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Strengthening Biostatistics Resources in Sub-Saharan Africa: Research Collaborations through U.S. partnerships

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SUMMARY

On September 30, 2009, the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) conducted a workshop on strengthening biostatistics resources in sub-Saharan Africa (SSA). An increase in global spending on health research over the last decade has boosted funds available to conduct biomedical research in low to mid income countries. The HIV/AIDS pandemic, the reemergence of malaria and tuberculosis, and other emerging infectious agents are major driving forces behind the increase in biomedical research and clinical care programs (clinical trials, observational studies and other public health programs) in SSA [1]. In addition, the increased engagement of the United States (US) government through the Global Health Initiative, which expands the traditional focus beyond infectious diseases to other causes of poor health and to the recognition of need to strengthen health systems for a sustainable response, only increases the need for in-depth in-country expertise in all aspects of biomedical research [2].

In this workshop, researchers both from the US and SSA were invited to discuss their collaborative work, to discuss ways in which biostatistical activities are carried out within their research projects, and to identify both general and specific needs for capacity building in biostatistics. Capacity building discussions highlighted the critical need to increase the number of

The authors dedicate this workshop summary to the memory of Steve Lagakos, who died in October 2009, shortly after the workshop. Steve had a decades-long commitment to the training and career development of young biostatisticians in Africa and in Asia. He had a leading role in planning Harvard-Africa biostatistics training programs, and the impact of his loss is enormous.

well-trained in-country biostatisticians, both to participate in ongoing studies and to contribute to an infrastructure that can produce the next generation of biostatistical researchers.

Keywords

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

INTRODUCTION

Our workshop focused on one discipline – biostatistics – that applies statistical theory and methods to biomedical, public health, and health services research. Of course many other biomedical research and health care disciplines are needed to address the medical and public health challenges in SSA. Fortunately, there is a history spanning many decades of collaboration between western schools of public health, medicine, and tropical medicine and SSA universities and health ministries. As pointed out by Glew [1], “In the past decade or so the biomedical sciences community worldwide has witnessed a marked increase in the number and scope of linkages between Universities and health sciences centers in the US and other developed countries and teaching hospitals in developing countries, particularly those in sub-Saharan Africa, where the overall disease burden is certainly the highest in the world and the gap in biomedical research infrastructure is the widest.” As a result there is now an increasing critical mass of researchers in the biological sciences and medicine to provide in-country research leadership and, equally important, populate the faculties in SSA universities and train those who come next. Growth in biostatistics lags far behind, as it certainly did historically in the west.

When seen in the context of epidemics such as HIV/AIDS, tuberculosis or malaria, the training of biostatisticians in SSA must be a priority to assure that the research questions addressed are those that offer the greatest relevance for the local people. Although the diseases causing the greatest burdens of morbidity, mortality, and reduced quality of life may be present in the west as well as SSA, the research questions in these two geographic regions differ substantially because of the background health care resources and general health status of the population in question. Those results that can impact public health practice most rapidly should receive the greatest priority. Local teams of researchers including experts with skills in quantitative sciences are most likely to understand which types of studies are likely to yield results that lead to cost effective interventions and/or ready for adoption as policy in a given region of Africa.

The workshop’s purpose was to gain an understanding of how researchers have been coping with the shortage of in-country biostatistics expertise for existing research programs. Their experiences revealed a range of needs, not only training per se, although training is clearly the greatest challenge. By learning from this recent history, participants were able to identify a number of approaches to assist SSA to build capacity.

THE NEED FOR TRAINING

The expansion of biomedical research in SSA requires the participation of interdisciplinary research teams both from SSA and the West [1]. Biostatisticians are critical members of the research teams and play an important role in biomedical research. Sustaining and expanding a biostatistics workforce is a serious challenge even in the US [3]. The challenge is much greater in SSA where biostatistics is not well established as an academic discipline. Although some universities have strong statistics departments with post-baccalaureate degree programs, there are only a handful of masters and no doctoral level biostatistics programs in SSA universities. Those universities that do provide training in statistics usually do not emphasize biostatistics, and usually are not linked to programs that provide access to biomedical-research activities. Such departments are usually not connected to Schools of Medicine and/or Public Health. Without such a connection it is often difficult for trainees to understand the context and the importance of biostatistics. As a result, the numbers of university faculty members with specific training in biostatistics remain limited and their interests are marginalized.

In addition to participating as partners in multi-national programs, clinical and laboratory researchers in SSA are eager to build their own research programs. Limited access to collaborating biostatisticians in their own institutions is a serious obstacle to developing research independence; some regard it as the *primary* obstacle. Many in the US recognize this obstacle and share the long-term goal of creating robust capacity in SSA for biomedical research, including biostatistics. This is critical both to improve the equality of the ongoing partnership and to accelerate the transition to creating the research programs in SSA. Dr. Myron Essex, Mary Woodard Lasker Professor of Health Sciences at Harvard University and chair of Botswana-Harvard AIDS Institute with 20 plus years of research experience in SSA said, “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”.

The importance of having project biostatisticians located in the same country as the other members of the research team may not be immediately apparent to all interested parties. With the internet, physical proximity is not always essential for professional collaboration, and biostatisticians in the US and elsewhere in the developed world have demonstrated a willingness to become involved in projects in SSA. In fact, however, internet access in many locations in SSA is unreliable. Even in the developed countries where access is reliable, most collaborative projects are led by clinical and laboratory researchers based at the same institutions as the biostatisticians; these researchers find it most effective to deal with biostatisticians close at hand, for frequent and convenient interactions that facilitate an evolving study design. This would certainly hold true for SSA researchers, if qualified biostatisticians were available locally. An additional advantage is the administrative convenience of arranging support for biostatisticians within the same institution. Also, as mentioned above, biostatisticians in developed countries cannot keep up with the demands for their expertise. The rapidity of biomedical discovery leads to greater research opportunities, increasing in turn the demand for biostatistical expertise. Such expertise is necessary to assure well-designed, well executed, and appropriately analyzed projects. The

creation of sustainable infrastructures in SSA that can coordinate and integrate the requirements of multiple clinical research projects with well trained interdisciplinary research teams is essential. The workshop participants identified an impressive array of strategies for coping with the severe shortage of biostatisticians in SSA.

Training programs aimed at building both long-term and short-term capacity are needed. It is tempting to focus training on only those activities needed for a specific research project; hence, many training programs are currently geared at teaching basic statistics and data analysis and data management. This activity is a necessary start; but to build long term capacity, it must be coupled with a commitment to invest the time and financial resources needed to generate biostatisticians at the Masters and PhD level and to support a career development pathway for them in their home institutions. Those trainees will be in a position to train the next generations of both professional and academic biostatisticians.

EXISTING TRAINING MECHANISMS

The Workshop included considerable discussion on the variety of mechanisms used for training. NIH supports training in SSA primarily through institutional research training grants funded through the Fogarty International Center (FIC) of the NIH. NIH, the US Centers for Disease Control and Prevention (CDC), US Agency for International Development (USAID), and several non-governmental organizations sponsor research programs in SSA that employ and provide on-the-job mentoring and training of local researchers according to the needs to each project; and biostatisticians have been mentored through these mechanisms. Several US universities have established ongoing biomedical and public health research partnerships with universities in SSA using a variety of public and private sources of funding, to promote capacity building including training of many kinds. The US Department of Education has a very broad Initiative for Higher Education in SSA. Some professional societies have offered scholarships to people from developing countries to attend pre-conference workshops and scientific meetings.

Below we will give short descriptions of the different training opportunities discussed in the workshop:

The Fogarty International Center at the National Institutes of Health

FIC is dedicated to advancing the mission of NIH by supporting and facilitating global health research conducted by US and international investigators. Fogarty's Research Training Grants (http://www.fic.nih.gov/programs/training_grants/index.htm) provide funding to train researchers, building sustainable research capacity in low- and middle-income countries.

Currently, FIC supports nine research training programs focused solely on the training of foreign scientists in low-and middle-income countries. These programs provide opportunities for the full breadth of biomedical and behavioral research training, but they have supported training in biostatistics at the masters and doctoral level for some trainees from Africa. Increasingly, the training grants are also focusing on developing in-country capacity to offer degree level training biostatistics.

Over the last 10 years, 23 (5 Ph.D. and 18 M.Sc.) trainees from SSA completed academic degrees in biostatistics at US or European universities through FIC research training programs. These trainees were funded mostly through the FIC AIDS International Training and Research program (AITRP) and Global Infectious Disease Research Training Program (GID). FIC has succeeded in having graduates in other disciplines return to their home countries by selecting candidates who have clear career paths in their home countries. There have been fewer trainees supported for higher degrees in biostatistics due, in part, to the lack of a clear career path for them. Below are few short bios of former FIC trainees and an example of FIC's biostatistics research capacity building in SSA:

Former Trainees—A trainee from South Africa completed her Master's in Public Health (biostatistics) through AITRP at Columbia University in 1999. She completed her Ph.D. at University of KwaZulu-Natal, South Africa. Currently, she is head of the WHO/UNAIDS Program on Statistics, modeling and estimations and heads the UNAIDS department that produces the global estimates of the HIV epidemic in Geneva, Switzerland. A trainee from Zimbabwe received PhD in Biostatistics from University of California at Berkeley through AITRP in 2006. He took a faculty position at Case Western. He continues to do trainings/work in Zimbabwe, but from a base in the US. A trainee from Uganda graduated with a Masters in Biostatistics at Johns Hopkins through AITRP in 2009. He returned to Uganda and assumed a leadership role of the Rakai Health Sciences program statistical unit.

One of the coauthors, Anneke Grobler, a former FIC trainee from Durban, South Africa presented her experience at the workshop: Anneke received her MS in Biostatistics in 2008 from Columbia University in New York through the Columbia University AITRP. She discussed her training experience at Columbia and her experience after returning to her home institution, in Durban, South Africa. The highlights of her Columbia experience were: combining theoretical and practical applications; taking advanced courses in clinical trials where topics like surrogate endpoints, futility analysis for clinical trials, non-inferiority trials and equivalency were discussed; availability of resources like books and scientific journals. She said, "The courses in this track at Columbia were less mathematical with more applied courses. Coming from mathematics and statistics background, the courses helped me to interpret results practically and to communicate results effectively with researchers from other disciplines." Upon her return, she became head of the statistics and data management core of the Center for the AIDS Programme of Research in South Africa (CAPRISA). CAPRISA was established in 2002 under the NIH-funded Comprehensive International Program of Research on AIDS (CIPRA) by five partner institutions including the University of KwaZulu Natal and Columbia University. CAPRISA, through the Columbia AITRP, recruits and trains biostatisticians. This was the research site of the recent successful microbicide clinical trial, and Anneke was one of the co-authors on the Science Express paper [4]. Some of the programs used by CAPRISA to build biostatistics capacity are: exposing post-graduates to biostatistics through internships, supporting staff to pursue post graduate training at local academic institutions, hosting in-country workshops with local and US faculty and hosting journal clubs and discussion with statisticians from other research organizations. The software licensing in her institution is through an SSA university. Although the University of KwaZulu Natal does not have a

Masters degree biostatistics program, students use CAPRISA data to conduct their applied research projects as part of masters degrees in applied statistics; thus being exposed to biostatistical methods and questions.

Through FIC research training grants, numerous trainees have received combined epidemiology and biostatistics masters degrees. Other trainees have received doctoral degrees in epidemiology which usually include some depth in biostatistical skills through the FIC research training program.

Biostatistics training capacity—Harvard FIC grantees have been working with collaborators at Muhimbili University in Dar es Salaam on a new 2 year Masters program in Biostatistics. Muhimbili would be the degree granting institution and Harvard faculty would help develop curriculum and travel to support one or more modules, supported by existing grants. There is nothing formal yet as far as the Master's project. There is ongoing planning related to development of the curriculum. The idea is that blocks for the Master's will be developed jointly by faculty at Muhimili and Harvard; these would be offered as short courses in Dar es Salam with credit toward the degree at Muhimili; these blocks would be assembled into a degree program when more resources are available for that to happen.

Partnerships between US and SSA Institutions

Botswana-Harvard AIDS Institute Partnership (BHP) for HIV Research and Education/Muhimbili University of Health Sciences and Harvard (MUHAS-Harvard) Research Collaboration—Researchers from Harvard University School of Public Health (HSPH) collaborated with the government of Botswana to establish the Botswana-Harvard School of Public Health AIDS Initiative for HIV Research and Education. They also collaborated with Tanzania's Muhimbili University of Health Sciences to form the MUHAS-Harvard Research Collaboration. The research collaborations have been ongoing for over a decade. Because of the nature of the research conducted by these groups, biostatisticians, as well as epidemiologists and clinical and laboratory researchers have been involved at all levels of training. In addition to their research mandate, these groups have a commitment to strengthening local research capacity. Capacity building has taken place in both formal and informal ways. Formally, training is conducted through the FIC's research training programs AITRP and another FIC program, Fogarty International Clinical Research Scholars and Fellows program (FICRS-F) which provides a one year mentored research experience to US and SSA graduate students and postdoctoral fellows. AITRP supported scholars from Tanzania and Botswana to pursue training in AIDS research techniques and procedures at Harvard and to date one Tanzanian and two Botswana received MSc degrees in Biostatistics. Through the FICRS-F program, both US and SSA clinical scholars (pre-doctoral) and fellows (postdoctoral) receive exposure to several biostatistics lectures at the three-week course offered at NIH before they begin their year-long clinical research experience in Tanzania and Botswana. Additional biostatistics lectures are provided through virtual (Elluminate) sessions over the course of the year. Although none have applied to date, potentially, a US or SSA biostatistician at a postdoctoral level could apply for a fellowship with an emphasis on biostatistics in the FICRS-F program. Informally, through the two research collaborations, US biostatisticians give lectures and conduct ad hoc

short courses on data analysis, clinical trials design, quality assurance, case report form design, data monitoring and other related topics for study staff and other collaborators.

Although both Harvard-related programs are among the largest in SSA, both lack adequate capacity in biostatistics and rely on Harvard for the provision of such expertise. Along with AITRP, the HSPH recently initiated the John McGoldrick Program for training in biostatistics (<http://www.hsph.harvard.edu/biostats/mcgoldrick/>). It accepts about 6 trainees per year (3 per semester), but limits training to one semester. It is targeted at physicians who have participated in the management of clinical trials. While focused on students from SSA, and providing them with a better understanding of statistical methods, this program is not directed at those who are likely to become Ph.D.-level biostatisticians.

Partnership between Indiana University (IU) and Moi University: Academic Model Providing Access to Health Care

—In 1989, a partnership started between the Indiana University School of Medicine and Kenya's Moi University School of Medicine to join together to develop leaders in health care for both the US and Africa. Around the same time, Brown University launched the Brown/Kenya program, initiating an exchange of scholars and clinicians between Brown and Moi Universities. In 2007, IU was awarded a \$60M grant from USAID/PEPFAR to roll out a comprehensive HIV treatment program in western Kenya; the program became known as the Academic Model for Prevention and Treatment of HIV/AIDS (AMPATH) [5, 6]. It currently serves over 100,000 individuals with HIV at 20 clinics in western Kenya; it has recently expanded its focus to primary care and is now known as the Academic Model for Providing Access to Healthcare.

In 2001, AMPATH developed an electronic health records system known as the AMPATH Medical Records System [7, 8]. It contains high-quality data on patient encounters, laboratory measures, treatment regimens, and a host of other variables, and has become an invaluable resource for research (and for program monitoring and evaluation). The AMPATH Consortium now includes 18 universities in the US and Canada, and conducts over \$40M of grant-funded research.

The expanding research program has given rise to a modest-sized biostatistics core charged with collaborating with Kenyan and US researchers in the development and execution of research, monitoring, and evaluation projects. The Core members comprise faculty and staff at Brown, Indiana and Moi Universities. A modest amount of funding for the core operations is provided by the AMPATH operating budget, but the small budget places limits on both research and training activities.

A major goal of the core faculty in biostatistics on both the US and Kenyan sides is to expand the opportunities for both professional and career training, and thereby increase the pool of qualified Kenyans to participate in research activities as biostatisticians. Statistics and applied statistics training programs are well established in Kenya at universities such as Nairobi, Kenyatta, Moi, and Maseno. These programs provide outstanding comprehensive training in traditional statistical theory; what is lacking is coursework that is specifically geared to biostatistics and opportunities for meaningful connections with biomedical research programs (where students can gain valuable experience in data analysis). In an

institution like Moi University, which houses graduate and undergraduate training in statistics, is home to a major academic medical center, and has stable and well-established research partnerships with US, Canadian and European universities, there exists outstanding potential for investment in both long- and short-term training of research biostatisticians.

High quality undergraduates with quantitative background are coming out of universities in Kenya including Moi and Kenyatta universities. If these students receive graduate training in biostatistics and if opportunities are provided to them to participate in actual research, and get access to strong mentors in computing and software infrastructure, the country will be able to have more Kenyan researchers by building on the existing infrastructure. Currently, the Brown University AITRP is supporting a PhD in biostatistics candidate from Moi University, and several Kenyans have been supported for Masters level biostatistics training by the University of Washington AITRP.

International Academic Partnerships on Observational Databases from East Africa IeDEA and PEPFAR—The International Epidemiologic Database to Evaluate AIDS (IeDEA) is a network of regional consortia around the world funded by NIH. IeDEA supports eleven different regional sites in the world; East African region is one of these sites. Currently, the East African IeDEA has three countries, Kenya, Uganda and Tanzania; and other countries will be added. The database for the region follows more than 120,000 adults and children with HIV from the three countries. In addition to conducting data analysis, the researchers provide monitoring and evaluation services to the Ministries of Health in the countries. They also give regular updates to the Ministries of Health and the National AIDS Control programs in the countries. Most of the IeDEA regions have concentrated their statistical and epidemiological expertise in their US and European headquarters. One of the things IeDEA East Africa is trying to do is involve more in country researchers in doing the research. IeDEA East Africa is building a regional data center in East Africa. The data center is now located in Eldoret where AMPATH's Data Analysis Team is located. The data center includes data managers, statisticians and IT professionals. They have started training in country researchers. Currently, the data center has a statistician trained in Belgium and a data manager retrained in the US. The East African IeDEA is trying to create both capacity building and transfer of knowledge so that the research can be run increasingly by in country researchers.

Initiative for Higher Education Partnership in Sub-Saharan Africa—Higher Education for Development (HED), manages a major program of international partnerships between US and overseas higher education institutions. This recently launched Africa-US higher education initiative further illustrates the great interest in partnership between US and African institutions toward capacity building. For this initiative USAID funded twenty planning grant awards. These grants are awarded for development of a strategy plan and the strategy plan will be funded later on for long-term collaboration. Five of the twenty grants are for public health partnerships. These public health partnerships have the potential to develop biostatistics training programs along with other public health programs.

Collaboration between the Republic of South Africa (RSA) and the US—The Phidisa program was established in 2003. It is collaboration between the South African

Military Health Service (SAMHS) of the South African National Defense Force (SANDF), the US Department of Defense (DoD) and the NIH of the US. As part of the program, a large randomized trial and a cohort study were designed and conducted. To carry out this research, six clinical sites and a central coordinating center were established. The clinical sites were already providing clinical services to South African military personnel and their families. The coordinating center was established de novo and staffs from the SAMHS and civilian personnel were reassigned/hired to provide data management and biostatistical expertise to the program. US personnel from the DoD, NIH, the University of Minnesota and the University of New South Wales provided training on site and in the US and Australia. The training in biostatistics and data management was provided by staff from the University of Minnesota. In addition to periodic staff exchanges, Phidisa staff took web-based courses in biostatistics and SAS programming. Training and communication was facilitated by installing a data management system and statistical software that was identical to that used by data management staff and biostatisticians at the University of Minnesota. This facilitated trouble-shooting and long-distance communication. The establishment of a coordinating center for project Phidisa in the RSA resulted in substantial on-the-job experience for the coordinating center staff.

US Center for Disease Control (CDC) in Kenya—CDC's field station in Kenya has large-scale research and programmatic activities. CDC operates in Kenya via a cooperative agreement with the Kenyan Medical Research Institute (KEMRI) in Kisumu and Nairobi. In Kisumu, there are approximately 40 research projects and provincial HIV control efforts (largely PEPFAR funded). In Nairobi, the group is split between providing technical assistance to the Ministry of Health and supporting a number of projects based out of an urban slum. Substantial informatics support is required to meet these needs, including statistical support. The factors that have helped retain or recruit new statisticians include the creation of more embassy-based positions that have better salaries, more short and long term training opportunities, increased opportunities to be professionally active, better employment benefits (such as health care), the relevance of the work, and increased emphasis on internships and student projects. Major efforts are made to fill in the voids in the education of young statisticians.

Other training programs

Short term biostatistics training programs in the US—A Number of US Universities with school of public health offer short term trainings in public health focused on biostatistics. These courses are attended by researchers from many countries including researchers from SSA. One of these training programs offered by University of Washington in Seattle, WA was presented at the workshop.

Summer Institute in Statistics and Modeling in Infectious Diseases (SISMID) and Summer Institute in Statistical Genetics (SISG), University of Washington: The summer institutes consist of a series of two-and-a-half day workshops sponsored by the Department of Biostatistics and funded partly through the National Institute of General Medical Sciences/NIH. SISMID is designed to introduce infectious disease researchers to modern methods of statistical analysis and mathematical modeling and to introduce

statisticians and mathematical modelers to the statistical and dynamic problems posed by analysis of modern infectious disease data. Some of the topics covered are infectious diseases and immunology, mathematical models of infectious diseases, and design and analysis of vaccine clinical trials. SISG has a comprehensive program in statistical genetics. The summer institutes are held in Seattle, Washington, US, in June. Researchers from the US and outside the US have attended the workshops. In 2009, because of funding shortage, few SSA researchers were able to attend these summer institutes.

Training SSA researchers through Sabbatical leave—Sabbatical leaves are for longer duration and can be used to train researchers, develop or improve existing curriculum, provide mentoring and work on methodological research. Sabbatical leaves are supported by existing projects (e.g. AMPATH), funding agencies (e.g. FIC); in addition many SSA research facilities and universities arrange for living accommodation.

Sabbatical visit of US researcher to Moi University: One of the coauthors, Dr. Joseph Hogan, spent three months (Jan/2010-March/2010) of a sabbatical leave at Moi University in Eldoret, Kenya. He worked full-time on several projects with Kenyan colleagues at AMPATH, participated in the hiring process for new masters-level statisticians, and delivered several lectures on general statistical methods to the biomedical research community. Another key activity of his stay included having discussions with faculty in the Department of Mathematics and Computer Science related to both long- and short-term objectives for enriching local training in biostatistics. Short term goals include development of new graduate courses in biostatistics; long-term goals include updating of existing statistics curricula to include applied biostatistics courses and to integrate existing biomedical research taking place at the Schools of Medicine and Public Health. Regarding his living arrangement Dr. Hogan said “In Eldoret, the infrastructure for long-term housing, administered by Indiana University, is an invaluable on-site resource. At any given time, the IU House complex hosts up to 80–90 visitors ranging from visiting medical students to senior faculty from US and Canadian universities.”

Training supports by other national or international agencies and professional societies—Agencies such as Wellcome Trust (England), the EDCTP (European and Developing Countries Clinical Trials Partnership), and the Canadian International Development Research Centre now offer programs for research training in various countries in Africa. They are usually built on the establishment of networks for training that include several countries in Africa (i.e., particular research institutions in those countries), and at least one institution in the developed country. Universities such as London School of Hygiene and Tropical Medicine (LSHTM), University of London has a long standing history of supporting training programs for researchers from low to middle income countries.

London School of Hygiene and Tropical Medicine (LSHTM), University of London: For example in 2008, LSHTM offered a ppostgraduate Training Fellowship in Medical Statistics for African Scientists (http://www.lshtm.ac.uk/prospectus/howto/Fellowship_MedStats.htm): This Training Fellowship provides two years' support. This

comprises one year's study for the Master of Science degree in Medical Statistics at LSHTM, followed by a one-year professional attachment at one of the African centers associated with the Tropical Epidemiology Group (TEG) research programme. During the professional attachment, Fellows will develop their skills by working on specific research studies with guidance and support from TEG staff. This support is intended to foster excellence in the field of medical statistics and epidemiology in sub-Saharan Africa.

Training through SSA Institutions: There are centers in SSA where training in mathematics, bioinformatics and disease modeling are offered. For example, the South African Centre for Epidemiological Modeling and Analysis (SACEMA) with Rutgers University from New Jersey, USA, has been running a course on *Meaningful Modeling of Biological Data (MMBD)* in Cape Town. The African Institute of Mathematical Sciences (AIMS) is closely linked to SACEMA and runs similar courses.

American Statistical Association(ASA): Sponsors educational ambassadors from different countries to attend the annual ASA meeting and to take classes at the annual meeting. Eshetu Wencheke from Ethiopia was the 2006 ASA educational ambassador. Wencheke, president of Alpha University College in Addis Ababa, and adjunct professor in the department of statistics at Addis Ababa University, took two classes during JSM 2006 in Seattle, Washington: *Generalized Linear Mixed Models and Generalized Linear and Latent Mixed Models*. He taught a class in generalized linear mixed models to 14 graduate statistics students in Ethiopia. One of the concentration areas in the department of statistics is biostatistics. Wencheke advises masters students in the department whose area of concentration is in biostatistics. Wanchedo said (<http://www.amstat.org/outreach/pasteducambassadors.cfm>), "In countries like mine, there exists a big gap in statistics knowledge after one has done the first or second degree and joined the world of work. Cognizant and fully aware of this fact, I believe that bridging this knowledge gap vis-à-vis wider CE and collaboration with ASA would definitely help many of my colleague statisticians in Ethiopia and elsewhere."

International Biometric Society (IBS): Is an International Society devoted to development and application of statistical and mathematical theory and methods in biosciences [9]. Members of the society are organized into regions, groups and networks across the continent. Members in sub-Saharan Africa are organized into a network, the sub-Saharan Network of IBS (SUSAN). IBS members from other networks and groups participate in the annual meetings of SUSAN by delivering lectures and engaging with both junior and senior researchers. IBS encourages programs to interact. Through this kind of interaction and motivated by IBS goals of education and outreach, members of other IBS groups sponsor researchers from SSA for short term visits to their institutes.

As with the existing programs with the US, biostatistics is often not emphasized as a training need as effectively as are other areas or sub-disciplines such as microbiology, epidemiology or general public health. The Fogarty research training programs are the only NIH-funded training programs that support degree training for trainees from developing countries. While they do allow training for biostatistics (mostly, to date, related to HIV/AIDS), and have made a contribution, it has been difficult to recruit applicants for degree training in

biostatistics, partially due to the lack of career potential in SSA. Most of the training slots are not used for in-depth training in biostatistics. With the new US government emphasis on sustainable health systems, new approaches might be considered so that a training program in biostatistics for SSA countries which would support both research and evaluation related to activities under PEPFAR, Global Health initiative and/or the Global Fund. The goal would be to link training in biostatistics to the need for evaluating the effectiveness of those programs based on analysis of in-country data.

PROPOSAL FOR FUTURE DIRECTION

The increase in biomedical research in SSA countries creates a demand for a greater number of in country biostatisticians. The key to meeting this demand is that SSA universities educate and retain in country biostatisticians at the masters and doctoral level, and US and other universities train additional students from SSA who want to return to their home country [10]. At this point, most of the universities in the region do not have the capacity or the infrastructure to produce in country biostatisticians or to retain those trained at the doctoral level. Essential to the retention of professional development of SSA biostatisticians, as well as their ability to remain abreast of new developments are university departments and research centers to which trained individuals can return to build their careers. While the long term plan is to build the capacity and the infrastructure of SSA research institutes and universities to produce more of their own graduates [10], effective short term plans are needed to train more biostatisticians and to lead the universities and institutes on the path to achieving their long term plans.

In addition to existing training mechanisms that support students for post graduate studies in the West, more short term training and continuing education classes both in the US and other developed countries and SSA will help the SSA researchers expand their knowledge base. In the US, many universities hold summer institutes for public health which offer classes in biostatistics. Because of funding shortage and other constraints, limited numbers of SSA researchers attend these summer institutes. The numbers of SSA researchers attending summer institutes for public health and short courses can be increased either by increasing funds available to SSA researchers to go to the US or elsewhere or by running regional summer institutes for public health and short courses in SSA. The latter is a cost-effective way of reaching more SSA researchers. These short courses can be used to identify candidates with potential for more advanced biostatistics training, including master and doctoral level. In addition, many US universities offer web-based courses that lead to certificates. A combination of local seminars, summer institutes and web-based courses may be an effective way to build interest and capabilities in biostatistics. A model for making courses/seminars available on the internet already exists in the field of epidemiology (<http://www.pitt.edu/~super1>)[11]. The site has few courses in biostatistics. A similar website can be developed for biostatistics or more biostatistics courses can be added to the site.

As demonstrated in many of the presentations in the workshop, the biostatistics resources in SSA are minimal and need to be strengthened. Below are some of the items discussed as long term and short term goals.

Long Term Goals

1. Building a center of excellence and coordinating centers in SSA for biostatistics and data management through a consortium of SSA universities

—The importance of a central coordinating center for multi-center studies has been recognized for many years. In the often cited Greenberg Report [12], the importance of a coordinating center to organize the collection and analysis of data for multi-center trials is emphasized. This Committee describes the key responsibilities of a coordinating center and notes the following: “Because of its important role, the coordinating center must be under strong and capable leadership that will remain stable for the duration of the trial.” The report and this quote illustrate several important points: 1) a coordinating center with data management and biostatistical expertise is a key to the proper conduct of multi-center studies; 2) the coordinating center infrastructure must be a stable organization otherwise the research studies may be at risk; and 3) strong leadership is needed. The latter is not possible without years of experience. It is critical that mechanisms for gaining this experience in SSA be developed and nurtured.

With the growing number of multi-center and multi-national trials, the concept of coordinating centers has expanded. In many multi-center studies and clinical trial networks (groups funded to conduct multiple collaborative studies), regional or international coordinating centers have been effectively used for patient recruitment, training and data collection (e.g. Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), Digitalis Investigation Group (DIG) trial, and International Network of Strategic Initiatives in Global HIV Trials (INSIGHT)). These networks are currently managed out of the US and not out of SSA.

Clinical trial networks can provide some long-term stability to the infrastructure required to conduct multi-national studies. If regional or international coordinating centers in such networks are established in SSA, this could be a mechanism by which a greater number of individuals, including biostatisticians obtain training and enter a career path in biostatistics by which lasting, cost-effective infrastructures for clinical research are established.

2. Conducting summer institutes in public health in the region with focus in biostatistics

—Different universities in the US conduct summer institutes in public health. These institutes teach both the subject matter and application of statistical methods specific to the area research. One example is the University of Washington Summer Institute in Statistics and Modeling in Infectious Diseases mentioned above. Availability of funding both from SSA institutions and outside funding agencies to foreign students will ensure that more SSA researchers are able to attend summer institutes offered at different US universities. In the long term, if summer institutes are conducted in SSA, they will be able to train a greater number of SSA researchers. Another benefit is that having the training sessions in SSA may make it a more conducive learning environment than sending isolated SSA researchers abroad. Students would be more likely to be in classes with others of a similar academic training and such an environment could foster partnerships amongst students that go beyond the classroom and into their professional careers.

3. Establishing graduate training programs in biostatistics in SSA universities

—In addition to attracting new students into biostatistics, these training programs can redirect students already enrolled in quantitative graduate programs or to faculty to apply their quantitative background to biomedical research problems. A wide array of beginning and advanced biostatistics courses will be valuable both to graduate students and to interested faculty members. These more advanced trained faculty members and graduate students can become the future trainers of biostatisticians. This kind of training needs to be integrated in the academic calendar of interested SSA universities so that students, faculty members, and trainers are able to attend and can prepare themselves to realize the maximum benefit from such a program. Trainers can do this through short term academic visits, sabbatical visits or any pre arranged training mechanisms.

4. Creating joint graduate degree programs between universities in SSA and the US

—A joint graduate program (sandwich program) in collaboration with SSA universities and US universities will help SSA universities to produce in country biostatisticians who are engaged in the research in their own institutions [8]. This program will also build the capacity of SSA universities to have their own biostatistics graduate program(s) in the future. Because SSA researchers will be conducting their research in their home country, this will encourage them to stay and continue their research work there. Masters level training is very valuable for a more rapid response to the needs of medical research team. However, without some expertise at PhD level, the long-term prospects for local training of biostatisticians and sustainable capacity are much less likely to materialize.

Short Term Goals

1. Mentoring within active research projects—Informal training and mentoring are an essential part of research capacity development. Because a cadre of biostatisticians at all levels are not available in most SSA research settings, questions that arise or problems that are easily resolved by US-based biostatisticians by a call or e-mail to a colleague or a thesis committee member or a broadcast e-mail to a listserv of biostatisticians within their institution, may pose greater barriers to SSA biostatisticians. Returning biostatisticians can be paired with mentors in the West that can partially serve this function.

2. Co-advising of graduate students in sub-Saharan universities—Many universities in SSA have adequate or strong statistics, mathematical statistics or applied statistics departments. Few have biostatistics departments or even staff with biostatistics knowledge or experience. If students enrolled in these statistics departments with local faculty advisors have a biostatistics co-advisor from the West, they will be able to complete their degrees with research exposure to the biomedical field.

3. Offering continuing education classes in SSA using guest faculty and/or distance learning—Offering continuing education classes in biostatistics, epidemiology, and data management to SSA universities with statistics programs will expose both the faculty and students to applications of statistical methods to biomedical research. The guest faculty for classes can be from groups with long term collaborative research in SSA.

4. Supporting travel and enrollment in career development classes offered at professional meetings in and outside of SSA—By attending career development classes offered at professional meetings, SSA researchers will be able to learn the applications of new and existing statistical methods to the biomedical field and thereby keep current. In addition, by attending the different technical sections at the meetings they will increase their knowledge base and can further develop capacity by sharing their knowledge with their colleagues upon return to their country. We encourage professional societies to consider sponsoring the attendance of SSA biostatisticians at their professional meetings.

5. Encouraging sabbatical visits by established biostatisticians to SSA universities or other research organizations—Because of the lack of graduate training programs in biostatistics in SSA and the focus on addressing immediate research needs, biostatisticians in SSA function almost exclusively as applied biostatisticians. The few doctoral-level trained SSA biostatisticians in-country seldom have the opportunity to conduct methodological research and thereby develop their institutions as sites for doctoral training programs. Although biostatisticians who conduct methodological research in the elsewhere visit SSA, the purpose of their visits is usually to move the applied research program forward. The length of the visits do not permit them to work on methodological research or to provide mentoring for writing grants to obtain funding to conduct methodological or applied research studies. Sabbatical visits of a longer duration could afford them the time to focus on long term capacity development.

6. Developing website for information exchange—An internet-based clearinghouse for information would be valuable to both SSA students and researchers and to those interested in contributing to capacity development from elsewhere. It would make it easier for those seeking training to identify opportunities. It would help others to identify opportunities to collaborate in providing assistance. This website can be housed in one of the biostatistics/statistics professional society websites.

Other Needs

1. Data management—High quality data management requires human expertise as well as hardware and application software needed to store and clean data. Many international research collaborations split the data management function between countries depending on where expertise and infrastructure exist or how much they are willing to invest in their development. For example, data collection, entry and initial data checks may be performed in the host country and additional data checks and data storage may be performed in the country where the coordinating center is based and queries are sent to the local data management center for resolution and update of case report forms. Availability of trained data managers and medical informatics expertise, vary depending on the host country and are a factor in determining how data management tasks are split between host and sponsoring groups. Usually there is no shortage of local staff that can be trained for performing data entry and basic data management. Data management skills are more likely to be available through access to local training programs related to corporate development, economics, and non-medical statistics. Availability of database developers with an interest in biomedical research and with working knowledge of major software packages such as

SAS, Stata and R however, are hard to find. The availability of good data management directly influences the productivity of the few available in country biostatisticians or external collaborators, since biostatisticians can end up spending a disproportionate amount of time cleaning data and ensuring data accuracy prior to analysis.

2. Access to research materials—a) Reliable computing infrastructure, including modern computers to conduct data analyses, reliable internet connectivity (still a major problem in much of SSA), and secure servers for holding data and making backups. b) Access to the latest versions of statistical software used in the modern biomedical computing environment. In some cases, personnel in SSA are licensed to use software through US universities because the costs are too high for local institutions. In other cases where SSA universities can afford to obtain academic licenses, SSA researchers are licensed to use software through their local universities. Major discounts are needed for most SSA institutions to be able to purchase and manage site licenses. c) The need for access to biostatistics reference materials, including books and hard copies of journals. Although the internet has made journals much more accessible, many SSA institutions must rely on a US partner for widespread journal access. Internet connections are slow enough that even simple downloads of papers can become prohibitive.

It is certainly possible that more can be accomplished through greater awareness of other related activities, and perhaps some creative coordination. For example, there is a vibrant, highly successful Summer Institute for Training in Biostatistics, a training initiative funded primarily by the National Heart, Lung, and Blood Institute of the NIH. Universities host quantitatively oriented undergraduate students for several weeks to expose them to biostatistics as a career opportunity. Except for those supported through FIC research training grants most NIH-funded training programs are limited to students who are US citizens/permanent residents. It would be useful to find a mechanism to support students from SSA who, apart from citizenship, have comparable preparation and some command of English. Of course the idea of the summer institutes is to get the students to consider the pursuit of graduate training in biostatistics. In the short term that training might not be an option within SSA.

Some of the goals described above are not being addressed, and will not be addressed, due to the limitations of what can be achieved by leveraging small amounts from sponsored projects whose objectives are not focused on training. New resources will have to be found. Having discovered through the workshop that agencies like NIH (DHHS), CDC (DHHS), USAID (Department of State), the Initiative for Higher Education Partnership (Department of Education), and the Bill and Melinda Gates Foundation have all found ways to help in this area, greater coordination of programs will provide impetus for improvement. In the current budgetary environment it is bound to be difficult to obtain funding for an entirely new initiative, especially one that overlaps the missions of multiple government departments. Thus it is important to continue taking the short-term measures, recognizing that they will not be sufficient by themselves, while at the same time exploring the possibility of a more comprehensive and long-term approach. Below are some examples where coordinating effort of funding organizations can be used to achieve some of the goals.

- Develop a more structured training program in SSA: For example in the Phidisa programme, coordinating center staff became so valuable at the site during the conduct of the studies, it was difficult for them to spend extended periods of time in training away from the site.
- A long-term view must be taken in planning initiatives: Five year research projects can provide a jump start for establishing an infrastructure for data management and biostatistics, but more consistent funding to support research and related research training over a longer period of time is needed to build an independent research team.
- If funding agencies collaborate, more research will be possible at lower cost: It is critical US and other governments work together to build the infrastructures required to conduct clinical research. Regulations require harmonization. Funding must be available from multiple sources. Research agendas must be established collaboratively.
- Regional centers: The concept of regional centers in clinical trial networks offers a possibility through which “research laboratories” can be established in developing countries. Such networks typically have a larger funding base and are of longer duration. Through such expanded collaborations, the creation of these centers will expose biostatisticians and other researchers to new ways of thinking about problems and offer the possibility of creating international mentoring teams for young biostatisticians and clinical researchers.

Referring to the shortage of biostatisticians in SSA, statisticians from University of Botswana, statistics department commented, “Most statistics department in Africa just teach theoretical statistics without any connection to med/school of public health even in those universities where there is med school/school of public health. University of Botswana-stats department is good example of that. What we propose is that there is no need to train a large number of biostatisticians abroad. All that is needed is to train a few who MUST go back to their countries and train others. Collaboration can exist if most staff in developed countries (e.g. from US) can visit these African universities through sabbatical appointments of about 6–12months. Similarly, staff from African countries can also visit universities in developed countries to strengthen their research skills in biostatistics. In Africa, I am not aware of any university with a full flesh biostatistics department. Wits University in South Africa is the closest (through the Department of Epidemiology). We would like to see this happening once biostatistics department is up and running in the University of Botswana.”

Building biostatistical capacity in SSA would take a long term (decades) effort. We have specified the goal of building capacity in SSA as long term and short term goals. The success of the specific goals can be evaluated in various ways. For example, the current research training evaluation effort at NIH focus mostly on individual trainees (publication records of trainees documentation of percentage of trainees who return to, and remain in, positions in their home countries that utilize their biostatistical skills, grant awards), the most effective way to date to capture the contributions of the FIC research training programs have been “stories” by in-country scientific leaders. More robust ways are being explored using an evaluation framework (http://www.fic.nih.gov/about/plan/eval_framework.htm) in

various program evaluations (for example see Evaluation of Fogarty Programs at (<http://www.fic.nih.gov/about/disppe.htm>)).

CONCLUSION

A healthy and sustainable clinical research enterprise in sub-Saharan Africa is a high priority. Extensive involvement of biostatisticians in the region on collaborative research teams is essential for this enterprise to succeed. The catalog of local efforts and future goals presented above reflect the widespread recognition of the importance of building biostatistics capacity in SSA, mostly in the limited context of HIV/AIDS research. Participants described very creative approaches, involving multiple US and other research organizations and multiple governmental and non-governmental funding agencies, but ultimately these constitute a patchwork of partial measures, when what is required is a serious, long-term response to the need of strengthening biostatistics resources in SSA.

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APPENDIX A: SPEAKERS AND DISCUSSION LEADERS AT THE 2009 WORKSHOP ON STRENGTHENING BISTATISTICS RESOURCES IN SUB-SAHARAN AFRICA

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 Joseph Rotich, Moi University, Kenya;
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APPENDIX B: WORKSHOP PLANNING COMMITTEE

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