Over the years, the department has conducted and garnered experience and expertise in Phase I and II HIV vaccine clinical trials and epidemiological studies. Moreover, the CTD has worked with unique populations within the general fishing communities. These have included healthy populations, special cohorts to characterize the general fishing communities, women, and emancipated minors, among others. Additionally, the program has a well-equipped, state-of-the-art laboratory and highly trained staff responsible for performing HIV-related experiments.

Laboratory capacity
The laboratory is comprised of four sections: safety, serology, immunology, and molecular. The safety section is dedicated to monitoring the safety of study products and is comprised of two units: clinical chemistry and hematology. Serology specializes in the serological testing for common and complex immunologic diseases. A range of qualitative and quantitative analytical methods including rapid testing for HIV and syphilis, enzyme-linked immunosorbent assay for HIV and Hepatitis C, Hepatitis B, and other disease profiles. Immunology includes a flow cytometry unit, which is integral to the complex monitoring of the immune responses to study vaccines during clinical trials as well as basic science research in immunophenotypic evaluations. An additional peripheral blood mononu-

UVRI-IAVI is a not-for-profit organization, located within the Uganda Virus Research Institute in Entebbe. The Program was formed in 2001 as a result of the partnership between IAVI and the Government of Uganda. The goal of the partnership was to support IAVI-sponsored activities in Uganda including the conduct of phase I/II HIV vaccine trials and feasibility studies and other activities in preparation for future large-scale HIV vaccine trials.

The UVRI-IAVI HIV vaccine program’s focus is to identify opportunities and priorities for research towards finding vaccines for HIV, TB, and emerging infectious diseases. The program conducts HIV epidemiological and prevention studies and research on related diseases. The program operates in strategic partnership with the UVRI which is the Government of Uganda’s virus research agency.

UVRI-IAVI has extensive experience in conducting clinical trials with integrity and professionalism in compliance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use/Good Clinical Practice (GCP) guidelines, providing continuous medical education, health care, HIV counseling and testing, and family planning services to volunteers and communities where the program conducts research.

The program’s clinical trials department (CTD) is primarily responsible for conducting clinical trials on behalf of the program. This includes registration of the trial protocols with local and international regulatory bodies and ensuring that the GCP guidelines are followed. The department has a fully equipped pharmacy where investigational and other medicinal products are stored and dispensed.
clear cells (PBMC) isolation/enzyme-linked immune absorbent spot (ELISpot) sub-unit has standard procedures for isolation of PBMC and ELISpot assays for both fresh and thawed cells.

The molecular section forms part of the basic sciences support lab and employs technologies for fast, easy quantification of gels and blots (macromolecules — proteins, or fragments of DNA or RNA — initially present in a complex mixture). The facility is used for IAVI’s Vaccine Immunology Science and Technology for Africa (VISTA) program research work, which is supported by the U.S. Agency for International Development through the U.S. President’s Emergency Plan for AIDS Relief.

People
The team at UVRI-IAVI is led by Brenda Okech B.Sc. Ch, Ph.D., executive director. The team includes a medical director, a clinical trials manager, a head of department community studies, a social science and community engagement coordinator, a laboratory manager, a quality management coordinator, a data manager, an administration manager, and a finance manager.

Community engagement
The community studies department contributes to the development of community engagement strategies in accordance with Good Participatory Practice guidelines to ensure ethical and compassionate treatment of community members and maximize their support and involvement in UVRI-IAVI activities.

The department is responsible for conducting epidemiological, social-behavioral sciences research. It also links the program agenda to communities and research participants; undertakes community advocacy; and strengthens capacity for research literacy and HIV prevention.

Over the years, the department has created a strong presence in fishing communities along Lake Victoria, through training village health teams, peer guides, and peer leaders on the importance of research for improving communities’ health and HIV prevention.

IAVI-supported activities

- Research preparedness: engaging communities and cohorts
- Identification and engagement of key populations for ongoing and future HIV prevention clinical trials
- Capacity strengthening
- International training
- Investigator-initiated research — a platform that strives to provide career development opportunities for junior investigators through funding for research
- Strengthening laboratory capabilities
- T-cell immunogen design and assessment

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