transmitted infections (STIs), and contraception; and population-specific studies that combine biomedical, socio-behavioral, and structural interventions for HIV prevention to maximize their effectiveness.

CGMRC has been working in collaboration with IAVI since 2003 with the aim of identifying populations at risk of HIV and preparing them for future HIV vaccine clinical trials. CGMRC has two sites that implement IAVI protocols: The key populations office at Malindi sub-county hospital and a site in Nyali, Mombasa, in collaboration with HAPA, a community-based organization.

Laboratory capacity
At the main campus in Kilifi, KEMRI’s state-of-the-art laboratory is GCLP-accredited and has capacity for hematology, biochemistry, and testing of HIV and other sexually transmitted infections (such as Hepatitis B, Hepatitis C, Herpes simplex virus, Trichomonas vaginalis, and bacterial vaginosis). The lab also has capacity for cell analysis techniques such as enzyme-linked immune absorbent spot (ELISpot) and flow cytometry, and a biobank for storage and management of samples. The lab is enrolled in a comprehensive external quality assessment program covering all assays facilitated by Contract Lab Services in Johannesburg, South Africa.

People
The staff of the CGMRC program includes clinical officers, a study coordinator, a data manager, pharmacy technologist, HIV counselors, and laboratory technologists, a community liaison officer and a social-behavioral...
research advisor. The teams are led by Eduard Sanders M.D., M.P.H., Ph.D., co-director, epidemiologist; and Eunice Nduati Ph.D., co-director, laboratory scientist.

Community engagement
The CGMRC program has a robust community outreach program with field workers who have been sensitized to engage effectively with vulnerable populations and a community advisory board (CAB) is in place specific to the vulnerable populations served in Mombasa and Malindi. The CAB consists of members of traditional communities, policy makers at the county level, members of men who have sex with men (MSM)/transgender women (TGW)/LGBTQ organizations, a human rights lawyer, and members of the research team.

The program maintains an MSM-sensitivity training website for Kenyan health care workers from which over 1,600 health care workers have graduated. Social and behavioral research and community engagement has focused on strategies to optimize engagement of key populations and providing care and prevention options, including through peer-led extension of HIV oral self-testing, and partner notification among MSM and TGW. A broader ongoing effort focuses on capacity building of affiliated community-based organizations in Malindi and Mombasa (to enable studies and prepare for trials), stakeholder sensitivity trainings, and engagement of a coastal CAB.

IAVI-supported activities
- IAVI Protocol B³ — Study to estimate the annual incidence of HIV infection, characterize early HIV infection, and prepare clinical trial sites for HIV preventive vaccine efficacy trials for which volunteers from this study cohort may be recruited.
- Tatu Parnoja Cohort (novel feature includes iris scanning to prevent co-enrollment)
- Acute and early HIV infection cohort
  - Protocol N² — Study to identify acute (pre-seroconversion) HIV infection
  - IAVI G001³ — a Phase I study to assess the safety of the vaccine candidate and to test the hypothesis that an immunogen could activate naïve B cells of the immune system that produce precursors to a certain type of bnAb.
- G003 — has the same aim as G001 but delivers the immunogen using mRNA and will be conducted in sub-Saharan African populations.
- Capacity strengthening
  - International training
  - Investigator-initiated research
  - Laboratory capabilities

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