

Institution: Academic Model Providing Access to Healthcare (AMPATH)
[An Indiana University-Moi University Partnership]
Eldoret, Kenya
<http://www.iukenya.org/hiv.aids.html>

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LAB RESOURCES

Please describe the laboratory facilities available in your research institute, including the items listed below (if applicable):

Lab space and equipment (general)
BSL-2 lab space and equipment
BSL-3 lab space and equipment
Flow cytometry equipment

The lab is essentially a comprehensive clinical care lab whose tasks include care for Hiv/aids, TB and Cancer patients care. The lab is a BSL2 Lab and comprised of the following sections:

- Chemistry
- Hematology
- TB
- Molecular – HIV DNA and RNA, CT/NG PCR
- Flow cytometry – CD4/CD8 Assays
- Serology – HIV, VDRL, HBSAG/AB, Urine HCG
- Microbiology

The lab has major equipment including:

- Cobas 400 plus and the Hitachi 902 for Chemistries
- Beckman Coulter ACT 5 DIFF for CBC
- MGIT 960 for TB cultures and DST
- CAP/CTM and the ABBOTT M2000 for HIN DNA/RNA and CT/NG PCR
- Facscalibur for CD4/CD8 assays
- ELISA Incubator, washer and Reader for HIV, HBSAG Serologies

In addition to the assay specific equipment the lab has the following support equipment:

- BSC 2 Cabinets – 10 pcs
- Type three water purifier (Reverse osmosis)
- Autoclave
- Freezers (minus 86°C) – 6 PCS

- Freezers (minus 40°C)
- Fridges
- Temperature monitoring system
- Lab information system
- Lab Data Management System

Please list the research groups in your institute, including the size and areas of expertise for each group:

We have 9 working groups within AMPATH Research Network:

- a. Pediatric Working group: The aim of this working group is to improve the health outcomes of children in Kenya and other resource-limited settings by promoting pediatric research.
- b. Adult Medicine Working Group: The purpose of this group is to facilitate the development and conduct of studies that involve adults including clinical trials, retrospective analysis of AMPATH Data, PK studies, field testing of new lab technologies and implementation research. Disease focus has been mainly HIV, Diabetes, Hypertension, Cardiovascular diseases, Infectious Diseases other than TB, and Chronic Diseases other than Cancer.
- c. Reproductive Health Working Group: This working group discusses research projects related to reproductive health as they develop guideline for care within the institution.
- d. PMTCT Working Group: The purpose of this group is to provide a forum for experts in Pediatrics, Reproductive Health, and Adult HIV to come together to develop and move forward the PMTCT research agenda. Scope of work within PMTCT include retrospectively assessing PMTCT protocols, programs, and interventions in order to disseminate information related to program outcomes to the International scientific community and also prospectively try new PMTCT interventions.
- e. Oncology Working Group: Focuses on oncology care for both HIV infected and uninfected patients. Research related to oncology is also discussed in this working group.
- f. TB Working Group: Focuses on research related to TB-HIV co-infection both in children and adults. Other focus includes intensive case finding and care of non-HIV infected and infected patients.
- g. Public Health and Primary Care Working Group: The purpose of this working group is to provide a forum to bring together researchers across multiple disciplines to build collaborative research programs in public health and primary care and to provide an interface with relevant clinical and public health programs within AMPATH.
- h. Behavioral and Social Science Working Group: Objective of this group is to promote and strengthen research on the prevention of HIV/AIDS and development, but has expanded to cover primary health care. It employs a holistic approach to health and development.

- i. Economic Working Group: Focuses on research related to socio-economic impact of HIV infection.

BIOLOGICAL SPECIMEN REPOSITORY

Please provide a description of the biological specimens stored at your institute.

Serum samples, Plasma samples, PBMCs, DBS, TB, Bacterial and Fungal Culture isolates, DNA/RNA Extracts

Do you have a database of all stored samples? Yes

Please provide details on methods for biological specimen storage (e.g. are Standardized Operating Procedures used?)

SOPS on each of the activities carried out in the lab are available at the point of use, e.g. Quality manual, SOP on specimen collection, storage and handling, etc.

Please describe the equipment/facilities available for sample storage at your institute, including items listed below (if applicable):

- Freezers (minus 86°C) – 6 pcs.
- Freezers (minus 40°C) – 1 pc.
- Fridges – 8 pcs.
- Nitrogen storage tanks – not available
- Dry ice is easily available when required

TRAINING AND EDUCATION

Please describe the training initiatives your institution has in place for individuals prior to working in clinical studies:

- GCP and GLP Training for research assistants and study coordinators
- CITI Training on Protection of Human Subjects in Research is provided to all the study team (investigators, research coordinators, assistants)
- Protocol specific trainings including SOPs

Please describe the training initiatives your institution has in place for individuals prior to working in the laboratory:

- Must be qualified as Medical Lab tech or Scientist. On appointment one has to undergo a one month mentorship in all the lab sections, followed by

initial competency testing before being approved to run tests and release results.

What assays/techniques do you excel in at your institute?

- CD4/CD8 assays, HIV and HBSAG serologies, DNA and RNA assays, Hematology and clinical chemistry, TB Culture, ID and DST

What training could you provide to visiting scientists?

- AMPATH Lab provides training on all the lab tests done to the visiting scientists.

What rank are the majority of your trainees? (e.g., approximate numbers of undergraduate students, masters, PhD, post-docs, MDs)

- Most of the research assistants are undergraduates, study coordinators are Masters level with the investigators at PhD and MDs level.

Do you offer training classes/courses for any of the following?

Grant Writing

Manuscript/abstract writing

Computer skills, excel, prism, endnote, word, powerpoint

Presentation skills

Epidemiology

Biostatistics

- Training classes on above topics are provided within our institution. Target group are the investigators, upcoming investigators and members of the institution who are interested in research.

Does your institute receive funds to support training initiatives?

- Yes. Our institution does receive funding from Fogarty to train the medical informaticians. Training of research assistants and study coordinators is funded by the institution.

Does your institution send trainees abroad for additional training?

- Yes. Our institution sends trainees abroad for additional training. Medical informaticians are trained at Indiana University for the first year of the program and spend their second year in Kenya. One (1) medical informatician is sent to Indiana University yearly for the 5 year grant period (Fogarty).

- Biostatisticians and data managers spent 2-3 months at Indiana, undergoing further training on analysis and data management funded by IU internal funds. Additionally, PhD courses have been supported for promising Masters level statisticians and research coordinators (Fogarty, foundation grant to Indiana University). A total of 3 PhDs have been awarded. Two others are expected to finish in May 2012. MDs have also undertaken their fellowship at Brown University and Indiana University.
- Students undertaking their Masters of Medicine in Pediatrics and Child health and also those in Internal Medicine have been going for an exchange program at Indiana University for a period of 3 months yearly.

What Masters and/or Doctoral programs does your institution offer?

- Moi University is the primary partner for AMPATH, courses being offered at a Masters level include Masters of medicine in Internal Medicine, Pediatrics and Child Health, Obstetric and Gynaecology, orthopedics, Public Health, International Ethics.

COLLABORATIONS

Please list and briefly describe any African institutes that you currently collaborate with for either research or training purposes.

- leDEA project is currently collaborating with institutions within Uganda, Tanzania and Kenya
- REACH Informatics is collaborating with institutions in Uganda, Tanzania, Ethiopia, Rwanda and Kenya
- AIDS Clinical Trial Groups (ACTG) is collaborating with institutions within Kenya, Uganda, South Africa, Zambia, Malawi.

Please list your institution’s plans for future collaborations within Africa (additional groups, sites, countries, etc.)

None

Please list your institution’s collaborations with entities outside of Africa (e.g., organizations and networks in the USA, Europe, etc. – including CFARS, NIH clinical trials networks, HPTN, HVTN, AMC, leDEA, USAID, PEPFAR, etc.):

- Universities in North America including: Indiana, Brown, Duke, Yale, Columbia, UCSF, George Washington, Purdue, Stanford, Notre Dame, Harvard, and NYU along with the Universities of Toronto, Washington, Missouri, and North Carolina.

CLINICAL COHORTS

Do you have access to existing clinical cohorts in Africa or USA? Yes

Please describe each existing clinical cohort that you have access to, including specifics like “HIV-TB infected HAART naïve adults”, sample size, sample type, sex, age, and whether clinical samples are currently being collected and/or stored (specify which samples).

- AMPATH Cohort: This is an HIV infected adults cohort that is now over 8 years old. Ever enrolled patients are 128,509; of which 103,038 are adults and 25,471 are children. 65,148 adults and 8,936 children have ever been started on ARVs.

Are you planning on establishing any new clinical cohorts over the next 5 years?

- Oncology institute within AMPATH is planning to develop a cohort of Cancer patients whose HIV status is positive and also of negative HIV status. Specifics have not been determined at the moment.

DATA MANAGEMENT

Please describe the DATA MANAGEMENT FACILITIES available in your research institute, including the items listed below (if applicable):

Data management expertise, including staff complement (general):

There are 139 personnel in the following cadres and numbers:

A) INFORMATICS

- System Engineers/Programmers (3): Degree
- System Administrators/Informaticians (3): Degree
- Networking and User Support (4): Diploma and Degree
- Head of Informatics (1) - oversees the above three categories: Masters

B) DATA (ELECTRONIC)

- Data Managers (6): Degree and Masters
- Assistant Data Managers (10): Diploma and Degree
- Data Assistants (90): Diploma
- Office Assistant (1): Certificate

C) PAPER RECORDS

- Manager (1): Higher National Diploma and Degree
- Records Clerks (17): Certificate and Diploma

D) RESEARCH DATA MANAGERS

- Managers (3): 1 Masters level and 2 degree level

On-site database design, implementation and trouble-shooting:

- A) On-site database design: We are running OpenMRS, an open-source system, which is a web-based medical record system with a MySQL backend. The system engineers add functionality to the design of the system.
- B) Implementation: We have a central server and seven (7) remote servers for off-site entry. The data is moved from the remote servers to the central server for processing. This is currently done manually once a week via a flash drive as we await Wide Area Network (WAN) to connect all our sites.

At the moment, there are more than 300,000 patients in the system for both the HIV program and the Primary Health Care program.

*The personnel mentioned above mainly manage the HIV data (about 120,000 patients)

The data is backed up automatically on a daily basis and weekly for off-site storage. There is also a daily automatic antivirus update system.

- C) Trouble-shooting: Focuses on the system itself and its infrastructure. All the above teams participate in different levels of trouble-shooting. However the main teams involved are the system administrators and the Network and User Support.

The system administrators focus on issues relating to the system. The Network and user support team focuses on issues relating to the infrastructure the system is running on.

There is a manual for reference on the same and periodic trainings.

- D) Dataset development: Research data managers are responsible for extracting and developing dataset based on the requirement of specific PI's requests. Datasets are extracted from master dataset developed from the production server.

Details of off-site support (if applicable):

- There are data assistants stationed at all remote form-entry sites who have received basic training on implementation and troubleshooting.
- There are quarterly scheduled visits and in-house trainings by system administrators, IT support and data management.
- Phone consultations, which include troubleshooting, are available for the off-site personnel.
- In the event that there is an issue that cannot be resolved by consultation, an immediate visit to the site is made by the relevant team to address the issue.

BIOSTATISTICAL SUPPORT

Please describe the BIOSTATISTICAL SUPPORT available in your research institute, including the items listed below (if applicable):

Biostatistical expertise, including staff complement/composition of PhD and Masters level biostatisticians:

- The program has 7 Biostatisticians; 5 PhD level and 2 Masters level.

Specific areas of biostatistical expertise/excellence:

- The team has expertise in:
 - Methods for observational studies
 - Methods for dealing with missing data
 - Lifetime data analysis
 - Methods for double sampling studies for handling drop out in survival analysis
 - Longitudinal analysis techniques

Details of off-site support (by whom):

- 3 Biostatisticians: 1 at Brown University (Joe Hogan) and 2 at Indiana University (Hai Liu, Constantin Yiannoutsos) provide off-site support in analysis.