

**FINAL ESTHER REPORT APRIL 2019**

<b>Title</b>	Strengthening capacity to optimally care for vulnerable groups at risk for sexually transmitted infections in Kampala, Uganda
<b>Country</b>	Uganda
<b>Goal</b>	To improve diagnosis and treatment of 3 key sexually transmitted diseases (syphilis, gonorrhoea and chlamydia) in Kampala in a sustainable manner, using innovative laboratory testing approaches
<b>Swiss institution</b>	Epidemiology, Biostatistics and Prevention Institute, University of Zurich, Hirschengraben 84, CH 8001 Zurich, Switzerland Contacts: Prof. Dr med Jan Fehr, (address: same as above), <a href="mailto:jan.fehr@uzh.ch">jan.fehr@uzh.ch</a> Dr. med George Abongomera, (address: same as above), <a href="mailto:george.abongomera@uzh.ch">george.abongomera@uzh.ch</a> Jenny Crawford, (address: same as above), <a href="mailto:jenny.crawford@uzh.ch">jenny.crawford@uzh.ch</a>
<b>Partner institution</b>	Infectious Diseases Institute, Makerere University College of Health Sciences Mulago Hospital Complex, P.O. Box 22418, Kampala, Uganda Contacts: Dr. Mohammed Lamorde, (address same as above), <a href="mailto:mlamorde@idi.co.ug">mlamorde@idi.co.ug</a> Dr. Edith Nakku Joloba, (address same as above), <a href="mailto:edith.nakkujoloba@gmail.com">edith.nakkujoloba@gmail.com</a> Dr. Andrew Kambugu, (address: same as above), <a href="mailto:akambugu@idi.co.ug">akambugu@idi.co.ug</a>
<b>Grant award (CHF)</b>	99,996
<b>Time frame</b>	18 months

The ESTHER Switzerland programme ( <https://www.esther-switzerland.ch> ) is implemented by the Institute of Social and Preventive Medicine (ISPM) of the University of Bern, on behalf of the Swiss Agency for Development and Cooperation SDC).

## FINAL ESTHER REPORT APRIL 2019

**Context:**

Sexually transmitted infections (STIs) are among the most common infectious diseases. The World Health Organization (WHO) estimates 376 million new cases of curable STIs (gonorrhoea, chlamydia, syphilis and trichomoniasis) occur annually, with young adults at highest risk (1). Complications from STIs can include infertility, chronic pelvic pain, ectopic pregnancy, maternal mortality, fetal loss, perinatal morbidity and mortality (1).

Syphilis infection is an important public health problem in Uganda and other sub-Saharan African (SSA) countries (2,3). Syphilis is of particular concern in pregnancy because it can be transmitted to the fetus. Congenital syphilis may result in fetal death and long term complications to surviving infants. The burden of syphilis in pregnancy in 43 countries in SSA is estimated at 12.5 million disability adjusted life years (DALYs) with Uganda contributing approximately 660,000 DALYs.(4) Although syphilis treatment is inexpensive, traditional methods for laboratory screening are time consuming and associated with loss to follow-up. Screening with recently introduced immunochromatographic point-of-care syphilis (ICS) tests and subsequent treatment of positive cases with penicillin is highly cost-effective, with an average cost/DALY averted of US\$11 (range: US\$2–US\$48) for all 43 countries in SSA (5). However, the tests are not routinely available in Ugandan public health system.

The Infectious Diseases Institute (IDI), one of the partner sites for this project, operates the Adult Infectious Diseases Clinic (AIDC) with 8000 HIV positive adults in Kampala region. AIDC is accredited as a specialized provider of HIV services and is located within the Mulago National Referral Hospital Complex. AIDC provides technical support to Kampala City Council clinics for management of patients with complex conditions. In Uganda, clinical management of STIs is outlined in Uganda Clinical Guidelines 2013, published by the Ministry of Health, where a syndromic approach is emphasized. For higher level health facilities, a district clinician manual is available that recommends testing for STIs but implementation barriers remain. New diagnostics offer greater confidence in diagnosis to clinicians, reduce drug wastage and support public health surveillance systems. In a recent research project at IDI, 3.6% and 2.6% of asymptomatic women were diagnosed with gonorrhoea and chlamydia, respectively, with women <25years at increased risk for STI (6). Notably, these women would neither be diagnosed nor treated with the syndromic approach. Furthermore, emerging antimicrobial resistance to gonorrhoea poses a challenge in the management of the infection (1). It is noteworthy that there is little or no data on the antimicrobial resistance profile to gonorrhoea in the majority of SSA countries including Uganda.

In western countries, diagnosis of STI is driven by diagnostics and treatment is tailored to the pathogen identified. This project will develop capacity for accurate diagnosis and treatment for 3 key STIs (syphilis, gonorrhoea and chlamydia infections) in a tertiary clinic setting in Kampala.

**Partnership:****Infectious Diseases Institute (IDI) at the College of Health Sciences, Makerere University**

The IDI is a not-for-profit organization within Makerere University in Uganda with a mandate of building African capacity for combating infectious diseases using a health-systems approach. It has a strong commitment and proven track record in clinical care, research, education and training. In collaboration with national and international partners, the IDI conducts projects in prevention, care and treatment and systems strengthening. IDI has over 30 ongoing research projects, has trained over 2500 health care workers across 28 African countries and directly and indirectly supports service delivery in three of the nine regions of Uganda. It seeks to deliberately develop and enhance research capacity through institutional research partnerships, especially in the area of basic and translational science.

**Epidemiology, Biostatistics and Prevention Institute, Department of Public Health, University of Zurich**

The Department of Public Health consists of the Division of Infectious Diseases, the Division of Public and Organizational Health and the Division of Health Promotion Canton of Zurich. The department brings together research, teaching and training and services all while translating innovative and applied research into education and action in many fields of the health sector. Embedding of the Cantonal Health Promotion in the Department provides a unique chance to transfer knowledge directly from academic research at the university to governmental structures, which is the essence of Public Health.

The Division of Infectious Diseases, focusing on infectious diseases at local, national, and international levels with an emphasis on travel medicine. It is one of the leading institutions in travel medicine worldwide. Health priorities of regional and national importance are also addressed, and imported pathogens surveillance monitoring is supported by its staff. The division also runs Switzerland's largest travel clinic, providing pre-travel advice to more than 17,000 clients annually. The department works in close collaboration with all different specialties in the University of Zurich and with various national and international partners.

**Partnership:**

The partnership between researchers from the IDI and UZH has organically grown over several years. The relationship is founded on mutual trust and shared ownership. Both institutions view the collaboration as mutually-beneficial. The research collaboration has been used for research capacity development, and in order to create a sustainable, long-lasting partnership, we are committed to investing in young researchers, clinicians, and laboratory technicians. Through shared time and resources we have collaborated to advise a PhD student through her training. This student will receive joint degrees from Makerere University and the University of Zurich. By fostering and promoting the local talent, we can ensure that our research partnership has a dedicated team in the future. In addition to our first joint PhD student, we have also supported the training of laboratory technicians on both sides of the partnership. This mutual training has led to shared expertise and increased the lab capacity and knowledge on both sides. collaboration is highly patient-centred: We explore research questions arising

## FINAL ESTHER REPORT APRIL 2019

from the bedside and we aim improve clinical outcomes for patients. The first joint project investigated the association between anti-tuberculosis (TB) drug concentrations in blood and treatment outcomes in TB/HIV co-infected Ugandans, and established a cohort of HIV/TB co-infected patients at IDI. This project has transformed into a multifaceted research, education, and clinical care platform resulting in a variety of nested projects. A second study, focusing on the emerging challenge of HIV drug resistance was completed in 2015. So far, the partnership has been focused on HIV and TB and has been highly successful leading to multiple publications. Our research was even highlighted in an article in the New York Times, which can be found attached to the end of this report. In future, we plan to expand our research portfolio to other infectious diseases and non-communicable diseases. More about this partnership can be found on website; Researchers for Global Health ([www.r4gh.org](http://www.r4gh.org)).

### **Partner Linkage to ESTHER:**

IDI, represented by Dr Lamorde, has recently joined a network of European Esther Alliance southern partners. This proposal represents the first application for a formal project supported through ESTHER mechanism.

### **Project Management:**

At the start of the project, a project steering committee was established comprised of both UZH and IDI representatives (Prof. Dr. Fehr, Dr. Lamorde, Dr. Keller and Dr. Kambugu). During the duration of the project, Dr. George Abongomera, based at UZH, worked as a liaison between IDI and UZH to ensure project objectives are met and that communication could flow freely across the partnership. As Dr. Abongomera is from Uganda but works in Switzerland, he has a good understanding of both cultures which was a plus to the project. We feel that having a liaison that understands the working culture of both partners is an important addition for each project to avoid communication gaps. Ms. Jenny Crawford, also based at UZH, joined the team in the final quarter of 2018 primarily to facilitate close out phase of the project and to support the Grant Management team at IDI. Given the complexity of the dual budgets for the projects, we recommend this additional administrative support for the researchers.

The project management team in Kampala was comprised of Study Physician Dr. Lamorde (Head of Department, Prevention Care and Treatment at IDI), STI Consultant Dr. Edith Nakku-Joloba (IDI) and Study Coordinator Joshua Mbazira (IDI). The study team liaised with nurses and clinicians working at the IDI and Kasangati Health Centres with the support of the District Health Office of Wakiso District. The project held weekly project management meetings for the first three months of the study, followed by monthly thereafter.

During the project cycle there were a number of key changes that had to be made to ensure that the project milestones were met in a realistic and timely manner.

- 1) **Recruitment of local STI expert:** Following reviewer's suggestions, the partners recruited Dr. Edith Nakku-Joloba, a medical epidemiologist and an expert in STI programming. Dr. Nakku-Joloba worked closely with Dr. Lamorde and was responsible for the development

## FINAL ESTHER REPORT APRIL 2019

of the documentation and logistics needed at the IDI clinic to implement the project. Her work resulted in the development of STI clinical diagnosis and treatment record forms within the IDI Clinic Sexual and Reproductive Health (SHR) Clinic. This was in an effort to streamline STI treatment and management at IDI in order to meet the WHO and Uganda National STI management guidelines. The forms were re-designed taking into account the syndromic approach to diagnosis as well as the etiologic diagnosis that the ESTHER project was implementing. This form has now replaced the old form at IDI which did not capture many elements of STI diagnosis and treatment.

- 2) **Inclusion of the Kasangati Health Centre Antenatal Clinic:** Following the appointment of Dr. Nakku-Joloba, she recommended including the Antenatal clinic of Kasangati Health Centre for syphilis screening using ICS in order to demonstrate the ability to implement syphilis screening using ICS at Health Centre level. The ESTHER team had a meeting with the Wakiso District Health authorities led by the District health officer and they welcomed the idea. With this green light, syphilis screening was established after staff training at the Kasangati Health Centre Antenatal Clinic.
- 3) **Readjustment of the project objectives 2 and 3:** This was due to the cost for the GeneXpert kits (for screening for chlamydia and syphilis) locally being remarkably higher than initially planned i.e. almost three times the planned cost. The only option to be able to manage these costs was to revise objective 2 by reducing the number of asymptomatic patients at high risk for acquisition of STIs to 400 rather than 1000 given the unexpectedly high cost of GenXpert kits. However, after this decision to reduce numbers to be screened, the prices of the GeneXpert kits was increased further i.e. almost six times the planned cost. This resulted to the ESTHER team going back to the drawing board and exploring other possible options of acquiring reasonably priced GenXpert kits. After several efforts the ESTHER team was able to establish contact with GenXpert kits from suppliers in South Africa (Cepheid). Since this company offered substantial discounts for resource limited countries, we were able to purchase the kits for a lower price than was quoted by the local suppliers in Uganda. This initiative eventually resulted into a cost saving in the budget line planned for purchase of GenXpert kits.
- 4) **Requested redirection for the ESTHER budget:** Given the inclusion of Dr. Nakku-Joloba to the project, her salary had to be accounted for in the ESTHER budget. We therefore were able to request a redirection of the budget to provide this salary through the lower prices for the GenXpert kits and cost saving techniques other areas of the budget, such as communication. One example of this is that we relied on low cost means of communication, such as What`sApp and Skype. These changes are highlighted and explained further in the accompanying financial report.
- 5) **Requested no cost extension for the project:** The reasons for this request are to: a) allow the project team time to accomplish Objective 2 of the project. There was a delay in the procurement of the remaining 150 cartridges required to achieve the project target of

## FINAL ESTHER REPORT APRIL 2019

screening 400 asymptomatic individuals and B) allow the Zurich based ESTHER project team time to travel to Uganda in March 2019. The purpose of the visit was for project close out and preparations for the final financial and study reports.

- 6) **The Exclusion of Objective 5:** This objective set out to monitor and report annual costs at facility level for implementation of STI screening. The reviewers of the project advised the team to drop objective 5 as it appeared to be rather ambitious and difficult to achieve. The team complied with the suggestion.

### Team building:

In addition to the scientific work within this partnership, the ESTHER team also had a boat trip and a cycling event in Uganda. This was held in March 2019 as part of the project close out and the main aim was to bring the team together in a different environment outside work. The team comprised of staff from IDI and visiting colleagues from UZH. Through this event the team was able to reflect, express themselves, enjoy each other's company and the beautiful nature Uganda has to offer. There was general consensus among the group to have a similar event the following year. The picture below is from the team building event.



*Photo: IDI and UZH team on a boat trip to cycling event (March 2019).*

### Project Goals and Objectives:

Goal: To improve diagnosis and treatment of 3 key sexually transmitted diseases (syphilis, gonorrhoea and chlamydia) in Kampala in a sustainable manner, using innovative laboratory testing approaches.

We have achieved this goal as is evident through our ability to meet all of the project objectives and enact lasting change to the local health system, thus creating sustainable improvements to the diagnosis and treatment of these three key STIs in Kampala, Uganda. We highlight these achievements throughout the remainder of this report.

Objectives: We met all four of our study objectives below.

## FINAL ESTHER REPORT APRIL 2019

1. 800 pregnant women screened during antenatal care for syphilis using Immunochromatographic Strip (ICS) tests and 30 women with syphilis linked to care.
2. 400 asymptomatic patients at high risk for acquisition of STIs or HIV screened for chlamydia, gonorrhoea and syphilis with 50 diagnosed patients treated.
3. At least 50-100 STIs diagnosed and 20 partners per year linked to care.
4. Held a total of 3 Continuous Medical Education (CME), with at least 25 health workers attending each CME during the project period.

### Objective 1 Outcome: Achieved more than Expected

*To screen and counsel 800 pregnant women during antenatal care for syphilis using ICS tests and link the positives to care, within a 12 month timeframe.*

### Discussion:

By May 2019, over 2040 pregnant women were screened for syphilis, of which 1325 were antenatal care (ANC) attendees at Kasangati Health Centre (HC) IV and the rest were screened at the primary clinic at the Infectious Diseases Institute (IDI). For those screened, 82 tested positive (58 at IDI and 24 at Kasangati). For those that tested positive, 100% of them were linked to care. These numbers are also reflected in Table 1.

We were able to screen more patients than expected in part because of the inclusion of the Kasangati Clinic. This is a semi-urban health center which serves a highly populated district of more than two million people called Wakiso. An average of 30 antenatal women are seen at the Kasangati clinic daily and with their involvement, the research team was able to provide syphilis testing and treatment in one of the busiest clinics in Wakiso. The awareness of availability of same day syphilis tests and treatment as communicated and advertised via the ESTHER project trained clinic staff increased the uptake of the tests amongst the mothers. Therefore we recommend clinics implementing ICS tests for syphilis to have syphilis treatment available on site as well, so that those diagnosed positive have access to treatment immediately.

**FINAL ESTHER REPORT APRIL 2019**



**Photo:** Patients waiting to receive care at Kasangati Health Center IV outpatient clinic (August 2018).

**Results:**

Site	No. Screened	No. Positive	No. Linked to Care	No. Partners Linked to Care
IDI	715	58	58	9
Kasangati	1325	24	24	12
Total	2040	82	82	21

**Table 1:** Shows the number of pregnant women screened for syphilis between March 2018 and May 2019.

**Objective 2 Outcome: Achieved with Amendments**

*400 asymptomatic patients at high risk for acquisition of STIs or HIV screened for chlamydia, N gonorrhoea, and syphilis with 50 diagnosed patients treated*

**Discussion:**

This objective was achieved. However, the achievement of this objective was delayed due to the high cost of the testing kits for chlamydia and gonorrhoea locally (more than planned budget). Finally, through negotiations, the ESTHER Team was able to purchase the cartridges for chlamydia and gonorrhoea testing through a supplier in South Africa (Cepheid). The kits arrived to IDI on August 7<sup>th</sup>, 2018 and screening was able to begin at the end of August 2018. The kits were split between the IDI clinic and the Kasangati clinic.

During this delay, a decision on the ground was made to continue the screening for syphilis among the high volume mothers attending antenatal clinics which resulted into exhaustion

## FINAL ESTHER REPORT APRIL 2019

of all the syphilis test kits for the study. Therefore, the data for this objective, shown in Tables 2-3 below, includes screening for only chlamydia and gonorrhea.

Our project timeline and milestones needed to be adapted/revised due to the aforementioned procurement issues with the testing kits for chlamydia and gonorrhea. We therefore recommend to future researchers to identify a back-up supplier for key items in the event that they run into procurement difficulties as we did. The amount of work that was required to find a back-up supplier took valuable time during our study and this could have been done prior to the start of the study.

### Results:

Site	No. Screened for gonorrhea and chlamydia	Sex		No. of positive gonorrhea and chlamydia
		Males	Females	
IDI	219	136	83	22
Kasangati	238	22	216	48
Total	457	158	299	70

**Table 2:** Shows the number of asymptomatic high risk individuals screened or gonorrhea and chlamydia between August 2018 and May 2019.

Site	No. of ONLY chlamydia CT Pos.	No. of ONLY gonorrhea Pos.	No. of Dual gonorrhea and chlamydia pos.
IDI	05	13	02
Kasangati	26	14	04
Total	31	27	06

**Table 3:** Shows the number of positive results for both chlamydia and gonorrhea in those that were screened.

### Objective 3 Outcome: Achieved more than Expected

*At least 50-100 STIs diagnosed and 20 partners per year linked to care.*

### Discussion

This objective was met as is evident through the data in Table 4. Through our screening efforts more than 100 participants (152 in total) were diagnosed with an STI after a positive test and all of them were treated. In addition, 51 of the partners of those tested were linked to care and treated as well. This data excludes couples who received testing at the same time.

This number far exceeds our expectations and according to local clinicians is also much higher than other clinics. We attribute our success in this area, in part, to our innovative testing approach. The use of this testing method allowed us to provide same day results. This

**FINAL ESTHER REPORT APRIL 2019**

quick turnaround both increased testing uptake as well as minimized the number of patients lost to follow-up. In addition, many of those tested were seen while visiting an Antenatal care clinics. Therefore, as many husbands accompany their wives to Antenatal clinics for other testing, e.g. HIV testing , and many are available in person to be linked for STI care. In clinics other than Antenatal care clinics, the number of men/other partners physically present at the time of testing is likely lower and thus fewer partners can be linked in person to care. This high linkage to care may therefore be unique to the function of the clinic where the testing took place.

Results:

Site	No. Pos. chlamydia	No. Pos. gonorrhea	No. Pos. syphilis	No. Partner Linked to Care
IDI	7	15	58	19
Kasangati	30	18	24	32
Total	37	33	82	51

**Table 4:** Shows the total number of positive results for all STIs that were screened by site along with the number of partners that were linked to care.

Objective 4: Achieved

*A total of 3 Continuous Medical Education (CME) to be held, with at least 25 health workers attending each CME during the project period.*

Discussion:

Trainings on STI management, project procedures and forms were started in February 2018 and continued through October 2018. A total of five trainings were conducted, with three of the five trainings attended by at least 25 people. The other two trainings were targeted towards the laboratory staff involved in STIs screening in the project. As there are fewer laboratory staff involved in STI screening , there were not as many total participants present for these trainings. An overview of the trainings can be found in Table 5. Of note is the joint CME conducted by teams from UZH and IDI on the 10<sup>th</sup> of August 2018. Dr. George Abongomera (UZH) led the clinical case presentation of Gonococcal resistance to both Azithromycin and Ceftriaxone and Dr. Edith Nakku-Joloba (IDI) led the discussion session with focus on the implications of Gonococcal antimicrobial resistance. Pictures from the above training can be found below.

FINAL ESTHER REPORT APRIL 2019



*Photo: Left to Right, Dr. Edith Nakku-Joloba leading discussions at the Joint IDI-UZH CME in August 2018 and the team listening attentively.*

Month of CME Training	Clinic at which CME was Held	No. of Participants Present
March	IDI	28
June	Kasangati	6
August	IDI Translational Laboratory	3
August	IDI	25
October	IDI	28

**Table 5:** Shows the number of CMEs conducted and participants involved between March 2018 and October 2018.

We consider the trainings to have been successful as measured by the fact that they increasing visibility of the ESTHER project for the clinic staff. In addition, as discussed further in the section on Impact, the trainings contributed to a paradigm shift in regards to STI screening at the clinics whose staff receiving the trainings. The trainings illustrated an innovative approach towards diagnoses, treatment, and understanding of STIs that was not only well-received according to verbal feedback but also led to a change in behavior in the clinics.

**Financial Management:**

The IDI has a Grant Management office responsible for the policy and financial administration of grants and their office managed the finances on the IDI side. In addition, during the project the UZH side hired Ms. Jenny Crawford as a Scientific Manager to manage their grants. The Scientific Manager assisted with the financial reporting for the UZH side in collaboration with the IDI Grant Management office, which was done in person during a project visit to Kampala in March 2019.

We are grateful for the in-kind contributions from both the participating centers as well as the IDI who generously contributed staff expertise, time and infrastructure to this effort. We estimate that the total in-kind contribution from the IDI and EBPI is upwards of 30'000 CHF and for this we are grateful.

## FINAL ESTHER REPORT APRIL 2019

### **Target Groups:**

We anticipate that all of the target groups as listed in the initial grant application were all reached during the course of the project. The details of which can be found below.

#### Pregnant woman

As mentioned, over 2040 pregnant women were screened for syphilis during the course of the study, exceeding the expectations for Objective 1.

#### Patients at risk for acquisition of STIs or HIV

We do not yet have the demographic data to assess how many of those screened were in our “patients at risk” category, described in the original grant application as those under the age of 25, sex workers, patients with multiple sex partners, etc. We anticipate that we will have this information after the final data analysis and intend to include it in any future publication.

#### Health workers

As seen in the data from Objective 4, we were able to reach 90 health workers for face-to-face trainings during the duration of the project.

### **Impact:**

This project was relevant given the burden of STIs in Uganda. With the implementation of new technologies through this partnership, patient waiting time for laboratory results was reduced and less effort was required by the laboratory staff to provide results. Through our partnership, local clinics realized the importance of our study and contributed in-kind through offering us access to their facilities and support with human resources (medical assistants, nurses, and physicians ) to facilitate the project. Without such a strong and ongoing partnership, we do not think this project would have been able to achieve these milestones.

Through the support from ESTHER, at an institutional level, routine STI screening for syphilis, chlamydia and gonorrhea with ICS tests and GeneXpert cartridges was made available.

Dr. Edith Nakku-Joloba (the STI expert on the team) provided the following quote in regards to the impact of the study,

*“While there were challenges with procurement, the benefits far outweighed the challenges. We now have proper STI testing methods at IDI and Kasangati clinics and proper training: this is pivotal to the health of our patients.”*

The project also contributed to a paradigm shift within IDI and the Kasangati Health Centre with regards to STI screening. In particular, the screening approach at IDI was changed both from a data collection and diagnostic standpoint. Prior to this project, no STI patient data was collected at the IDI main clinic. However, in large part thanks to this study, the clinic has implemented a data collection tool that now routinely captures STI signs and symptoms. In

## FINAL ESTHER REPORT APRIL 2019

addition, the practice has shifted from syndromic diagnosis of STIs to syphilis rapid testing using SD Biotest; chlamydia and gonorrhea testing using GenXpert at the IDI clinic.

### **Outlook:**

The ESTHER team would like to share the experiences, challenges and achievements of this project with the wider scientific community. This is planned to be shared in form of abstracts and communications at national meetings. In Uganda, we plan to share the results with the Ministry of Health, sexual and reproductive health division. In Switzerland, we plan to share the results at the [Swiss Infectious Diseases Conference](#) in Lausanne. Lastly, we also plan to share the results at the Institute for Social and Preventative Medicine.

Beyond the objectives of the study itself, this project has also spurred further study ideas. Antimicrobial resistance testing of *N. gonorrhoea* isolates is one of the priority areas for further studies with this partnership. The partnership is already drafting a research proposal to seek funding for a follow on project to continue this work.

### **Sustainability:**

STI screening is now part of the IDI day to day practice, integrated within the clinic routine care. We developed a datafax system for data collection purposes and are currently processing the final data at the IDI clinic. This system will be used for data collection purposes from this point forward. We also modified the STI module in the Clinic ICEA (Integrated Clinical Enterprise Application) system that is used to collect STI-related data. Training on this STI module in ICEA is intended to go on even after this project concludes. The IDI clinic will be responsible for training the staff in the use and maintenance datafax system. The only challenge foreseen is the datafax system cannot be extended to other clinics in close proximity. However, IDI team will continue to lobby to the Ministry of Health on the benefits of using such a system to capture STI data.

As mentioned above in regards to the impact of the study, the practice at the hospital has now changed, creating sustainable change to STI management at IDI. This is in part due to the better understanding of the issue through the CME trainings, and also through the visibility of the project in the clinics themselves. The work in this project will continue through the work of Dr. Lamorde and the WHO, as well as from promised support from the Ministry of Health. This project was the first step in a hopefully a long line of projects aimed at better diagnoses, treatment, and understanding of STIs in Kampala and beyond.

Lastly, we thank ESTHER Switzerland for their support of their work and the opportunity to write this report.

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