

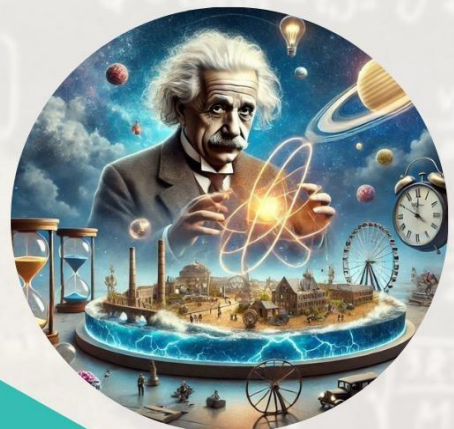
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Collaborations between US and Sub-Saharan African nations to Strengthen Biostatistics Infrastructure

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SUMMARY

Low and middle income nations now have more resources to do biomedical research because to a worldwide increase in health research investment over the last decade. Research and clinical care programs (clinical trials, observational studies, and other public health initiatives) in sub-Saharan Africa (SSA) have increased in response to the HIV/AIDS pandemic, the resurgence of TB and malaria, and other new infectious pathogens [1]. There is an ever-increasing demand for comprehensive in-country knowledge in all areas of biomedical research due to the US government's growing involvement in global health initiatives like the Global Health Initiative, which shifts attention from infectious diseases to other sources of poor health and acknowledges the need to improve health systems for a long-term solution [2].

Keywords

biostatistics; sub-Saharan Africa; collaboration; data management; global health; training program

INTRODUCTION

Biostatistics, which integrates statistical theory and methodology into research in the fields of biomedicine, public health, and health services, was the subject of our workshop. To solve the medical and public health problems in SSA, a plethora of other fields of biomedical study and healthcare are obviously required. Thankfully, universities and health ministries in SSA have worked together with their western counterparts for decades in the fields of public health, tropical medicine, and medicine. Teaching hospitals in developing countries, especially in sub-Saharan Africa—where the overall disease burden is undoubtedly the highest and the gap in biomedical research infrastructure is the widest—have witnessed a marked increase in the number and scope of linkages between universities and health sciences centers in the US and other developed countries, as pointed out by Glew [1]. Consequently, a critical mass of researchers in the medical and biological sciences has grown, which is great news for the country's research leadership and, just as importantly, for the faculty at institutions in sub-Saharan Africa (SSA) and for the next generation of researchers. Unfortunately, biostatistics is falling far behind, just as it did in the West in the past. Training biostatisticians in sub-Saharan Africa should

be a top priority in the face of epidemics like HIV/AIDS, TB, and malaria so that researchers may ask questions that really matter to the local population. The research questions in the west and SSA differ significantly due to the background health care resources and general health status of the populations in question, even though the diseases causing the greatest burdens of morbidity, mortality, and reduced quality of life may be present in both regions. Priority should be given to findings that can have the most immediate effect on public health practice. Researchers on the ground, particularly those with backgrounds in quantitative sciences, are in the best position to determine which studies will provide cost-effective treatments and which are suitable for policy adoption in a particular African location.

The goal of the workshop was to hear about researchers' strategies for dealing with the lack of biostatisticians in the host nation who may contribute to ongoing research projects. Although training is obviously the biggest obstacle, their experiences exposed a variety of demands. Participants learned a lot about how to help SSA develop capacity by reflecting on this recent past.

The Importance of Education

In order to advance biomedical research in sub-Saharan Africa, multidisciplinary research teams from both the region and the West are needed [1]. Biomedical research relies heavily on biostatisticians, who are essential team members. Even in the United States, it is very difficult to maintain and grow a biostatistics staff [3]. In sub-Saharan Africa, where biostatistics is still in its early stages as a field of study, the situation is far more dire. While some schools provide robust statistics departments leading to post-baccalaureate degrees, schools in sub-Saharan Africa (SSA) offer little master's and none at the PhD level in biostatistics. While some schools do offer statistics courses, they often do not place an emphasis on biostatistics and are not associated with programs that provide students access to scientific research. There is often no relationship between these divisions and medical or public health schools. Many trainees struggle to grasp the significance and context of biostatistics in the absence of such a link. Consequently, there is a dearth of biostatistics-trained university faculty members and a general disregard for their work.

Researchers at SSA's clinical and laboratory settings are keen to establish their own research programs, in addition to being active participants in international collaborations. For others, the lack of readily available cooperating biostatisticians inside their own institutions is the biggest barrier to being truly independent researchers. A large portion of the American population is aware of this challenge and works toward the common objective of building strong biomedical research (including biostatistics) capabilities in sub-Saharan Africa. To speed up the process of developing research programs in SSA and to make the current relationship more equitable, this is essential.

Dear Dr. Essex, "In sub-Saharan Africa, biostatistics is the area that I am aware of in the greatest need of training, more so than laboratory sciences or even straight epidemiology or infectious diseases," stated Myron Essex, a distinguished health scientist with over two decades of experience in sub-Saharan Africa and a professor of health sciences at Harvard University. He also chairs the Botswana-Harvard AIDS Institute.

It could take some time for everyone involved to grasp why it's crucial to have the project biostatisticians in the same nation as the rest of the research team. Biostatisticians from the United States and other industrialized nations have shown a readiness to participate in initiatives in Sub-Saharan Africa, proving that geographical closeness is not

always necessary for professional cooperation thanks to the internet. Despite this, many places in SSA have spotty internet service. Clinical and laboratory researchers often lead collaborative projects, even in developed nations with reliable access. This is because these researchers find it most effective to work closely with biostatisticians, as it allows for convenient and frequent interactions that help shape the study design. This would definitely be the case for researchers in SSA if there were competent biostatisticians in the area. Having biostatisticians' support staff all under one roof also has administrative benefits. Furthermore, as previously stated, the demand for biostatisticians' knowledge is outpacing supply in industrialized nations. The need for biostatistical experts is on the rise due to the multiplicity of research options made possible by the lightning-fast pace of biomedical discoveries. Properly planned, carried out, and evaluated projects cannot be guaranteed without such knowledge. It is critical to establish long-term systems in sub-Saharan Africa (SSA) that can manage the needs of several clinical research programs staffed by highly skilled multidisciplinary teams. In response to the critical scarcity of biostatisticians in sub-Saharan Africa, the workshop attendees came up with a remarkable variety of solutions. There ought to be training programs that focus on both the long and short term to increase capacity. Training programs nowadays sometimes just cover the bare minimum of statistics, data analysis, and data management since it's tempting to tailor instruction to the needs of individual research projects. While this is an important first step, it won't be enough to increase capacity in the long run unless we also commit to investing in the education of biostatisticians at the master's and doctoral levels and providing them with opportunities to further their careers within their home institutions. They will be able to pass their knowledge on to future generations of biostatisticians in academia and the workforce.

EXISTING TRAINING MECHANISMS

There was a lot of talk on the different training processes during the Workshop. Biostatisticians have been mentored through research programs in SSA that employ and provide on-the-job mentoring and training of local researchers according to the needs of each project. The training in SSA is mainly supported by institutional research training grants funded through the Fogarty International Center (FIC) of the NIH. Other organizations that have helped with this training include the US Centers for Disease Control and Prevention (CDC), US Agency

for International Development (USAID), and various non-governmental organizations. A number of US universities have formed long-term agreements with SSA institutions to conduct biomedical and public health research. These partnerships use a mix of public and private financing to support capacity development initiatives, including as various forms of training. Higher education in sub-Saharan Africa is part of a vast federal initiative. Scholarships are available from many professional organizations for individuals from underdeveloped nations to attend scientific meetings and pre-conference courses. Brief summaries of the several training possibilities covered in the program are provided below:

The National Institutes of Health's Fogarty International Center

By providing financial and logistical assistance to US and foreign researchers working in the field of global health, FIC is committed to furthering the goals of the National Institutes of Health (NIH). Funding to teach researchers is provided by Fogarty's Research Training Grants (http://www.fic.nih.gov/programs/training_grants/index.htm), which helps low- and middle-income nations create sustainable research capacity. The Fellowships for International Cooperation (FIC) now fund nine research training programs in low- and middle-income nations that educate international scientists exclusively. Some African trainees have been able to pursue master's and doctorate degrees in biostatistics thanks to these programs, which provide chances for training across the complete spectrum of behavioral and biological research. Building national ability to provide biostatistics degree programs is another growing emphasis of the training funds.

The FIC research training programs have sent 23 SSA students to schools in the US and Europe for biostatistics degrees, with 5 earning Ph.D.s and 18 earning M.Sc.s throughout the last decade. The majority of the funding for these trainees came from the Global Infectious Disease Research Training

Program (GID) and the FIC AIDS International Training and Research Program (AITRP). Because FIC only accepts applicants with well-defined job prospects back home, it has been successful in luring graduates from other fields back to their home countries. There isn't a crystal obvious career route for trainees in biostatistics, which is one reason why fewer of them have been sponsored for further degrees in the field. The following is an example of FIC's capacity development in biostatistics research in sub-Saharan Africa, as well as brief biographies of some of its previous trainees:

Trainees Past—In 1999, a South African trainee earned a Master of Public Health (biostatistics) degree from Columbia University via AITRP. The University of KwaZulu-Natal in South Africa is where she earned her doctorate. She now leads the UNAIDS department in Geneva, Switzerland, which generates worldwide estimates of the HIV pandemic, and she is also in charge of the WHO/UNAIDS Program on Statistics, modeling, and estimations. Through AITRP, a Zimbabwean trainee was able to get a Ph.D. in biostatistics from Berkeley in 2006. He joined the faculty at Case Western Reserve University. Despite establishing a base in the US, he is working and conducting trainings in Zimbabwe. A trainee from Uganda earned a Master of Science degree in biostatistics from Johns Hopkins University in 2009 via the AITRP program. Upon his return to Uganda, he became charge of the statistics section for the Rakai Health Sciences program.

The session heard from one of the coauthors, Anneke Grobler, a former FIC trainee hailing from Durban, South Africa. In 2008, Anneke earned a Master of Science degree in biostatistics from Columbia University in New York, thanks to the Columbia University AITRP. In her talk, she compared her time as a trainee at Columbia University to her time back at her alma mater in Durban, South Africa. Taking advanced clinical trials courses at Columbia, where she learned about surrogate endpoints, futility analysis for clinical trials, non-inferiority trials, and equivalency, and having access to books and scientific journals were the highlights of her experience there. "There were more applied

courses and less math in this track at Columbia," she said. The classes helped me, as someone with a background in mathematics and statistics, both realistically comprehend findings and communicate them effectively with researchers from different fields. She returned to South Africa and took charge of the Center for the AIDS Programme of Research's (CAPRISA) statistics and data management core. In 2002, five partner universities, including Columbia University and the University of KwaZulu Natal, formed CAPRISA under the National Institutes of Health-funded Comprehensive International Program of Research on AIDS (CIPRA). The Columbia AITRP is a conduit through which CAPRISA finds and educates future biostatisticians. Anneke was a co-author on the Science Express article [4], and this was the location of the just completed microbicide clinical study. To increase its biostatistics capabilities, CAPRISA runs a number of programs, including internships that introduce post-graduates to the field, financial aid for employees to attend graduate school in their home country, in-country workshops with faculty from both the US and abroad, journal clubs, and opportunities to network with statisticians from other agencies. Her school gets its software licenses from an SSA university. Despite the fact that UKN does not have a

To complete their applied research projects for their master's degrees in applied statistics, students in master's degree biostatistics programs delve into biostatistical methodologies and problems by using CAPRISA data. The FIC research training grants have enabled a large number of trainees to earn master's degrees in both biostatistics and epidemiology. In contrast, some of the trainees have earned Ph.D.s in epidemiology, a field that often requires extensive biostatistical training as part of the FIC research training curriculum.

Training capacity in biostatistics—a new two-year master's degree in biostatistics has been developed by a group of Harvard FIC grantees in collaboration with faculty at Dar es Salaam's Muhimbili University. The degree would be conferred by Muhimbili, and one or more modules may be supported by travel and curriculum development by Harvard faculty members, who could use

existing funding to do so. Regarding the Master's project, nothing official has been announced as of yet. Plans for the future of the curriculum are always in the works. The plan is for faculty from both Muhimbili and Harvard to work together to design Master's course modules. These modules would then be taught as fast courses in Dar es Salaam and count toward the Master's degree at Muhimbili. When funding becomes available, the modules would be put together to form a degree program.

Alliances between American and SSA-affiliated organizations
The Botswana-Harvard School of Public Health AIDS Initiative for HIV Research and Education was established by researchers from Harvard University School of Public Health (HSPH) in collaboration with the government of Botswana. This partnership is known as the Botswana-Harvard AIDS Institute Partnership (BHP) for HIV Research and Education. Muhimbili University of Health Sciences and Harvard was also involved in this research collaboration. The Muhimbili University of Health Sciences in Tanzania was also a founding member of the MUHAS-Harvard Research Collaboration. For more than ten years, the researchers have worked together. Due to the interdisciplinary character of the research undertaken by these organizations, academics from many academic backgrounds, including biostatisticians, epidemiologists, clinicians and laboratory scientists, have been actively engaged. Along with their research mission, these organizations are dedicated to enhancing the ability of local research institutions. There have been official and informal methods of capacity development. Training is formalized via two FIC programs: AITRP, which is a research training program, and FICRS-F, which is another program. FICRS-F offers a year of supervised research experience to graduate students and postdoctoral fellows from the US and SSA. Two students from Botswana and one from Tanzania have earned Master of Science degrees in biostatistics thanks to funding from the AITRP, which allowed them to attend Harvard University and learn about AIDS research methods and processes. Prior to beginning their year-long clinical research experiences in Botswana and Tanzania, pre-doctoral and postdoctoral

clinical scholars from the United States and Sub-Saharan Africa participate in a three-week course at the National Institutes of Health (NIH) where they are exposed to many biostatistics courses. Throughout the year, students have access to supplementary biostatistics lectures delivered via online (Elluminate) sessions. Despite the lack of applications so far, the FICRS-F program offers a fellowship with a biostatistics concentration to postdoctoral biostatisticians from the United States or the Southern African region. The two research partnerships allow US biostatisticians to provide informal lectures and short courses to study staff and other collaborators on data analysis, clinical trials design, quality assurance, case report form design, data monitoring, and related subjects. Both schools are dependent on Harvard for biostatistics knowledge, despite being among the biggest in SSA; yet, neither program has sufficient in-house resources in this area. The John McGoldrick Program for Biostatistics Training (<http://www.hsph.harvard.edu/biostats/mcgoldrick/>) was recently launched by the HSPH in collaboration with AITRP. It takes in about six trainees annually, three each semester, but only allows them one semester of training at a time. Doctors who have worked in clinical trial management are the intended recipients. Although this program aims to improve the statistical literacy of SSA students, it is not structured to prepare students for careers as biostatisticians at the doctoral level.

Academic Model for Health Care Access: A Collaboration Between Indiana University (IU) and Moi University in Kenya—In 1989, the medical schools of Indiana University (IU) and Moi University (in Kenya) began working together to train future medical leaders for the United States and Africa. The Brown/Kenya initiative, which began an exchange of faculty and staff between Brown and Moi Universities, was also initiated about the same time by Brown University. With a \$60 million funding from USAID/PEPFAR in 2007, IU launched AMPATH, the Academic Model for Prevention and Treatment of HIV/AIDS, a comprehensive HIV treatment program in western Kenya [5, 6]. The Academic Model for Providing Access to Healthcare has shifted its emphasis to primary care and is now serving more than 100,000 people

living with HIV at 20 clinics in western Kenya.

In 2001, AMPATH created the AMPATH Medical Records System, an EHR system [7, 8]. Research (and program monitoring and evaluation) have found it to be a useful resource due to the high-quality data it provides on patient contacts, laboratory measurements, treatment regimens, and many other characteristics. Eighteen institutions throughout North America are currently part of the AMPATH Consortium, which manages more than forty million dollars in grant funding. As a result of the growing research program, a small biostatistics core has been established to work with researchers in the US and Kenya on research, monitoring, and evaluation initiatives. Members of the Core come from Brown, Indiana, and Moi universities' professors and personnel. The operational budget for AMPATH provides a little amount of money for the main operations, however due to the budget's short size, research and training activities are limited.

Expanding chances for professional and career training is a significant aim of the core faculty in biostatistics on both the US and Kenyan sides. This will improve the pool of competent Kenyans who may engage in research activities as biostatisticians. Several Kenyan institutions, including those in Nairobi, Kenyatta, Moi, and Maseno, offer courses in statistics and applied statistics. The programs offer a solid foundation in traditional statistical theory, but they could benefit from biostatistics-focused courses and more opportunities to network with biomedical research groups so students can obtain hands-on experience with data analysis. With a large academic medical center, strong research linkages to institutions in the US, Canada, and Europe, and a strong emphasis on statistics, this area offers great promise for the future of research biostatisticians, both in the short and long term.

CONCLUSION

We place a premium on ensuring that the clinical research sector in sub-Saharan Africa is robust and long-lasting. The success of this endeavor depends on the active participation of biostatisticians in the area who work on collaborative research teams. The relevance of strengthening biostatistics capabilities in sub-Saharan Africa (SSA), albeit mostly within the

narrow framework of HIV/AIDS research, has been widely acknowledged, as shown by the list of current and prospective local initiatives and objectives provided above.

While the participants' innovative approaches drew on a wide range of US and non-US research organizations as well as public and private funding sources, they amount to little more than a band-aid solution to the pressing problem of biostatistics resource deficiency in sub-Saharan Africa (SSA).

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