially the network’s qualitative studies. Betty, who is a member of the Contraception Action Team – a group created at MTN in 2012 to expand the range of effective contraceptive methods available to women participating in network studies – has been central to the success of caring for women participants at MU-JHU by providing for their contraceptive needs. Rita is the study coordinator for REACH, and Maxie, the B-PROTCTED protocol chair.

Carolyne Akello talks about the dapavirine vaginal ring at the REACH study stakeholder consultation in Kampala, Uganda in 2017.

The emergence of strong and motivated women researchers at MU-JHU is no surprise to Monica Nolan, MBBS, chief operating officer, JHU-Kampala CTU. “Within MU-JHU, you have very supportive, empowering leaders who genuinely want to make a difference in the lives of women,” she says. “Within the MTN, you have Sharon Hillier who has really sought and respected the input of African investigators. I think this has been incredibly empowering and created a lot more space for career growth among Ugandan investigators.”

“I appreciate all that we’ve been able to share and learn from Dr. Clemensia and our work with the MTN,” adds Brenda. It has been a learning journey, a very great experience, and I believe it is shaping our futures.”

- Clare Collins

Photos: Lisa Rossi (unless otherwise noted)

“A Look Back …” is an occasional series to honor the communities, researchers, staff and study participants who have made countless and meaningful contributions to the work of the MTN since 2006.