The Chronic Diseases Clinic of Ifakara, St. Francis Referral Hospital (CDCI), and the Kilombero and Ulanga Antiretroviral Cohort Study (KIULARCO)

Activity Report, October 2013

A collaboration between

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I. Background

As an integral part of the St. Francis Hospital Referral (SFRH) in Ifakara, the Chronic Disease Clinic (CDCI) has been uninterruptedly functioning since 2005. Initially built to support the Tanzanian National AIDS Control Programme, the activities conducted at the CDCI have been progressively expanded to take care of all outpatients and inpatients with HIV being visited at SFRH, including pregnant and non-pregnant adults, HIV-exposed and HIV-infected children. In addition, the CDCI includes now the Tuberculosis (TB) clinic of SFRH, in order to integrate services and improve the outcome of patients with TB and HIV.

All patients attending the CDCI are asked for informed consent to be enrolled in the Kilombero and Ulanga Antiretroviral Cohort (KIULARCO), which is associated with a plasma repository and provides thus a unique opportunity to analyze the trends of the epidemic in the Kilombero region. Since its foundation, more than 6,800 patients have been recruited in KIULARCO, with more than 5000 having started antiretroviral therapy (ART).

In addition, the CDCI offers voluntary counselling and testing (VCT) as well as provider initiated testing and counselling (PITC) services, supervision of other centres for care and treatment (CTC) in the Kilombero district, and educational activities to the community.
The CDCl aims to be a center of excellence in the management of HIV in rural Africa, with three main integrated activities, namely clinical care, research driven by the local needs, and training. In the past year, special attention has been put in optimizing the functioning of different areas of the CDCl, including clinical care, laboratory, pharmacy, and Voluntary Counselling and Testing (VCT) services. The different activities undertaken in this optimization of the CDCl are described below.

II. Number of patients attended until September 2013

Table 1 shows a summary of the total number of patients ever enrolled, and ever initiated ART stratified by age group, at the end of September 2013.

<table>
<thead>
<tr>
<th></th>
<th>Adult (≥ 15 year-old)</th>
<th>Children (&lt;15 year-old)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>Cumulative number of persons enrolled, n</td>
<td>4060</td>
<td>2167</td>
</tr>
<tr>
<td>Total, n</td>
<td>6227</td>
<td></td>
</tr>
<tr>
<td>Cumulative number of persons on ART, n(%)*</td>
<td>2998 (74)</td>
<td>1549 (71)</td>
</tr>
<tr>
<td>Total, n(%)</td>
<td>4547 (73)</td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Number of patients attended at the CDCl, by age and ART status. n: number of observations. % refers to column percentages. ART: Antiretroviral therapy. * Out of the 5010 patients ever started on ART, there were 726 transferred out, 549 confirmed deaths, and 1583 lost to follow-up/unknown.
III. Staff of the CDCI

There are 35 staff members permanently based at the CDCI. This staff is being hired by four different organizations, namely IHI/Swiss TPH (20), SFRH (7), TUNAJALI/USAID (6), and Swiss TPH (2). The CDCI team is composed of clinicians (10), registered nurses (3), counsellors (2), auxiliary nurses (4), pharmacist (1), data clerks (6), biologists (3), lab technician (1), and auxiliary staff (1). Despite a recent turnover of the medical staff, a well balanced team has been successfully rebuilt in order to accommodate the current challenges of the project at a clinical, research, and training level. This medical team includes two expatriate specialist medical doctors, five Tanzanian medical doctors, two Tanzanian assistant medical officers, and one Tanzanian clinical officer.

IV. Infrastructure

The CDCI is placed at the outpatient department of SFRH. Due to the recent expansion of activities, a new building has been programmed to bridge the current shortage of office space, to improve infection control by separating TB from HIV patients, and to habilitate a room for a HIV day hospital and an intermediate step between the outpatient clinic and the wards for those patients being admitted (Fig.1). This aims to improve the provision of initial care, often critical for the outcome of the patients, as well as to provide with a suitable space for diagnostic procedures such as lumbar puncture, paracentesis, thoracocentesis and veno-puncture among others. This building is also intended to be used as a day hospital to provide diagnosis and treatment for those patients that can be managed on an outpatient basis (i.e. patients with Kaposi sarcoma needing chemotherapy). This
very much needed step in the upgrade of the CDCI will require additional nursing staff and material for diagnostic and therapeutic procedures.

In addition, a new drug storage room has been made available at SFRH to improve the storage and stock management of antiretroviral drugs. This in turn will allow more space at the triage, currently partially used as a drug storage room.

Fig.1 Renovation of the CDCI, showing the new building in red
V. Clinical Activities

Paperless Clinic

Since December 2012, a new optimized data collection system has been implemented, allowing for the progressive transition to a paperless clinic, which was made effective in June 2013. This system serves both the harmonisation of the data collection among the CDCI clinicians and the collection of comprehensive data to provide a better understanding of several aspects of the daily work. The CDCI, the pharmacy and the laboratory are interconnected through this system, which has improved the efficiency of the patients' circuits, reducing the waiting times and increasing the patients' satisfaction. The implementation of this system has required the acquisition of 11 desktop computers, the installation of a wireless internet access and the adequacy of the electric installation to bridge potential power cuts, increasing the budget needed for maintenance of IT and electric items.
Expansion of the CDCI activities to the SFRH wards

In order to provide a comprehensive service to all HIV-infected individuals attending SFRH, an agreement has been reached with the medical director and with the Internal Medicine and Paediatric departments at SFRH to ensure that the admitted patients will benefit from the expertise generated at the CDCI. This is also serving educational purposes for intern doctors and students rotating at SFRH. In this sense, ward rounds and bed-side teaching are undertaken everyday by CDCI clinicians on a rotational basis. In order to accomplish this complex task with success, the clinical team has had to be reinforced with the addition of new doctors. Furthermore, this has increased the number of tests performed at the IHI lab with subsequent budget constraints that need to be addressed.

Integration of HIV and Tuberculosis activities

In order to maximize the bidirectional screening and treatment of these two often fatally associated diseases, the CDCI has taken over the TB clinic of SFRH and is
now in charge of providing outpatient and inpatient TB care. Associated costs related to the diagnosis of TB, namely GeneXpert and chest X-ray have put additional pressure on the CDCI budget constraints. One of the newly hired Tanzanian doctors has been appointed as the TB focal person for training and research activities. This person will be sent to the TB clinic at the Ifakara Health Institute in Bagamoyo to exchange knowledge and procedures, which are aimed to improve and harmonize the quality of care between both settings. At the same time, this will capacitate this doctor in the very relevant area of TB-HIV co-infection, which eventually may result in new research projects driven by the local needs.

**Integration of the CDCI with the Antenatal and Under-five Clinic of SFRH**

Aiming to improve the linkage to care of HIV-infected pregnant women, uptake of the guidelines on prophylaxis of mother-to-child transmission, early infant diagnosis, and clinical outcomes of both pregnant women and HIV-exposed and infected children, a linkage with the Antenatal and Under-five Clinic of SFRH has been established. A CDCI consultation room at the antenatal clinic has been set up, and a paediatrician and a Tanzanian doctor working at the CDCI have been allocated to exclusively attend children and pregnant women respectively in this setting. This consultation room is functioning since March 2013 and has increased the linkage to care of HIV-infected pregnant women and HIV-exposed children by 60-80%. This good preliminary results encouraged us to pursue the establishment of a One-Stop Clinic for HIV-infected mothers and their families. This clinic aims to be a referral clinic at the Kilombero district with periodic exchanges and supervision of five CTCs in the district. Universal ART to all pregnant women will
be administered following the recently adopted new WHO recommendations. An increase in the number of patients and associated needs in terms of staff and medical resources is anticipated.

**Improving Retention in care**

Long term retention in care is a challenge that can hinder the success of the rollout of antiretrovirals. The new data collection system includes the collection of data that will eventually make possible tie linkage with the health demographic surveillance system (HDSS) platform in Ifakara. This platform routinely collects information on births, deaths and migration within the study area which covers 300,000 inhabitants. By linking both databases, it is intended to establish an active patient tracking system which will enable us to detect defaulter patients and increase retention in care.


**Pharmacy**

The management of stocks of antiretroviral drugs will be further improved by the periodic reports extracted from the recently implemented electronic data collection system. The main limiting factor for the optimal functioning of the CDCI pharmacy will be the shortage of staff. Currently, only one pharmacist is working at the CDCI, and no back-up exists for him.

**VCT services**

A trained counsellor has been hired to optimize this essential section of the CDCI. He will be in charge of ensuring the implementation of the Tanzanian guidelines for VCT and provided initiated testing and counselling (PITC). In line with the integration of the CDCI within the SFRH wards, the plan exists to implement universal testing to all patients admitted at SFRH, with the subsequent increase of HIV diagnosis and linkage to care. The expected newly diagnosed patients will increase the work burden of the CDCI staff and additional clinical personnel maybe required.
VI. Laboratory activities

Screening and diagnosis of Opportunistic Infections

Several protocols for screening and diagnosis of HIV-associated opportunistic infections have been developed, namely tuberculosis screening and diagnosis through GeneXpert technology, cryptococcal meningitis screening and diagnosis through Cryptococcus antigen lateral flow analysis test, hepatitis B screening and diagnosis through HBsAg determination, syphilis screening and diagnosis through VDRL assessment, and cervical cancer screening through visual inspection with acetic acid at existing facilities at SFRH. An increase in the use of these tests has resulted in additional budgetary constraints that will need to be addressed.

Monitoring of patients on Antiretroviral Treatment

The plan exists for implementing HIV monitoring for patients on antiretroviral treatment with plasma HIV RNA. The IHI lab has the necessary human and
technical capacity to implement this very much needed technique, which is anticipated to result in better outcomes and survival of the patients attending the CDCI. This technique will be validated through the collaboration with the laboratory of the University Hospital Basel and further routinely implemented provided that the funds were made available.

**Early Infant Diagnosis**

In line with what it has been mentioned above, it is intended to establish DNA PCR for early infant diagnosis. Again, the facilities and technical and human capabilities exist at the IHI lab, but the funding and sustainability of the routine implementation of this technique will need to be ensured.

**VII. Research activities**

The research activities at the CDCI are driven by the local needs and are primarily aimed to impact the quality of care in our setting as well as contributing to the generation of knowledge that may eventually be extrapolated to similar settings in Tanzania and other African countries. Moreover, the research activities provide a unique opportunity for capacity building and career development of the Tanzanian staff. Six major lines of research have been developed, each of them ascribed to one Tanzanian medical doctor.

- Prevention of Mother to Child Transmission (PMTCT) and Paediatric HIV
- Cryptococcal Meningitis
- Tuberculosis-HIV
- Liver Outcomes in HBV-HIV co-infected patients
- Antiretroviral Outcomes (including adherence to treatment)

Besides the partners involved in the CDCI/KIULARCO platform, some of the
studies within the above mentioned research lines will be pursued in collaboration with international partners of renown expertise such as the Infectious Diseases Institute-Makerere University in Kampala, Uganda, the University of Minnesota, USA, the Hospital Clínica of Barcelona, and the Barcelona Centre for International Health Research. Remarkably, in October 2013, a specially designed project with the support of the Division of Infectious Diseases & Hospital Epidemiology of the University Hospital Basel, the Swiss Tropical and Public Health Institute, Basel, the Social and Preventive Medicine Institute, University Zürich, the Division of Clinical Pharmacology and Toxicology, University Hospital Basel, the Institute of Psychosomatic Medicine, University Hospital Basel, and the Department Biomedicine, Haus Petersplatz, University of Basel has started recruiting patients. This is a study aimed to assess and improve adherence to ART, which is a poorly assessed in Africa fundamental determinant of the long term success of ART and retention in care, thus falling in the research line of ART outcomes. This project is being coordinated in the field as part of a sabbatical period by Dr. Stefan Erb, University Hospital Basel.

The collaborations are mainly intended to increase the visibility of our project and
to ultimately revert in an increasingly better quality of care, training and research.

**VIII. Training activities**

A program of in-house weekly sessions has been established at the CDCI, including 5 types of weekly sessions:

- Clinical case discussions
- Soft skills and research methods
- Clinical HIV Medicine
- Antiretroviral committee
- Journal clubs

Each type of session is coordinated by a Tanzanian medical doctor on a rotational basis, thereby contributing to a continuous medical education and fostering clinical discussion among the members of the team.

In addition, a first workshop on cryptococcal meningitis has been organized in conjunction with the Tanzanian Training Centre for International Health. This workshop, which will take place in November 2013, is intended to raise awareness of this fatal disease associated with HIV. Epidemiological, clinical, prevention, diagnostic, and management aspects will be discussed. The workshop will be imparted by world renowned experts in this topic from the University of Makerere and Minnesota, in the frame of the collaboration with these institutions in this area.

If successful, this is intended to be the first of a series of annual workshops with an ultimate aim of improving the quality of care at SFRH and become a center of
excellence in the management of HIV/AIDS and associated opportunistic infections.

Furthermore, currently one medical doctor of the CDCI is pursuing by distance learning a MSc in clinical trials at the London School of Hygiene and Tropical Medicine, and opportunities for MSc studies at the University of Basel and abroad may arise for other doctors of the team. In addition, currently one statistician is pursuing a PhD at the University of Basel based on KIULARCO. It is intended to offer further PhD opportunities to the current staff in the frame of their career development.

**IX. Conclusions**

Nine years after the CDCI was established, a consolidation of the work done so far and an optimization at different levels is taking part. This results in an improved quality of care, efficiency of the circuits, data collection, and better training and career development opportunities for the staff working at the clinic. In addition, the collaboration with some key partners in different relevant areas may result in a further capacitation of the project which may gain visibility at a local, national and international level, further reverting in an improved quality of care, which is at the core of the project. The unique conjunction of clinical care and good training and research capabilities in a rural African setting, together with the strong links with international partners with expertise in different key areas for success, makes of the CDCI/KIULARCO project an ideal platform to generate evidence tackling the real challenges of HIV in Africa, which may be extrapolated to similar settings in Tanzania and abroad.