

Opening Doorways

TRANSFORMING LIVES:
CONTRACEPTIVE CHOICE IN
HIV PREVENTION RESEARCH



“May your choices reflect your hopes, not your fears.”

- NELSON MANDELA

For a young woman in Africa, having a say about whether or when she becomes pregnant can alter the course of her life. Key to her ability to make a choice is having access to a range of contraceptive methods and the power to decide, on her own terms, the one that’s best for her.

Yet, in the context of HIV prevention studies – in which participants of reproductive age must use contraception due to the investigational nature of the study products – young women haven’t had many options. In the best of circumstances, participants have been offered door number one – a hormonal contraceptive pill, or door number two – an injectable contraceptive.

These methods may be right for some women, but having only one or two contraceptive choices has been detrimental to the reproductive health needs of young women participating in HIV research, says Sharon Hillier, PhD, professor and vice chair for faculty affairs in the department of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of Medicine. This has led to less uptake of contraceptives generally and more product discontinuation over time.

“Increasing contraceptive options allows women to choose what they want, which leads to better choices and fewer unplanned pregnancies,” adds Sharon, also principal investigator of the Microbicide Trials Network (MTN).

The Contraceptive Action Team – Key to unlocking new doors

In early 2012, Sharon invited MTN colleagues Katherine (Katie) Bunge, MD, MPH, and Catherine Chappell, MD, both assistant professors of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of Medicine, to her office at Magee-Womens Research Institute. They were there to plan a meeting she had asked them to lead taking place in Johannesburg, South Africa, in the coming months.

An MTN study on the dapivirine vaginal ring called ASPIRE (A Study to Prevent Infection with a Ring for Extended Use), also known as MTN-020, was about to launch and Sharon wanted to find out from the study sites – located in Malawi, South Africa, Uganda and Zimbabwe – whether it would be feasible to diversify contraceptive options for participants. About two or three representatives from each site would be invited to attend – a group the trio decided to name the Contraceptive Action Team (CAT), whose members later affectionately called one another CAT sisters and brothers.

ASPIRE

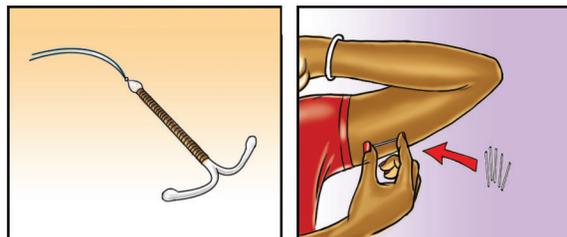
A Study to Prevent Infection
with a Ring for Extended Use

The urgency to form the CAT stemmed from concerns that a three-month injectable contraceptive called depot medroxyprogesterone acetate, or DMPA – more commonly known as Depo-Provera, and widely used around the world, perhaps especially so in Africa – may be increasing women's risk of HIV. Sharon and Jeanna Piper, MD, senior medical officer at the Division of AIDS, National Institute of Allergy and Infectious Diseases (MTN's primary funder), felt strongly that women participating in ASPIRE should be offered other options. ASPIRE protocol co-chairs, Jared Baeten, MD, PhD, then a professor at the University of Washington, and Thes Palanee-Philips, PhD, MMed, director of clinical trials at Wits Reproductive Health and HIV Institute (Wits RHI) in Johannesburg, both longtime champions of contraceptive choice, felt similarly and were highly supportive of expanding options through the study.

"If there was any possibility that Depo-Provera was associated with increased HIV risk, we felt it was our ethical obligation to make sure women in MTN studies were provided a range of options and fully informed about the pros and cons of each method," recalls Jeanna. (Results of a major long-term study called ECHO released in 2019 found that Depo-Provera did not increase risk of HIV acquisition, but these data were still being collected at the time the CAT was formed.)

In particular, they wanted to add long-acting reversible contraceptives (LARCs) to the mix, which included implants – tiny flexible rods placed under the skin in the

upper arm that release contraceptive hormones and can last up to three years – and intrauterine devices (IUDs) – t-shaped devices inserted into the uterus that can last up to a decade. Highly effective, LARCs offer long-lasting pregnancy prevention – acting as "set it and forget it" methods. Notably, too, as LARCs, both implants and IUDs can be easily removed by a health care provider when a woman decides she wants to start a family or switch to a different contraceptive method.



Long-acting reversible contraceptives provided through the ASPIRE study included both intrauterine devices (left) and implants (right).

"Facing pregnancy at 16 or 17 years old, having to drop out of school, unable to pursue a career because you have to find a job – that is life changing," says Yuthika Naidoo, MBBS, former research clinician at Wits RHI and CAT sister. "Young women often find it hard to negotiate condom use or may be in situations where they face intimate partner violence and gender-based violence. Being able to access long-acting contraceptive methods provides peace of mind that should they face any of these challenges, they can still make a decision for themselves."

Rolling out the welcome mat

Katie and Catherine were nervous during the long flight from Pittsburgh to Johannesburg for the first CAT meeting. Although diversifying the contraceptive method mix was a meaningful objective, how would the ASPIRE teams perceive what they were about to be asked? Would there be too many obstacles on the ground to provide LARCs as real options for study participants? "We honestly didn't know what the site staff or community members would think," admits Katie. "This could be something people wouldn't be interested in or didn't see the benefit of doing," she recalls thinking at the time.

One of the CAT's primary goals they had discussed some months before in Sharon's office might be particularly tricky – that every clinical site involved in ASPIRE offer participants at least four contraceptive options. "We really wanted to move forward with these efforts, especially if it could improve a woman's ability to make choices about herself," adds Catherine. "But we weren't sure what kind of stigma existed around the use of implants and IUDs in some of the countries conducting ASPIRE."

Still, after engaging in thoughtful discussion over the course of the two-day meeting, they found an incredible amount of enthusiasm. There would be challenges – chief among them addressing community-based myths and misconceptions about LARCs and securing the products and training needed for contraceptive insertion and removal – but the meeting participants rallied behind the idea of choice. Each left the CAT meeting with concrete action plans they had developed for their sites back home.



Photo courtesy of Jeanna Piper.

Attendees at a 2013 CAT meeting in Johannesburg, South Africa, work with arm models to learn the proper placement of contraceptive implants.

“The first CAT meeting really got me thinking that maybe this is the correct bunch of people we need,” says Felix Mhlanga, MBChB, MMed, an obstetrician and gynecologist with the University of Zimbabwe Clinical Trials Research Centre, and one of the team’s few, but much-loved CAT brothers, along with Bonus Makanani, MBBS, FCOG, an obstetrician and gynecologist with the College of Medicine-Johns Hopkins University Research Program in Blantyre, Malawi, and a member of the CAT steering committee. “There were people at that meeting who were really excited and from diverse backgrounds, and it was quite some fun,” remembers Felix. “I said to myself, ‘I think we’re on to something.’”

Turning the doorknob & walking through

In time, the CAT meetings – held twice a year – became learning grounds where the sites were trained on all aspects of providing LARCs in their communities – from insertion and removal of IUDs and implants to contraceptive counseling and support for study participants. Although there were different levels of experience across the sites, the meetings were a “safe space” for people to talk

about the challenges they experienced locally providing contraception, says Nelly Mugo, MBChB, MMed, senior research scientist at the Kenya Medical Research Institute in Nairobi, and a leading contraceptive expert invited to speak at one of the early CAT meetings.

To keep the meetings educational, but also engaging and fun, Katie, Catherine, and another pivotal CAT meeting co-leader, Devika Singh, MD, an MTN safety physician and assistant professor of medicine at the University of Vermont, employed a variety of learning methods. They used pelvic and arm models for IUD and implant insertion (site staff were able to take the arm models home for continued learning), demonstrated the ease of implant placement through a video of Felix with a patient who was so relaxed she chatted throughout the procedure, invited outside speakers for inspiration – one meeting included several young women who shared their views about LARCs, and facilitated role playing around scenarios to address common myths and misconceptions about LARCs and approaches to handling difficult situations. One of the most memorable of these scenarios centered around a very angry and disapproving grandmother, skillfully played by Betty Kamira, MBChB, CAT sister from Makerere University-Johns Hopkins University



Photo courtesy of Jeanna Piper.

Betty Kamira from MU-JHU (middle) and other CAT members role play during a meeting in Johannesburg in 2019.



Members of the CAT gather for a group photo during the 2015 MTN Regional Meeting in Cape Town, South Africa.

Research Collaboration (MU-JHU) in Kampala, Uganda, who brings her granddaughter into the clinic to confront the clinic staff because they had provided her with contraception.

Nompumelelo Zungu, a nurse at the Centre for the AIDS Programme of Research in South Africa (CAPRISA) in Durban, who worked on the ASPIRE study, remembers she was literally sweating at her first CAT meeting. She had never even seen a birth control implant before, but the atmosphere of sisterliness and acceptance quickly set her at ease. “No one felt inferior,” she says. “We were all together as nurses and clinicians and all the same in that regard.” Today, Nompumelelo trains other nurses on how to insert and remove implants and feels as though the CAT empowered her professionally “as a woman helping other women.”

“For some of us, who did not have these methods in our countries, it seemed hard and scary at first,” agrees Betty. “But with time, meetings, training and encouragement, we became sisters. If your sister had a problem at the site, you’d talk about it, help them resolve it and they’d go back a happy woman. Anyone’s problem became the other person’s problem.”

One of the keys to the success of the CAT can be attributed to the diversity of its membership, says Felix. The CAT helped to address provider biases and misconceptions about LARCs by bringing together a wide range of site staff – not only medical doctors, but counselors, nurses and outreach workers.

“We had people who became comfortable counseling participants because they understood deeply most of the issues associated with LARCs,” he says. “Prior to the CAT training, I don’t think people had that kind of approach. It would more be like, ‘If you come to this clinic, the easiest thing we can give you is Depo.’”

While providing LARCs was initially an investment in site capacity building and training for ASPIRE, it ended up saving time during follow-up visits. If a participant had

an implant or an IUD, site staff didn’t have to take the extra time necessary for an injectable, for example, that lasts for only three months. They also wouldn’t have to wait on their pharmacies to secure additional contraceptive supplies during the course of the study.

And so, with support and guidance from both their CAT brothers and sisters, site staff gradually learned to overcome the many challenges to implementing the contraceptive-focused goals for ASPIRE. As their confidence grew, they also began to identify themselves as contraceptive experts and passionate advocates for choice, says Katie.

Forging ahead

In 2016, four years after the first CAT meeting, the long-anticipated ASPIRE study results were released – the monthly dapivirine vaginal ring helped protect women against HIV. And, for its part, the CAT reached its goal in diversifying contraceptive options for study participants, with no more than half of participants on a single contraceptive method.

Across the ASPIRE sites, the initiatives spearheaded by the CAT greatly improved accessibility and use of IUDs and implants by study participants, with fewer opting for oral contraceptives. By the end of the study, nearly half of the participants were using LARC methods – about 20 percent opted for IUDs and 30 percent for implants. The number of those choosing oral contraceptives had decreased by more than half.

Just as compelling, when ASPIRE started, nearly a quarter of the participants had not been using any form of contraception before they enrolled. By the end of the study (when participants were no longer required to use birth control), only 5 percent had stopped using contraception.

“The distribution of contraceptive use in ASPIRE really tells the story,” says Sharon. “If women only have a choice of Depo and oral contraceptives, then that’s what you see.



Catherine Chappell looks on as women share their views about LARCs at a CAT meeting for the REACH study in Johannesburg in 2017.

If you provide more options – like implants and IUDs – you end up with a much more diverse distribution. Importantly, you also end up with fewer women who choose nothing at all.”

Indeed, the CAT demonstrated that investing in a diversity of methods provides much more persistent use of contraceptives over time, and that when women are offered a broad range of contraceptives, many will choose LARCs as options that work for them. The CAT also helped add many more providers across Africa who were trained and skilled in inserting and removing LARCs, says Jeanna.

Given its success, the MTN has continued the CAT for subsequent studies of the monthly dapivirine vaginal ring – HOPE (HIV Open-label Prevention Extension), or MTN-025, a follow-on study to ASPIRE, which reported results in 2019, and REACH (Reversing the Epidemic in Africa with Choices in HIV Prevention), or MTN-034, a study of the ring and Truvada® as oral PrEP in adolescent girls and young women, currently underway.

In REACH, says Yuthika, the counseling skills the Wits RHI site staff learned from the CAT have been “absolutely crucial” since in some instances study counseling involves both participant and parent. “The CAT meetings have really helped me counsel mothers and daughters about the benefits of LARCs, which I didn’t have much knowledge of beforehand,” adds Reginah Stuurman, a nurse at Wits RHI and CAT sister for the REACH study. “Meeting with the CAT sisters gave me the support I needed to go back to the clinic and advocate for long-acting methods.”

“In a nutshell, the CAT taught us that you don’t need anything fancy or complicated to expand contraceptive options and give people choices,” says Sharon. “You just need to empower people to actually deliver good quality family planning care.”

The CAT provided a tangible change for both site staff and participants, adds Ishana Harkoo, MBChB, research clinician at CAPRISA and ASPIRE CAT sister. “Years later, participants were still saying to us, ‘I put this in, and it changed my life.’”

“At the bottom of it all, we cheered each other on and supported one another in every way we could,” says Ishana. “We celebrated each other’s successes, in addition to the success of the entire team. The CAT has truly been an incredible initiative.”

- Clare Collins

Photos: Lisa Rossi (unless otherwise noted)



At the same meeting, Devika Singh (standing in the foreground), Katie Bunge and Sharon Hillier listen attentively to a young woman holding the mic.

“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.