

JOINT CLINICAL RESEARCH CENTRE



**Annual Report
2009**





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Acronyms

ACTG	Adult AIDS clinical trial group
ARROW	Anti-Retroviral Research for Watoto in Africa
ART	Anti-Retroviral Therapy
CBO	Community Based Organisation
CeSSRA	Center for Social Science Research on AIDS
CHAPAS	Children in Africa with HIV Pharmacokinetics Adherence / Acceptability of Simple Anti retroviral Regimens
CHAI	Community HIV/AIDS Initiative
CLVs	Community Liaison Volunteers
CME	Continuing Medical Education
CMO	Clinical Monitoring Only
COHRE	Clinical Operational & Health Services
CRS	Catholic Relief Services
CWRU	Case Western Reserve University
DART	Development of Antiretroviral Therapy in Africa
DNA	Deoxyribonucleic Acid
EARNEST	Europe Africa Research Network to Evaluate Second line Therapy
EAP	Expanded Access Program
EGPAF	Elizabeth Glaser Paediatric AIDS Foundation
ERC	Endpoint Review Committee
FDA	Food and Drug Administration
FWA	Federal Wide Assurance
GCP	Good Clinical Practice
GTZ	German Agency for Technical Cooperation
HAART	Highly Active Anti-retroviral Therapy
ICTU	International Clinical Trials Unit
IDI	Infectious Disease Institute
IDP	Internally Displaced Persons
IRB	Institute for Research in Biomedicine
IRCU	Inter-Religious Council of Uganda
IRIS	Immune Reconstitution Inflammatory Syndrome
JCRC	Joint Clinical Research Centre
JPF	JCRC PEPFAR
JTV	JCRC Therapeutic Vaccine
MOH	Ministry of Health
MOMS	Maintaining Options for Mothers Study
MRC	Medical Research Council
MRC	CTU Medical Research Council - Clinical Trials Unit
MSF	Medecins Sans Frontieres

MSH	Management Sciences for Health
MTCT	Mother To Child Transmission
MUJHU	Makerere University, John Hopkins University
NDA	National Drug Authority
NFP	Not For Profit
NGO	Non Governmental Organization
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside/Nucleotide Reverse Transcriptase Inhibitors
NUMAT	Northern Uganda Malaria and Tuberculosis Programme
NVP	Nevirapine
OBT	Optimized Background Anti-retroviral Therapy
OHRP	Office of Human Research Protections
OI	Opportunistic Infection
OVC	Orphans and Vulnerable Children
PCR	Polymerase Chain Reaction
PCRD	Patient Card & Research Database
PEPFAR	Presidential Emergency Plan for AIDS Relief
PIDC	Paediatric Infectious Disease Clinic
PIs	Protease Inhibitors
PMTCT	Prevention of Mother to Child Transmission
PPD	Pharmaceutical Product Development
PSI	Population Services International
QA/QC	Quality Assurance/Quality Control
RCE	Regional Centres of Excellence
RCT	Randomized Clinical Trials
SCMS	Supply Chain Management System
STI	Structured Treatment Interruptions
TASO	The AIDS Support Organization
TREAT	Timetable for the Regional Expansion of Antiretroviral Therapy
UNCST	Uganda National Council of Science and Technology
URCS	Uganda Red Cross Society
USAID	United States Agency for International Development
UWESO	Uganda Women's Efforts to Save Orphans
VCT	Voluntary Counseling and Testing

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Director's Message

Dear Reader,

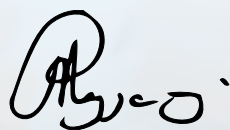
We are delighted to share with you our achievements over the last 12 months. JCRC has continued to grow and support Ministry of Health, work with national and international partners towards the expansion of ART coverage, intensify research to inform practice and offer training and learning opportunities to young professionals and health care workers.

Currently, JCRC continues to be the leading provider of HIV care and ART services across the country, a service that is provided through its RCEs and more than 52 MoH supported facilities. The RCEs continue to provide specialized clinical and laboratory support across the country and have been instrumental in supporting the scale up of the National Early Infant Diagnosis program.

Our research agenda continues to grow as we work with national and international partners to provide important information to guide policy on health care provision in Uganda. This year a number of new networks have been established and findings published in both international and local forums.

The centre continues to contribute tremendously to research capacity building through the various training and fellowship programs based at JCRC. The programs at JCRC have continued to support Universities in Uganda through sponsoring or introduction of courses that are relevant to research capacity enhancement. The capacity of health workers to provide care has been improved through training programs which also provide opportunities to the young and the upcoming scientist to get involved in the work JCRC is doing.

I would like to thank all our national and international partners, collaborators and funders for the enthusiasm and interest you have shown in working with us. To the staff we say thank you for the tireless work to conduct quality medical research, training and health care.



Prof. Peter N. Mugenyi
Director
Joint Clinical Research Centre



Who we are:

JCRC is a non-profit organization founded in 1991 to serve as a national AIDS care, treatment and research Centre to address the challenges of HIV/AIDS in Uganda. It was born as collaboration between Makerere University's School of Medicine and Uganda's Ministries of Health (MoH) and Defense.

We are involved in HIV/AIDS research, care and treatment through a countrywide network of JCRC supported facilities. Besides the direct provision of HIV treatment, JCRC continues to strengthen the capacity of healthcare providers and researchers through training.

Vision

A vibrant self sustaining centre of excellence in medical research, training and health care services.

Mission

To conduct quality medical research and training, provide equitable and sustainable HIV/AIDS care and other health care services in Uganda and other parts of Africa.

Core Values:

Integrity, Confidentiality, Compassion, Mutual Respect, Teamwork, Accountability, Continuous Learning and Excellence.

JCRC coverage

By 2009 JCRC had become the largest provider of ART in Uganda, supporting 52 satellite sites and supporting more than 25 out reaches reaching more than 74,000 clients through Ministry of Health, Faith Based Organizations and Community Hospitals.

JCRC has a network of 8 regional centres of excellence (RCEs) namely Gulu RCE (Northern region), Kabale (South Western Region), Mbarara (Western Region), Kakira and Mbale (Eastern region) Mubende (central region) and Fort Portal. All RCEs have state of the art laboratories that support National health care and research and have the ability to conduct clinical research, basic science research and social behavioral studies

Our Partners and collaboratoryorations

JCRC is funded and works closely with a number of organizations to include, Ministry of Health, Makerere University, Mbarara

University of Science and Technology, Uganda Christian University Mukono, national HIV/AIDS implementing partners and other International partners like, USAID, NIH, Case Western Reserve University, JHU, MSH, MRC UK, Imperial College London, WHO, California Public Health Department

1.0 CLINICAL SERVICES

JCRC continues to be one of the leading HIV service providers in Uganda, offering a range of comprehensive HIV/AIDS care services. The centre runs both adult and pediatric programs under various arrangements including corporate/private packages offered at a subsidized payment arrangement, free services for project patients and patients exiting studies. Despite the financial crunch and limited funding throughout 2009 patient numbers continued to rise. Clinical services are offered in the out patients department, department of pediatrics, In patients department/ the ward, Pharmacy and the psychosocial support team that includes counselors and adherence officers.

ADULTS OUT PATIENTS DEPARTMENT

The clinic registered a total of 32,998 clinic visits this year, an average of 2,750 visits per month and of these almost 30% were doctor visits while 70% were nurse visits, highlighting the increasing role of nurses in rolling out programs in the country. Guided by findings of the DART trial, the clinic was able to cut down on the frequency of laboratory monitoring while at the same time maintaining high quality services thereby reducing on the per capita cost of care. The cost savings along with other initiatives enabled us to enroll some additional patients on ART with special focus on the pregnant patients and breast feeding HIV infected mothers in order to reduce parent to child transmission of HIV. The number of private and corporate clientele increased from 120 per week in the previous year to an average 200 per week in 2009 an indication of increased confidence from this group of patients.

THE PEDIATRICS DEPARTMENT

The JCRC Pediatric department is a dynamic program offering outpatient services, in-patient care, a nutrition program and a couple of other specialized services as outlined below. The program is also actively involved in local and international studies aimed at informing best practices in pediatric care. By the end of 2009, several collaborative studies were in advanced stages of development and are expected to start participant recruitment by mid 2010.

Approximately 50-70 patients go through the Kampala pediatric outpatient clinic daily. In 2009 a total of 2,064 children with various medical needs were seen by a team of dedicated and specialized staff. These included 753 who came for VCT services 148 of whom tested positive and were all enrolled into the program. Fifty three (53) new children were referred to the clinic from our partners making a total of 201 children newly registered by December 2009. The schedule for the visits of the registered patients is as follows:

- Asymptomatic ART naïve children are seen every three months
- Symptomatic ART naïve children are seen every month
- Patients starting ART are seen two weeks after initiation and then monthly until deemed stable
- Children stable on ART are seen every two months
- This excludes unscheduled sick visits

Targeted Clinic Services within the OPD

1) Private and corporate clientele

To help private/corporate clients who find it difficult to find time during working hours to visit well established HIV treatment centers, JCRC has put in place a system that recognizes this special group of our clientele. Apart from assigning specific doctors to be on the ready to see private and corporate clients whenever they report to the clinic, a special arrangement is now operational to ensure that such clients are fast tracked though the

system right from the reception to the very end of the system. As part of this approach a special window in the pharmacy has been created to cater for such patients. By laying these strategies, the waiting time for this group of clients has effectively reduced. We believe that this service will help increase access to proper ART management to a vast number of people who would have otherwise failed to access the service because of the nature of their work schedule and subsequently boost the public-private partnerships.

2) The chest clinic

This clinic was conceived in February 2009. It is a nurse led clinic with two doctors on hand when needed. The clinic does active screening for TB. Patients with chronic cough for more than two weeks are triaged to this clinic from the reception daily. Screening for TB through sputum smears is done for all triaged adult suspects. Those found to have TB are enrolled into the chest clinic for care and follow up. These patients do not get back to the main clinic for follow up of any kind until they are; either no longer infectious or they have completed their 8 month duration of treatment. All their ART needs and other HIV care requirements are handled in this specialized clinic. For children, this clinic enrolls only confirmed TB patients who have been diagnosed from the pediatric clinic. A total of 292 patients were referred to the TB clinic this year and of these 99(34%) were smear positive, an increase from last years rate of 20%.



3) The adolescent programme

Adolescents and young people present with special needs that may determine how well they adhere to treatment and care programs. To cater for some of these needs and to promote adolescent friendly services, special clinics for them are conducted on Wednesdays and Thursdays. This ensures that the young people meet their peers thereby facilitating sharing of clinical experiences and limiting stigma. We also continue to have adolescent peer support groups meetings for the 10-14 yr olds and the 15-19yr olds, as well as a youth (young adult) group for those above 19yrs. These meet weekly on Saturdays to allow the school going children to attend. Through these group meetings the young people are given the opportunity to express their fears and offer psychosocial support to their friends who may not be fairing as well.



A cross section of some adolescents attending one of the peer support meetings

4) Adolescent's transition clinic

Transiting from the pediatric clinic to the adult one usually creates huge challenges to the adolescents sometime leading to non adherence or loss to follow up. Recognizing this in this reporting period, the clinic put in place a transition program to facilitate the transition of adolescents into the adult clinic. As part of this arrangement adolescents graduating to the adult clinic are received by the clinic manager in order to make them feel welcome. On subsequent visits they are attended to by one of the doctors familiar

to the adolescent. They are also encouraged to cluster according to nature of their schools or jobs. Arrangements for their peer group meetings and other activities to start in 2010 are in advanced stages.

5) Palliative care

We have integrated specialist palliative care into our services in the adult clinic by forming a palliative care team with one of the nurses qualified as a trainer, registering palliative care patients in a PAIN register at the reception, developing a pain management SOP, and establishing timely referrals for PAIN patients.

6) Family Planning Clinic

A family planning clinic was set up to provide counseling and services to clients. The number of clients accessing these services has continually grown through out the year

7) The nutrition programme

The emphasis of the nutrition program within the pediatric department is to care for the nutrition needs of the severely malnourished children according to the recommended guidelines. The program carries out monthly (for those < 36 months) or quarterly (for older children) growth monitoring for all children seen in the clinic to identify malnourished children requiring closer monitoring. The severely malnourished children are admitted and treated with High Energy Milk, whose constitution by the kitchen staff is supervised by the nutritionist. Once stable, the children are then weaned off to "plumpy-nut", a ready to use therapeutic feed (RTUF) that is peanut based. This plumpy-nut is provided by Clinton Foundation/ UNITAID program. As part of the long term nutrition monitoring, the nutritionist assesses food security of the child's family an activity that may involve visiting the child's home. The acutely food insecure children/families are given a package that comprises of Soya, Maize/

millet flour, Milk powder, Sugar, Margarine, Peanut/Simsim paste, fish powder and eggs. All the children receive multivitamin supplements irrespective of their nutrition state. In addition to the group nutrition education and counseling to the caretakers, the nutritionist also gives targeted nutrition education and counseling to individualize recommendations or advice.

8) The PATA Expert patient programme

In collaboration with the Paediatric AIDS Treatment for Africa (PATA), an expert patient program was started in July 2009. In this program, 6 clients attending the adult clinic at JCRC offer various services in the clinic for 2 to 24 hours a week for which they receive monthly stipends. These clients are involved in such roles as play room supervisors (2), treatment support personnel (2), community liaison personnel (1), and an adolescent peer support group facilitator (1). As a result of the program, the children that attend the clinic are occupied as they wait for the clinic services, their mid morning snack is supervised, skill building sessions are held in the adolescent peer support meetings, a number of children have been identified in communities and brought into care and 11 children with extremely poor adherence to antiretroviral therapy have had support from treatment buddies near their homes.



A play room supervisor attending to the children painting in the waiting area

Clinic systems improvement at JCRC OPD

JCRC strives to strengthen health systems to facilitate the provision of quality and efficient services to its clients. In 2009, the clinic launched a Clinic Systems improvement campaign that mainly focused on the information management systems, service delivery through the development of Standard Operating Procedures (SOPs), reinforcement of Nurse Visits, interventions to reduce client waiting time and increased patient education.

Information Management:

Electronic Data capture. .

The Clinic adopted a new electronic database (Clinic Master) which captures all patient information electronically (visits and reasons for visits). The system is linked to all departments making it easy to quantify all client visits for different services which greatly enhances planning and projection for the logistics and human resource for the different clinic activities . By The end of 2009,all clinicians were able to make electronic prescriptions and laboratory test requests and this information gets to the pharmacy or laboratory before the patient physically gets there. Electronic prescriptions have greatly reduced backlog of data in the pharmacy and have reduced patient waiting time in the pharmacy. It has enhanced tracking of patient drug pick ups as well as laboratory transactions.

Quality Assurance enhanced

JCRC has strengthened quality assurance and control activities within the clinic through a number of ways. As a quality control measure, on a daily basis, all patient files from clinicians are checked for errors, and incompleteness by an independent team. Identified queries and points of corrections are promptly forwarded back to the doctor concerned for action. Quality checks are also performed on the electronic database which is prompted to generate monthly reports and feedback which is then given to the relevant personnel for corrective action. As a result of this exercise the number of errors generated from data entry by clinicians into patient files have remarkably reduced.

Lost to follow up update exercise

The ability of HIV/AIDS care programs to adequately follow up clients is vital for effective programming and maximum utilization of resources. JCRC Kampala uses the Patient Care and Research Database (PCRD) system to track patients who were lost to follow up since the program began. An intensive data cleaning and update exercise to establish why and how many patients were lost to follow up was embarked on. For this exercise, lost to follow up was defined as patients who did not make clinic visits or pick drugs within 6 months or longer. Of the people who were classified as lost to follow up, we discovered these included people who were dead, transferred out, self referrals and some people whose contact information had changed and were not yet updated in the clinic data base.

When patients were traced and asked why they were not attending clinics in the last 6 months, a few cited religious and traditional remedies as alternatives they had sought to help them overcome HIV/AIDS.

Improved dispatch of Laboratory Results.

The clinic gazetted a station for dispatch of laboratory results which is managed by a full time staff. All results dispatched are documented in order to maintain a good audit trail. This coupled with the improved turn around time for laboratory results has markedly reduced the waiting time of patients scheduled to see clinicians after receiving laboratory results .

Improved service delivery

Standard Operating Procedures were finalized

The Standard operating procedures for most sections of the clinic were drafted by the relevant personnel and a multi disciplinary SOP review team formed. Authorization of these SOPS will be completed in 2010 after appropriate review. The Standard operating Manual is also undergoing final review before authorization

Reinforcement of the Nurse Visit

The nurse visit was promoted from a drug refill visit to a full clinical visit with proper interaction with the nurses, empowering nurses to become more involved in clinical monitoring of patients. More than 70% of patients (mostly stable ones) attended nurse visits in the clinic daily. Two nurse stations were established; one in the adult clinic and one in the pediatric clinic. Activities include measurement of Blood pressure and weight, capturing of illnesses and side effects, drug refills as well as referrals of serious conditions to the doctors. All information generated during this visit was recorded on a nurse visit form which is kept in the patient file and also captured electronically into the PCRD. This greatly improved tracking of patients previously thought to be lost to follow up.



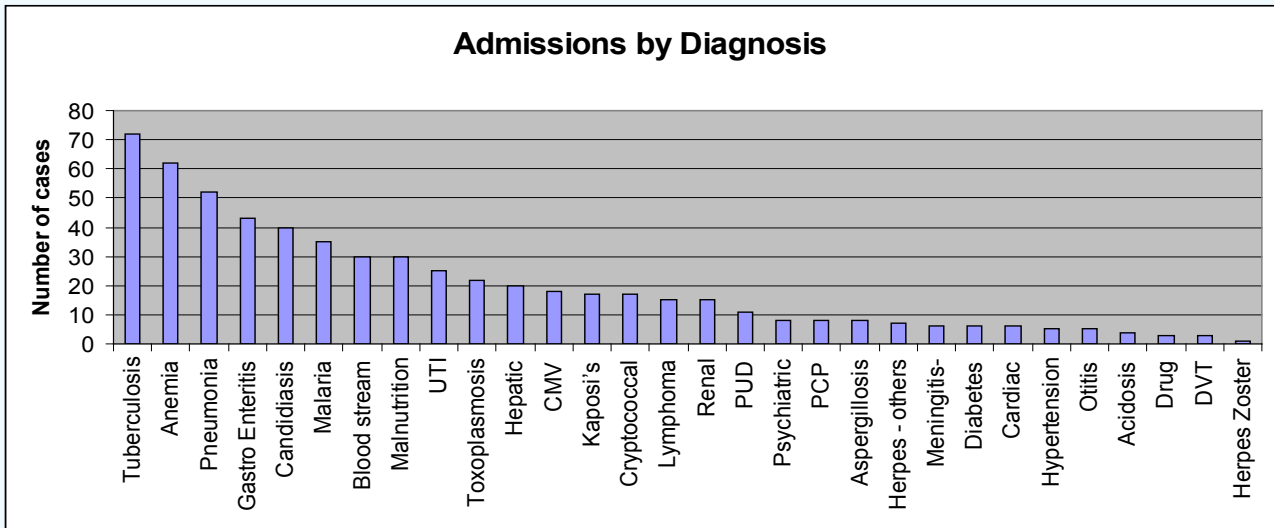
Nurses mark the 2009 Nurses Day celebrations

Interactive Health discussions

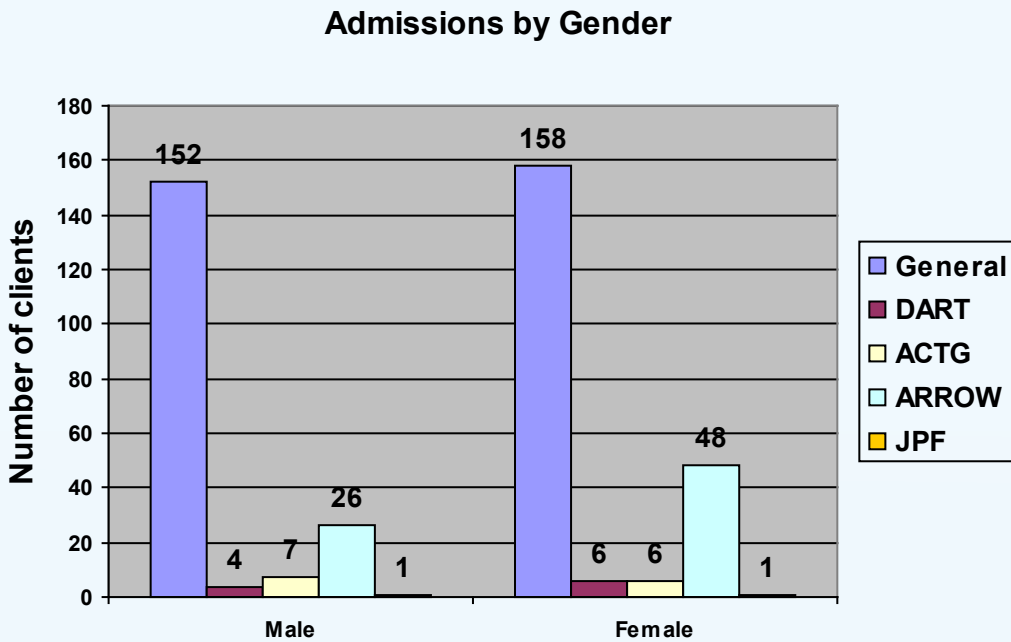
A key prevention and treatment strategy used in the JCRC clinic is behavior change communication through IEC material distribution and health talks in patient waiting areas. This year the clinic transformed the previously held health talks into interactive health discussions which unlike the previous talks given, are conducted by a multidisciplinary team consisting of clients, clinicians, nurses, adherence counselors, pharmacists, TB nurses, radiologists and clinic management. Topics for discussion are generated from the clients themselves and they are scheduled on a monthly basis. The discussions are lively, educative and provide a forum for receiving feedback from patients and emphasize the GIPA principle.

IN PATIENTS DEPARTMENT

JCRC runs a 20 bed capacity ward that offers comprehensive in patient services to both adults and pediatric patients. This was established to cater for study and general patients who may need in patient care during the course of their disease management. All patients admitted on the ward pay for the service in an arrangement that is determined by which program the patient happens to be under. In 2009, there were 310 total admissions 52% of whom were children. Like in the previous years the majority of admitted patients (83.13%) were ART experienced. , Many of the ART naïve patients admitted presented with advanced HIV disease with serious opportunistic infections. This highlights the continuous emphasis on VCT and enhanced HIV education in the community so that initiation on ART is timely. The commonest reasons for admission this year were Tuberculosis (TB), anemia, and pneumonia. The graphs below summarize the other causes of admissions as seen on the medical ward this year.



There was no significant difference between the proportion of females and males admitted on the ward this year. This however does not mean that the proportion of males seeking HIV services has improved over the year.



Psychosocial support Department

The level of readiness by patients to follow healthcare worker recommendations is a major factor that can be addressed through information, education and counseling. Interventions within the adherence and counseling departments are to ensure clients are prepared for VCT, Research studies and that treatment preparedness and adherence support is given to optimize the effectiveness of ART and minimize the development of drug resistance.

The counseling department offered counseling to over 3,600 clients who needed HCT services and supported provision of PMTC, Screening and enrollment of clients for various studies, follow up clients for JCRC Immuno Pathogenesis (JIP) Study and provided Family Planning and Psycho-Social Support services to clients in care. The department prepared more than 370 clients who were enrolled in the JPF study and more than 200 patients enrolled in the various ACTG protocols.

The adherence department: The ability of patients to follow treatment plans is frequently compromised by various factors, including stigma and discrimination against them and their families, treatment costs they cannot afford, and the nature and tolerability of available ARV therapies. Several activities are carried out in this department to facilitate adherence to therapy.

Health education talks continue to be conducted covering various relevant topics in the clients' interests such as personal hygiene, nutrition, Septrin prophylaxis, and ART adherence, Tuberculosis in HIV/AIDS, Caring for children with HIV/AIDS, PMTCT, and Importance of joining psychosocial support groups. Clients also participated in conducting health education talks, and sharing of their personal experience of HIV/AIDS and ART. This has encouraged self disclosure amongst fellow clients thus improving adherence.

Young adults reproductive Health: HIV positive young people engage in unprotected sex due to insufficient preventive information resulting into "undesired pregnancy", re-infection, and transmission of the virus to others and sexually transmitted infections.

At Kampala in the pediatric clinic, it was observed that a number of female adolescents become pregnant and "disappear" from the clinic. To address this gap, this year, sex education was one of the areas that was addressed in the Young adults (15-24yrs) peer support group to empower young people to make practical informed decisions about their sexuality



One of the young Adults meetings

Get together parties as well as monthly meetings were conducted in all RCES targeting different patient audiences. This boosted the patient's confidence and thus reduced on the stigma. Adult clients through their monthly meetings were empowered with income generating skills including indoor mushroom growing, vegetable growing in sacks, hair plating and knitting

Client clubs provide an optimum atmosphere for sharing experiences, expressing feelings, developing new skills and boosting the psychological wellbeing of clients. They create avenues for clients to renew their esteem and face challenges with confidence; after all they explore peer support. Meetings are a way clients manage stress as they get an opportunity to interact and share good moments. During these meetings different activities have been done like making of soap, giving out starter kits (mosquito nets, jerrycans, water guards etc from PSI), talks about ART and adherence. These meetings are facilitated by adherence officers.

Strengthening support systems. The CLV program: The program worked with a network of 350 trained Community Liaison Volunteers countrywide, these conducted HIV/AIDS/ART awareness and provided basic psychosocial support services in the community and also played an active role in the clinic.



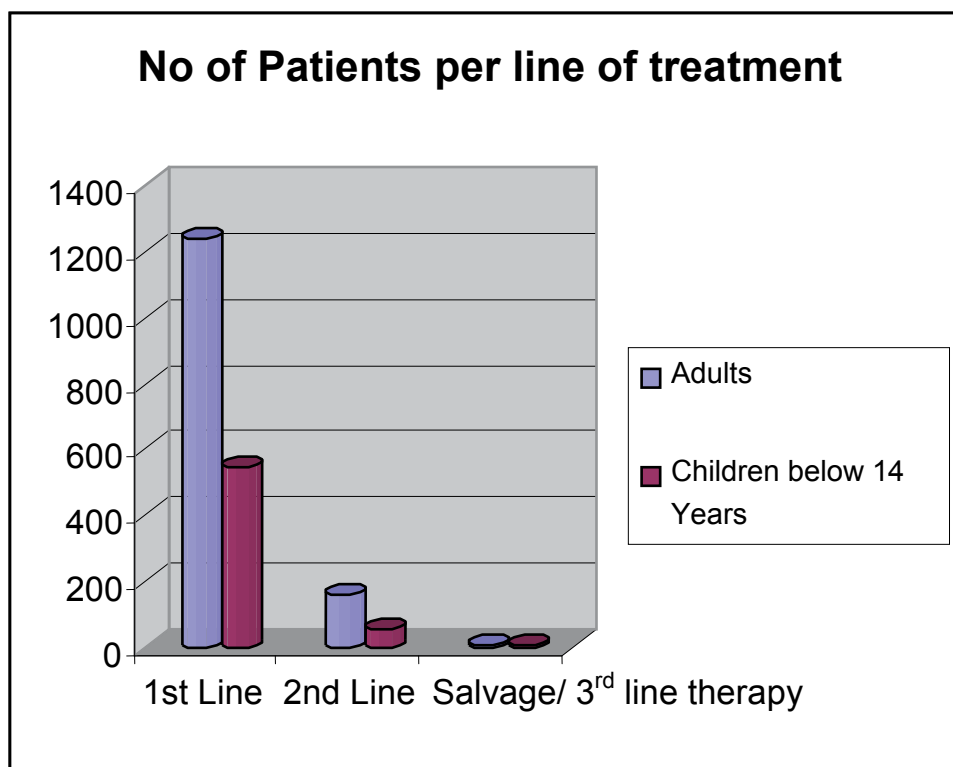
The National Adherence officer (Right) moderating one of the Community Out reach



Staff answer questions during local leaders workshop in Makindye Division sensitization meetings

The Pharmacy Department

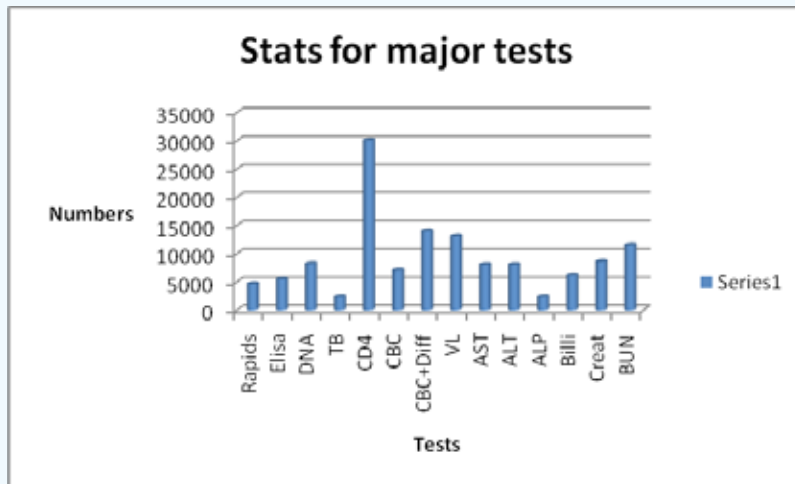
The pharmacy department provides both Antiretroviral and opportunistic infections drugs to both adults and pediatrics with the goal of ensuring rational use of drugs. The O.I drugs are put in the common pool with the drugs supplied by other stakeholders in the clinic. Pediatric O.I drugs are dispensed in the O.I Pharmacy from a different window. Like in the previous years, the JCRC has continued to enjoy a year of no stock out on the essential ARVs and on many occasions we have continued to support the Ministry of Health with buffer stocks for both the first line and second line drugs thanks to our robust drug logistics system. We are currently working in close partnership with the Maternal Child Health department of Mbarara Regional Referral Hospital to provide ARVs for the PMTCT program.



2.0 LABORATORY SERVICES

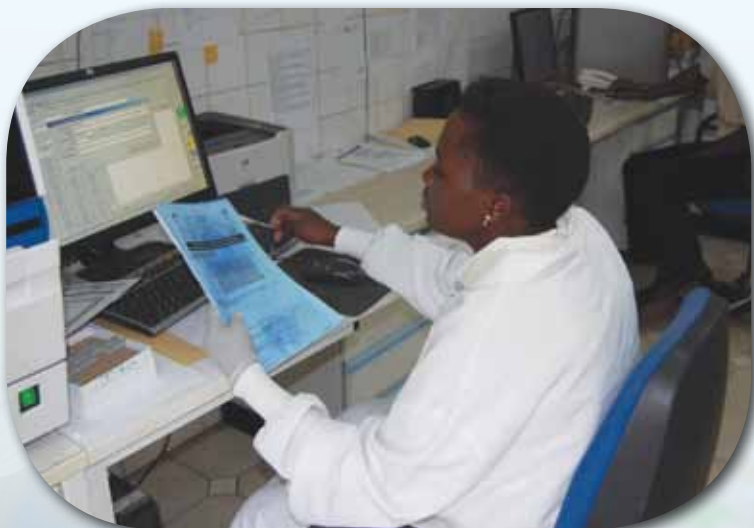
The JCRC Kampala laboratory continues to strive to ensure that quality services are provided to all customers. The laboratory continues to play the role of a reference laboratory for both local and international ART and research programs. The Quality Assurance and Safety managers have worked hand in hand with all sections to ensure that specimens are processed in a timely manner while at the same time not compromising on the quality of services as well as the safety of patients and laboratory staff. Because of this, our partners have continued to have confidence in our services and as a result we have seen an increase in the number of samples sent to the laboratory throughout the year.

The graph below summarizes the 2009 laboratory performance broken down by test type.



During the year the laboratory also developed capacity to perform additional tests such as the STD PCR (gonorrhea, Chlamydia and Mycoplasma genitalium PCR) in the virology section, chamydia Elisa IgG, IgA in the immunology section, and HSp60 a hormonal assay in the biochemistry section.

During the year the laboratory management instituted simple but very effective measures that have seen remarkable improvements in the turnaround time. For example the introduction of shifts in the laboratory and more regular internal support supervision has been able to reduce the turnaround time in the heamatology and biochemistry sections from 5 days to an average of 24-48 hours, while the virology section has brought down the turnaround time to 5 working days mainly attributable to the introduction of a laboratory data clerk.



Staff at work in the Chemistry Lab

JCRC has continued to provide DNA PCR services to the MOH Early Infant Diagnosis (EID) Project through JCRC Kampala laboratory and the RCEs across the country. Specimen referral and feedback of results to lower health facilities is being strengthened through using alternative feedback mechanisms like calls to pick results and emails in addition to poster services.

QUALITY ASSURANCE

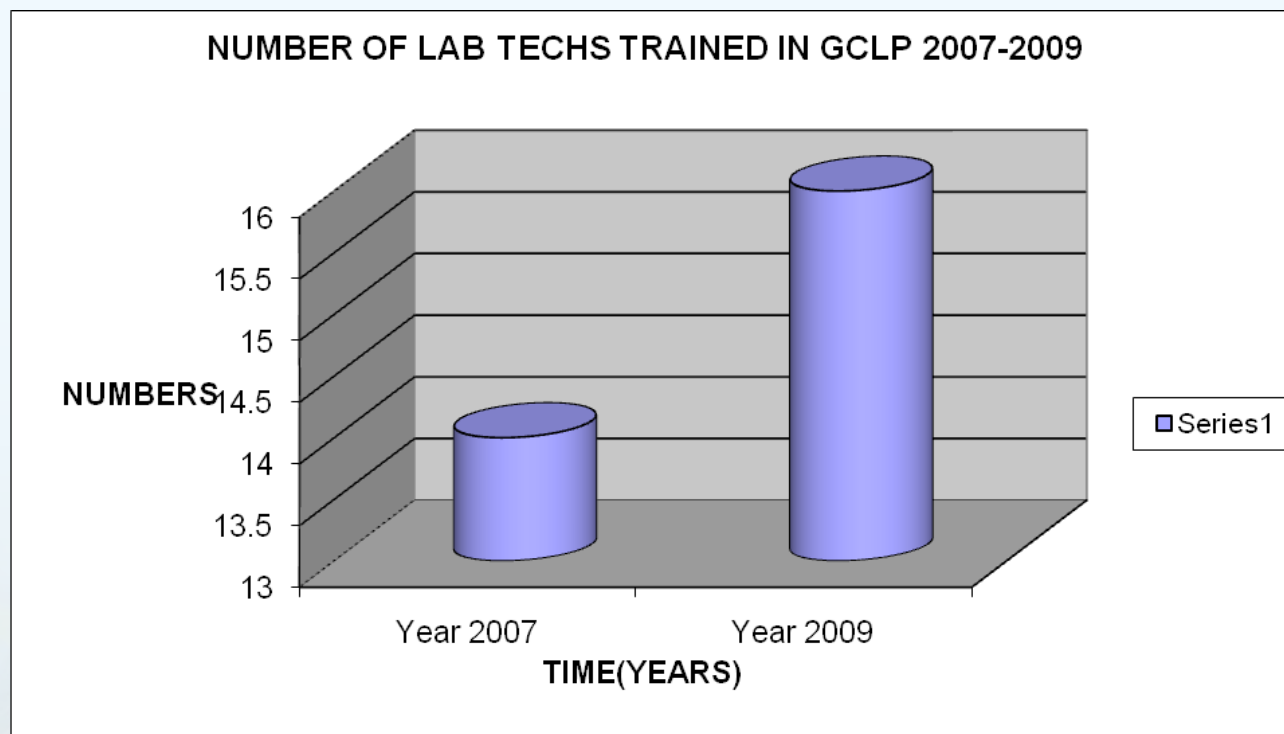
Laboratory quality management at the JCRC hinges on the pillars of strong Internal quality monitoring systems, External quality assessment (EQA) and Staff skills development through training. Other Quality management measures such as accreditation are in advanced stages especially as the JCRC moves to its new complex in Lubowa.

Internal Quality management Systems (IQM): The year 2009 has been a successful one as far as implementing the IQM is concerned. The development of a functional internal quality management system that continuously monitors the testing processes in all the Laboratory sections

has improved the management of QA systems at the center. Our target in all these internal QC systems is to reach 100% and this will be the first assignment in the year 2010.

External quality assessment (EQA): EQA is a vital component of a Laboratory's quality system. The JCRC participates in College of American Pathologists (CAP), the United Kingdom External Quality Assessment Scheme (UKNEQAS), the Virology Quality Assurance (VQA), Centers for disease Control and Prevention (CDC) and Canadian Quality Assurance Scheme (QASI). Performance in all the EQA schemes for this year has been excellent for all the tests. With technical support from SMILE (USA QA Specialists), the center has embarked on a quality improvement plan for all JCRC affiliated laboratories.

Laboratory Training: The Joint Clinical Research Centre Laboratory runs numerous clinical trials and it's a requirement that laboratory staff undergo GCLP every after two years. This is so because trial laboratory requirements and regulations may change and there is need to continuously update staff for better trial compliance.



Laboratory audit: Laboratory auditing is an independent review of a laboratory's quality management system to determine compliance levels. Our Laboratory is audited in all aspects of quality management, safety and overall trial compliance by PPD every year. The last audit took place in January 2009. An audit action plan was generated and it has been our major focus of 2009.

3.0 RESEARCH AND DEVELOPMENT

Research in HIV/AIDS was and still remains one of the core objectives of JCRC since its inception in 1992. Through emphasizing operational studies and involvement in internationally recognized clinical trial activities, the research program at JCRC has continued to grow and produce interesting results. This year a number of new networks have been established and a number of findings published in both international and local forums. Our capacity to design, implement and coordinate large international trials has continued to improve and our contribution to the international scientific community is now more recognized.

The program's emphasis

The core business of JCRC as a research institution is to engage in Medical Research particularly in HIV/AIDS and related conditions. The institution of JCRC was established as part of the national HIV/AIDS response and in this regard was mandated to carry out clinical research on HIV/AIDS to guide national policies and guidelines on care and treatment of HIV/AIDS in Uganda. The key driver for HIV/AIDS research at JCRC therefore, should be the effort to find evidence for the effectiveness, efficiency and relevance of the interventions and products used to fight the epidemic. The scope of research that JCRC engages in has since expanded to include not only clinical research but also operational and implementation research, basic science research, social sciences research, etc. Our research priorities as an institution are aligned to the 3 broad thematic areas of the National Strategic Plan as follows:

1. HIV prevention- by evaluating the risk factors and drivers of the epidemic

2. Care and treatment- by participating in clinical trials and observational studies that aim to provide evidence for what interventions and processes work in our context

3. Social support- through social sciences research

Systems and Capacity building for Research

International Clinical Operational and Health Services Research (COHRE) training programs (further details are on page 30. Trainings section) has one of its goals conducting training in research and operationalizing research findings in order to strengthen the national capacity to address the public health and scientific challenges of the evolving HIV and TB epidemic in Uganda. The program identifies and builds research skills of promising young and upcoming scientist through a mix of long and short term training arrangements.

Fogarty International Centre (FIC) International Clinical Research Scholars (ICRS) and Fellows (ICRF) Program: Working in collaboration with the Case Western Reserve University (CWRU), JCRC is one of the training sites for the International Clinical Research Scholars (ICRS) program. This fellowship addresses global health challenges through innovative and collaborative research and training programs, supports and advances the NIH mission through international partnerships. The Ugandan scholar was matched with a fellow from CWRU to undertake a one year (July 2009-June 2010) full time clinical research program based at JCRC. The fellows are expected to develop and implement their own research projects, in addition to attending tailored short courses organized by JCRC. Fellows on this program benefit from highly qualified and experienced research mentors who help scholars advance their educational and professional growth. This year's fellows were Samar Mehta, PhD, MD candidate from SUNY Downstate Medical Center and Juliet Akao, MBChB, MMed from the Joint Clinical Research Center.

Center for Social Science Research on AIDS (CeSSRA): The Center for Social Science Research on AIDS (CeSSRA) is a training and research collaboration between researchers at Makerere University, Joint Clinical Research Centre (JCRC) in Kampala, Uganda, Mbarara University of Science and Technology (MUST) in Mbarara, Uganda, and the Case Western Reserve University, USA. CeSSRA started in 2007, funded by the National Institute of Health (Grant: R24HD056917) USA. The Center has two complementary missions: 1) to develop and expand local capacity to undertake social science research on HIV/AIDS in Uganda, through infrastructure development, training, and enhancement of local resources to undertake such work; 2) to promote, and conduct social science research on HIV prevention and treatment through specific research building upon and expanding the research programs of the current CWRU-Uganda research collaboration. As one of its objectives, CeSSRA is conducting a longitudinal study (**See below**) to examine the social context of HIV treatment.

Case-JCRC Center for AIDS Research (CFAR): The Uganda-CFAR virology laboratory was established in 1998 with support from the CFAR and the Fogarty training grant and is under the supervision of Dr. Eric Arts at Case. This laboratory is performing a number of assays including viral propagation, Drug resistance testing for the reverse transcriptase and protease regions for patients on ARVs, DNA PCR techniques, automated DNA sequencing for sub typing and drug resistance testing as well as most techniques routinely performed by advance molecular biology laboratories. The center laboratory is equipped with the personnel and equipments required for molecular virology studies including. In this reporting period, a CEQ 8000 automated DNA sequencing system from Beckman Coulter was installed and is used for HIV drug resistance testing, clade classification, and viral diversity analysis. HIV-1 RNA loads, PBMC separation and freezing, as well as HIV-1 virus propagations are also performed by the laboratory. In addition to genotypic drug resistance testing, the laboratory is in the process of starting phenotypic drug resistance testing. The laboratory is VQA certified

to run viral loads. It is also involved in different external quality assurance schemes for drug resistance. These include the TAQAS (Treat Asia Quality Assurance Scheme) and the VQA from NIH. It is in the process of being WHO accredited for drug resistance testing.

UGANDA-CWRU-JCRC IMMUNOLOGY

Laboratory: The Uganda-CWRU Immunology laboratory at Joint Clinical Research Centre (JCRC) is a research laboratory which works in collaboration with Case Western Reserve University, Cleveland, Ohio and Oregon Health Sciences University (OHSU). The Laboratory continues to engage in studies seeking to understand the pathogenesis of TB in Uganda. Studies currently active in the laboratory include the Kawempe Community Health Study (KC), Cytokine studies (CT), Tuberculosis Treatment Consortium (TBTC) studies [Nucleic Acid Amplification study (NAA), Study 29 Rifapentin pharmacokinetic Studies], CD8 Study, Tuberculosis Immunity in Children (TU) study and Gates Challenge (GC) study. The Punctuated Anti-retroviral Therapy (PART) study was successfully completed in July 2009 and data is currently being analysed. Also concluded and manuscripts submitted for possible publication are the CT12 (Detection of latent TB-infection in patients with HIV immunodeficiency), CT14 (Role of HIV/TB in antigen presenting cell function) and CT16 (CD8⁺CD25^{hi+} T-reg Expansion and Function during pulmonary HIV/TB).



A cross section of some adolescents attending one of the peer support meetings

The JCRC Tuberculosis Laboratory: The JCRC-Case Collaborative Tuberculosis Laboratory based at Joint Clinical Research Center is primarily a research laboratory, culturing TB samples for the Uganda-Case TB research projects at Mulago, as well as private and project patients at JCRC. The laboratory is capable of performing, processing and decontamination of patient specimens, liquid cultures in the Bactec 960 MGIT instrument and solid cultures on 7H10 media to detect *M. tuberculosis* (Mtb). Additionally antigen based identification or *molecular* assays including PCR for identification of *M. tuberculosis complex* are performed on acid fast bacilli positive cultures, and drug susceptibility testing of Mtb isolates. Second line drug testing of multiple drug resistant (MDR) Mtb strains can presently be performed by the agar portion method. However we are in the process of validating second line drug testing in the Bactec 960 which will provide much more rapid results.

A Roche LightCycler 480 real-time PCR instrument has recently been added which will enable rapid sputum testing of all TB suspects but especially HIV positive smear negative TB suspects who are often in need of the most rapid diagnosis of TB possible. When validated, this instrument will also allow for rapid MDR testing, strain typing and further molecular characterization of the Mtb strains in the Ugandan population.

CTL laboratory: The CTL has continued to progress, working under strict Good Laboratory Practice (GLP), and maintaining a high level of organization. The laboratory has continued to support various immunology research activities. The highlights of the year have been the successful completion of 30 HIV positive patients in the JTV Lfnp24 therapeutic vaccine phase and re-enrollment of 26 of these patients into the phase 1B protocol that required boosting and drug interruption.

Current studies in the laboratory include, JTVa Phase 1B, Safety and Immunogenicity of LFN-P24C in HIV infected Adult Ugandan Volunteers who undergo monitored treatment interruption; HPTN 027a PHASE I study to evaluate the safety

and immunogenicity of ALVAC-HIV vCP1521 in infants born to HIV infected women in Uganda; and the JIP study: HIV immuno- pathogenesis in a Ugandan adult population.

Some of the on-going research at the Centre PASER studies

The PASER-M protocol is a prospective, multi-centre, observational cohort study, which is currently operational in 13 clinical sites within six countries in sub-Saharan Africa. In addition to the routine HIV care provided at the clinic, periodic genotypic HIVDR testing is performed (at baseline, at annual follow-up visits, when switching HAART regimen, and at the end of program). Patient follow-up duration is between 24 and 48 months. The JCRC laboratory is the reference laboratory for HIVDR monitoring for East Africa. In Uganda the program runs in three JCRC sites, Kampala, Fort Portal RCE and Mbale RCE. The objectives of the program include 1) Assessing HIVDR prevalence amongst patients initiating first-line ART or switching to second-line after failing therapy 2) Assessing the effectiveness of first-line and second-line regimens, 3) Assessing individual and program determinants of drug resistance. At the JCRC sites we continued to follow up a total of 640 participants enrolled on first line therapy. Preliminary results show that of the 252 Ugandan participants with VLDR results by the end of the year, the prevalence of HIVDR was on average 10.7%. Overall, the prevalence of HIVDR within the cohort is higher in sites that have had prolonged exposure to ART

DART Trial

The Development of ART in Africa (DART) trial came to a conclusion and results of the study findings were published in the December 9th issue of the Lancet journal. The trial investigated whether it is safe and cost effective to deliver ART without the use of routine laboratory blood tests. This trial was coordinated and managed by the JCRC together with our partners in Zimbabwe, and the MRC in the UK. The results of the trial show that doing laboratory tests routinely for ART monitoring (3 monthly) makes no difference to

patients especially in the first 2 years of initiating ART. The trial also found that routine laboratory monitoring for ART as it is done in both Zimbabwe and in Uganda (3 monthly) is also very costly in addition to adding no value in the first two years. Conclusions from these findings are that ART can be delivered safely without routine laboratory monitoring for toxicity effects. However, CD4 count monitoring still plays a significant role after the second year to guide the switch to second line treatment.

RAND STUDY: The JCRC and the RAND Corporation are jointly conducting a study entitled-EVALUATION OF IMPACT OF HIV TREATMENT ON HEALTH AND QUALITY OF LIFE IN UGANDA. This study combines qualitative formative research with prospective longitudinal cohort assessments to examine impact of ART on multiple dimensions of health including economic (work status; utilization of assets), social (household remaining intact, children attending school), mental (depression), and sexual (risk behavior, disclosure of HIV status). The project draws from the Social Cognitive Theory, to examine patient characteristics, including physical and mental health, and characteristics of the household and clinic to develop a multi-level model that explains the pathways that link ART to these specific health domains and how these outcomes may be related to each other. The study has so far recruited a total of 602 clients on both the ART and non ART arms respectively. Of the 602 study participants recruited, 24 have passed away and 22 lost to follow up leaving 556 active participants to date. Preliminary findings indicate that, 71% of all participants perceive their general health as being fair, 77% of participants reported that their health affects their ability to work, while 23% lost their job because they tested positive. Over all this early analysis indicates that 18% of all participants have one or more early signs of depression, while 57% met the study criteria for food insecurity. Analysis for this study is still ongoing and findings will be published in a peer review journal to shade more light on the QOL for people on ART in Africa.

ATRIPLA FOOD study

This study will investigate the effect of a meal on the pharmacokinetics of the component drugs of Atripla. Fifteen HIV-infected Ugandan adults will participate in this open laboratoryel, multiple doses, two-phase intensive PK study. The study duration is 21 days and enrolment began in December 2009. This is a study conducted with the IDI and the JCRC's role is to recruit patients, take off and process blood samples for pharmacokinetic studies.

Adult AIDS clinical trial group (ACTG) protocols

1) A5221

- This study is investigating the optimal time for the initiation of ART among previously ART-Naive patients that present with active tuberculosis.

2) A5207

- This study is investigating various approaches to PMTCT, particularly the benefit of introducing extended use of NRTIs and or a Boosted PI, in the prevention of ART resistance that has previously been observed in PMTCT interventions that rely on Single dose Nevirapine.

3) A5208

- This is also known as the MOMs Study. This study is investigating the optimal first line ART regimen for women that were previously exposed to Single dose nevirapine during labour.

4) A5234

- This is an intervention study to evaluate the added benefit of trained treatment support partners to supervise ART at home, for patients initiating second line ART after failure of the first line. It is conducted in limited ACTG sites.

5) Anti retroviral therapy for Watoto in Africa (ARROW) Study:

This is a randomised multi center trial testing two strategic approaches for management of ART in 1200 symptomatic HIV infected infants and children aged 3 months and 17 years in Uganda and Zimbabwe. The first strategy compares clinically driven monitoring (CDM) with laboratory plus clinical monitoring (LCM). The second approach compares a continuous first line ART 3 drug 2 class regimen comprising two NRTIs plus one NNRTI with induction with 4 drugs (2 classes) followed by maintenance with 2 drugs. Eligible patients are HIV infected children whose adult carers are able to have appropriate access to ART. The enrolment phase ended and now patients are being followed up. It is jointly being conducted by the JCRC, MRC, University of Zimbabwe and the Paediatric Infectious Disease Clinic of Makerere University.

6) MERCK study

This is an Early Access study of MK-0518 (raltegravir) in Combination with an Optimized Background Antiretroviral Therapy (OBT) in Highly Treatment Experienced HIV-1 Infected Patients With Limited to No Treatment Options. Clinically stable HIV 1 positive male and female patients of 16 years and above, with limited or no treatment options due to resistance or significant intolerance to ARV regimens are recruited for this study. At the start of the study, the investigator will select an OBT for each participant based on the patient's prior treatment history and genotypic and phenotypic antiretroviral resistance testing and follow the patients according to the standard of care. The primary end points are safety and tolerability. Analysis of safety will be based on the "All patients as treated (APaT) approach". The study will continue until Raltegravir is commercially available in Uganda.

7) JCRC PEPFAR (JPF) study

This program assesses the impact of routine laboratory monitoring through CD4 T cell enumeration, plasma HIV RNA levels, and antiretroviral resistance testing among patients

receiving ART at the JCRC Kampala site. The study seeks to test the hypothesis that the use of routine testing, in addition to standard of care clinical and CD4 monitoring will lead to improved virologic, immunologic and clinical outcomes in this setting, and hasten the identification of patients at risk for disease progression while receiving ART.

8) Damaged Niche Hypothesis study

This is an observation prospective study seeking to compare the amount of collagen and number of CD4 T cells in the T-cell Zone (TZ) of secondary lymph nodes and GALT in HIV+ and HIV- individuals in Kampala; and to compare measures of lymphatic tissue architecture from tissues obtained in Kampala to age matched controls in Minnesota. This is a proof of concept study that will recruit and follow 20 HIV positive initiating ART and 10 HIV negative patients for 12 months. The study seeks to assess the immunologic integrity and function before and after initiation of ARVs (for the HIV + participants).

9) Center for Social Science Research on AIDS (CeSSRA)

A Longitudinal study of the social context of HIV treatment seeking in urban and rural Uganda during the era of increased availability of ARVs. The study essentially targeted a total of 800 enrolled HIV-infected persons for interviews into the social context of HIV/AIDS. The study has two phases, a baseline phase and a follow up phase. The baseline was completed in 2009 while the follow up of participants to measure adherence and for an ethnographic study of treatment experiences is ongoing. The study seeks to meet three objectives namely, to examine treatment seeking practices and barriers in the context of lifelong HIV/AIDS treatment and care, to identify factors that impact long-term adherence to care and treatment among those on antiretroviral therapy, and to describe and compare the experience of patients on antiretroviral therapy.

10) JCRC Therapeutic Vaccine (JTV) study

This is a phase 1B therapeutic vaccine clinical trial whose purpose is to see if the HIV vaccine is safe

for HIV-infected adults who are receiving ARV treatment. The vaccine in this study is called LFN-P24C. The study protocol requires evidence of viral suppression by effective ART. This approach will allow the optimal generation of functionally intact CTL in the absence of concomitant viral evolution and T cell destruction. About 30 volunteers, aged 18-60, currently receiving stably suppressive ARV treatment with CD4 > 400 and HIV RNA < 400 copies/mL will be included in the study. Phase I is 12 months. Secondary immunologic endpoints will be collected prior to and following the second and third vaccination and at six month and one year.

New and upcoming research:

Europe Africa Research Network to Evaluate Second line Therapy (EARNEST) study

This is a three arm parallel group, open-laboratory, multi-centre, randomised controlled trial the objective of which is to ascertain what, if anything, needs to be combined with a bPI backbone in second-line therapy in order to maximise the chance of a good clinical outcome following WHO-defined failure on a first-line NRTI and NNRTI-containing regimen with probable extensive NRTI and NNRTI resistance mutations. A total of 1200 patients who have taken a first-line NNRTI-based regimen continuously for a total period of at least 12 months, and developed treatment failure defined by modified WHO 2006. Patients will be randomised in a ratio of 1:1:1 to one of the following three treatment arms:

1. Arm A: bPI + 2 NRTIs
2. Arm B: bPI + raltegravir 400 mg twice daily, and
3. Arm C: bPI alone (after an initial 12-week induction phase with raltegravir).

The trial will have a 12 months recruitment period and each patient will be followed for 144 weeks. The analyses will compare Arm A with Arm B and with Arm C by intention to treat (ITT). The primary outcome measure will be the attainment of good HIV disease control.

MARCH (Monitoring Antiretroviral Resistance in Children)-in Uganda

This is a study that will be carried out as an EDCTP senior fellowship award to Dr Cissy Kityo. Similar to the PASER study in adults, the study will aim to determine what proportion of children on antiretroviral therapy at three JCRC sites (Kampala, Mbale and Fort-Portal) achieve HIV Drug resistance (HIVDR) prevention as measured by viral load suppression and what the HIVDR mutations and mutational patterns are in patients not achieving HIVDR prevention. Each of the study sites is expected to recruit 150 participants.

Children in Africa with HIV Pharmacokinetics Adherence / Acceptability of Simple Anti retroviral Regimens (CHAPAS 3)

The CHAPAS 3 clinical trial is a multi-centre three arm phase I/II open randomised trial of 420 HIV-infected children, aged one month to 13 years enrolled over 18 months and followed for 96 weeks in three clinical centres, one in Zambia (University Teaching Hospital (UTH), Lusaka) and two in Uganda (Joint Clinical Research Centre (JCRC), Kampala and the Paediatric Infectious Diseases Centre (PIDC), Mulago Hospital, Kampala). The trial will test whether new paediatric fixed dose combinations of baby and junior scored dispersible tablets which contain abacavir (ABC) or zidovudine (ZDV) rather than stavudine (d4T) provide superior toxicity and/or adherence/acceptability profiles whilst maintaining adequate pharmacokinetics and similar cost-effectiveness and viral load suppression. The target is 140 children to be enrolled at JCRC, Kampala and 30 children at JCRC, Gulu as a satellite site.

The CHAPAS 2 trial

This will be an open, randomised controlled phase I crossover trial randomising 24 children (aged 4-12 years able to take paediatric LPV/r tablets and either currently receiving LPV/r or about to start LPV/r containing ART) in a 1:1 ratio to LPV/r either in sprinkle or tablet formulation. Children will be followed at 2 sites: JCRC, Kampala, Uganda and PIDC/Mulago, Kampala.

The JCRC Children's Study (JCS)

This observational study is currently going on at 9 JCRC sites namely: Kampala, Fort-portal, Mbarara, Kabale, Kakira, Mbale, Gulu, Lira and Kasana-luero.

977 of the expected 2000 patients have been recruited. There are 267 participants at JCRC Kampala. The main emphasis in 2009 has been on data cleaning and updates.

Within JCS, is an ongoing adherence sub-study using electronic methods (the Adherence ecaps) sub-study. This is aimed at monitoring adherence in adolescents on antiretroviral therapy and has 15 participants. These are seen in the clinic on a monthly basis.

SALIVA study

A cross-sectional study nested within the PASER-M observational cohort whose objective is to validate a simple, affordable method for Therapeutic Drug Monitoring (TDM) of NVP in saliva of HIV-infected Ugandans.

Others include,

The PAINT study (The TMC278-TiDP38-C213 trial)

This is a study that will involve ART naïve adolescents and will investigate use of a new NNRTI manufactured by Tibotec referred to as TMC278. It will include pharmacokinetic studies, and intense clinical and laboratory monitoring, TMC 278 being a new investigational product. At JCRC, we hope to enroll 25 adolescents (aged 12-18 years into this study.

BREATHER (PENTA 16)- The overall aim of the PENTA 16 trial is to evaluate the role of Short-Cycle Therapy (SCT) in the management of HIV-infected young people who have responded well to antiretroviral therapy (ART) and to determine whether young people with chronic HIV infection undergoing Short-Cycle Therapy of five days on ART and two days off maintain the same level of viral load suppression as those on continuous therapy, over 48 weeks. The study aims to recruit 160 participants from Europe, Asia, South America and Africa. 50 participants are expected to be recruited from JCRC, Kampala into this study.

ART A- Field Evaluation of Affordable Resistance Testing in African Laboratory Settings

JOINT CLINICAL RESEARCH CENTRE INSTITUTIONAL REVIEW BOARD (IRB):

The Joint Clinical Research Centre - Institutional Review Board (JCRC – IRB) was registered on August 27, 2002, both in Uganda and the USA, according to the Uganda National guidelines for research involving humans as research participants. It is established under the FWA for Uganda National Council of Science and Technology (UNCST) with its own FWA number – FWA00001293 and registration number IRB00002647. The JCRC is one of the top active biomedical research institutions in Uganda. The current membership of the board include Dr. Kagimba Jesse (Chairman), Dr. Peter Mugenyi, Dr. Cissy Kityo, prof. Ojok Lonzy, Prof. Elly Katabira, Dr. Samson Kibende, Mr. Nelson Kakande, Dr. Gitta Jessica, Prof. Ogwal-Okeng Jasper, Mr. Mpeirwe Arthur, Ms Angelina Wapakaburo, Dr. Grace Ndezi and Prof. Acon Johnson.

Important Publications and Presentations during the year

Papers

1. DART Trial Team. Routine versus clinically driven laboratory monitoring of HIV antiretroviral therapy in Africa (DART): a randomised non-inferiority trial. *The Lancet*, Early Online Publication, 9 December 2009
2. Adele L. McCormick, Ruth L. Goodall, Aengus Joyce, Nicaise Ndembi, Mike Chirara, **Pauline Katundu**, Sarah Walker, David Yirell, Charlie Gilks, and Deenan Pillay, on behalf of the DART Virology Group and Trial Team. Lack of minority K65R resistant viral populations detected after repeated treatment interruptions of Tenofovir/Zidovudine and Lamivudine in a resource-limited setting. *JAIDS* in press
3. Ndembi N, Goodall RL, Dunn DT, McCormick A, Burke A, Lyagoba F, Munderi P, Katundu P, Kityo C, Robertson V, Yirell DL, Walker AS, Gibb DM, Gilks CF, Kaleebu P, Pillay D. Viral Rebound

and Emergence of Drug Resistance in the Absence of Viral Load Testing: A Randomized Comparison between Zidovudine-Lamivudine plus Nevirapine and Zidovudine-Lamivudine plus Abacavir. *Journal of Infectious Diseases* 2010 Jan 1; **201**(1):106-13 and 2009 Nov 25. [Epub ahead of print]

4. Nyanzi Wakholi B, Medina Lara A, Munderi P, Gilks C, Grosskurth H on behalf of the DART trial team. The role of HIV testing, counseling, and treatment in coping with HIV/AIDS in Uganda: A qualitative analysis. *AIDS Care Journal (In Press)*
5. Canaday DH, Wu M, Lu S, Aung H, Peters P, Baseke J, Mackay W, Mayanja-Kizza H, Toossi Z, 2009. Induction of HIV type 1 expression correlates with T cell responsiveness to mycobacteria in patients coinfecting with HIV type 1 and Mycobacterium tuberculosis. *AIDS Res Hum Retroviruses* 25(2):213-6
- 6.

Conference presentations

1. **[Oral – Special Session]** Mugenyi P, Walker S, Hakim J, Munderi P, Gibb DM, Kityo C, Reid A, Grosskurth H, Darbyshire J, Ssali F, Bray D, Katabira E, Babiker A, Gilks C on behalf of The DART trial team. Impact of routine laboratory monitoring over 5 years after antiretroviral therapy (ART) initiation on clinical disease progression of HIV-infected African adults: the DART Trial final results. 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 19-22 July 2009, Cape Town, South Africa
2. **[Oral – Special Session]** Medina Lara A, Kigozi J, Amurwon J, Muchabaiwa L, Nyanzi Wakholi B, Walker S, Kasirye R, Ssali F, Grosskurth H, Babiker A, Kityo C, Munderi P, Hakim J, Mugenyi P, Gibb DM, Reid A, Darbyshire J, Gilks CF and the DART trial team. Cost effectiveness analysis of routine laboratory or clinically driven strategies for monitoring antiretroviral therapy in Uganda and Zimbabwe (DART Trial). 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 19-22 July 2009, Cape Town, South Africa
3. [Poster] Munderi P, Wilkes H, Tumukunde D,

Chidziva E, Nalumenya R, Gilks CF, Zalwango E, Spyer M, Kyomugisha H, Lutwama F, Kikaire B, Kityo C, Reid A, Gibb DM and the DART trial team. Pregnancy rates and outcomes among women on triple-drug antiretroviral therapy (ART) in the DART trial. 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 19-22 July 2009, Cape Town, South Africa: Abstract WEPEB261

4. [Poster] Reid A, Stohr W, Walker AS, Hakim J, Ssali F, Munderi P, Lutwama F, Kityo C, Grosskurth H, Gilks CF, Gibb DM and the DART trial team. Glomerular dysfunction and associated risk factors through four years following initiation of ART in adults with HIV infection in Africa in the DART trial. 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 19-22 July 2009, Cape Town, South Africa: Abstract TUPEB184
5. [Poster] Kityo C, Ford D, Walker AS, Hakim J, Munderi P, Lutwama F, Ssali F, Reid A, Grosskurth H, Gibb DM, Gilks CF, Babiker AG and the DART trial team. Effect of WHO stage 3/4 events after ART initiation on survival of HIV-infected African adults in the DART trial. 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 19-22 July 2009, Cape Town, South Africa: Abstract MOPEB003
6. [Poster] Borok M, Palfreeman A, Munderi P, Ssali F, Reid A, Lutwama F, Wilkes H, Winogron D, Tembo R, Musana H, Musoro G, Taylor K, Burke A, Gibb DM, Peto TEA and the DART trial team. Difficulties in assigning AIDS endpoints in clinical trials in resource limited settings: Lessons from DART. 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 19-22 July 2009, Cape Town, South Africa: Abstract TUPEB098
7. [Poster] Gilks CF, Ford D, Walker AS, Munderi P, Hakim J, Kityo C, Lutwama F, Grosskurth H, Reid A, Ssali F, Mugenyi P, Gibb DM, Babiker AG and the DART trial team. Impact of daily cotrimoxazole prophylaxis in severely immunosuppressed adults in Africa started on combination ART in the DART trial. 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 19-22 July 2009, Cape Town,

South Africa: Abstract MOPEB020

8. [Poster] Walker AS, Munderi P, Kityo C, Babiker AG, Ssali F, Reid A, Grosskurth H, Mugenyi P, Gibb DM, Gilks CF and the DART trial team. Long-term randomised comparison of clinical outcomes following ART initiation with triple-nucleoside (Combivir/Abacavir) or NNRTI-based (Combivir/Nevirapine) therapy in Africa: the NORA substudy of the DART trial. 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 19-22 July 2009, Cape Town, South Africa: Abstract MOPEB057
9. [Poster] Ndembi N, Kaleebu P, Pillay D, Bachelier L, Pattery T, Goodall R, Dunn D, Katundu P, Chiara M, Gilks C, Yirell D, McCormick A, Munderi P, Kityo C on behalf of the DART Virology Group. Phenotypic data to guide selection of reverse transcriptase inhibitors in second-line therapy following extended virological failure in Uganda. XVIII International HIV Drug Resistance Workshop, 9-13 June 2009, Fort Myers, Florida: Abstract 134
10. [Poster] McCormick A, Burke A, Katundu P, Lyagoba F, Parry C, Yirell D, Munderi P, Robertson V, Kaleebu Pontiano, Pillay D on behalf of the DART Virology Group. Prevalence and *in vitro* characteristics of Reverse Transcriptase (RT) N348I Mutation in Non-B subtypes, in the Absence of Viral Load Monitoring, in the DART Study (NORA substudy). 16th Conference on Retroviruses and Opportunistic Infections, 8-11 February 2009, Palais des Congr s de Montr al, Montr al Canada: Abstract 643
11. [Poster] Joyce A, Ndembi N, Goodall R, Chiara M, Gibb D, Gilks C, Hakim J, Kityo C, McCormick A, Dunn D on behalf of the DART Virology Group. Lack of Minority K65R Resistant Viral Populations Detected after Repeated Interruptions of Tenofovir DF/ Zidovudine/ Lamivudine. 16th Conference on Retroviruses and Opportunistic Infections, 8-11 February 2009, Palais des Congr s de Montr al, Montr al Canada: Abstract 681
12. [Oral – late breaker] Kityo C, Walker AS, Lutwama F, Ssali F, Nalumenya R, Tumukunde

D, Kawiya J, Munderi P, Reid A, Gilks CF, Gibb DM, Khoo S on behalf of the DART Trial Team. Impact of efavirenz and nevirapine on pharmacokinetics of lopinavir/ritonavir as capsules and tablets in African patients. Ninth International Congress on Drug Therapy in HIV Infection 9-13 November 2008 Glasgow, UK. Abstract O125.

4.0 TRAINING PROGRAMS

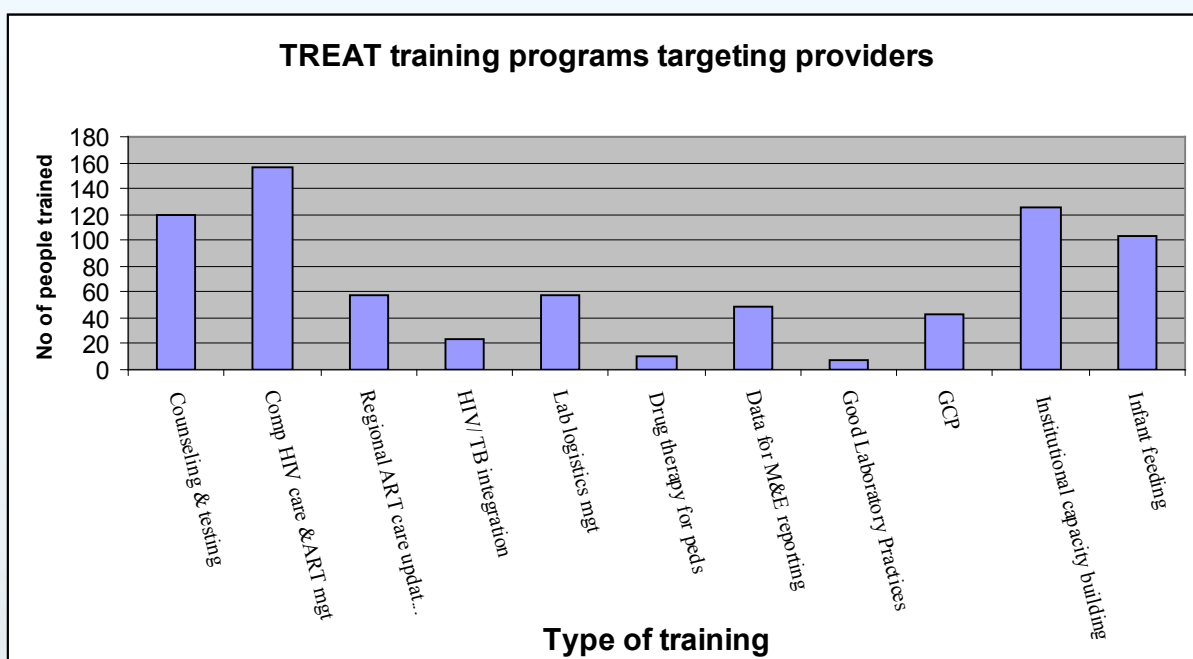
The goal of the JCRC training programs is to strengthen the continent's capacity through training to provide quality HIV/AIDS care and treatment and conduct quality research. The JCRC training programs are multidisciplinary in nature targeting health care professionals, researchers, students and community based support networks. This report will focus on five programs i.e. the TREAT training program, International Clinical Operational and Health Services Research (COHRE) program, JCRC professional development programs, Forgyat Fellowship Program, and the WHO Knowledge Hub.

THE TREAT TRAINING PROGRAM

This program offers training for three major categories of personnel working in TREAT supported sites. These include; staff providing care, those supporting implementation of HIV care programs, as well as service recipients. This program seeks to provide regular and continuous update of health professionals in all aspects of HIV care and management given this is a rapidly evolving field. Personnel targeted include, clinicians and nursing staff, laboratory technicians and technologists, counselors, adherence officers and data managers. Service recipients targeted include clients in care (children and adults), caretakers, community leaders and members who can help address aspects of HIV prevention, care, ART treatment management and adherence support.

In 2009, the program provided capacity building to over 600 health workers across the 52 sites where JCRC was operational. JCRC has put in place mechanisms and programs that offer continuous training of all health care providers offering HIV care, and has continued to build capacity for health care providers in form of on the job training, regular continuing medical education (CME) sessions in specific sites and regions, placements in clinics and laboratories, workshops and support to attend short courses offered by partner training institutions. In the year 2009, a total of 1,932 unique individuals attended various types of training as presented in graph below.

Table showing the number of health care providers trained in 2009



Key accomplishments for 2009 include:

In 2009, most of this training was conducted in the RCEs. 20 new health workers in Ministry of Health ART supported ART clinics were trained in **Comprehensive HIV care** and ART and 30 community workers from Mubende district were trained from Mubende RCE in basic HIV care support for children. The didactic programs included clinical placements within the RCEs. In Kampala, HIV care update training was held to benefit new staff and update others on the new issues and trends in HIV care and ART management.

Continuous professional development programs to include **CMEs** and regional update trainings were held. CME sessions and Journal club meetings continue to provide health care professionals with opportunities of updating themselves with the most recent clinical and research based data in the area of HIV care and treatment. Staff in all RCEs and Kampala has continued to have CME sessions every week. On average, 85 staff have been trained through weekly CMEs and Journal club meetings.

Regional update programs were held at regional training centers located in the RCEs. These targeted staff in lower sites in each region and were held with support from University of Wisconsin. These trainings were aimed at updating clinicians on HIV treatment practices so as to provide quality care to all under the TREAT program. 29 Clinicians attended the Regional HIV update meetings in Fort Portal RCE which targeted clinicians from South, South Western region while 28 clinicians attended the HIV update meeting in Mbale RCE which targeted clinicians from the East and Northern region.



Laboratory training programs JCRC which has the largest laboratory network supporting ART management in Uganda has continued to provide tailored training programs to respond to identified needs nationally. 23 staff from Kampala were trained on Early Infant Diagnosis. This training was beneficial in equipping the health care workers with knowledge and skills in early infant HIV diagnosis and care given that JCRC is supporting MoH in the National roll out of this program. 30 Laboratory technologists from Kampala were trained in sample quality assurance. This training was beneficial in equipping staff with skills in handling samples and ensuring that quality is prioritized at all times. 20 Laboratory technologists and 30 clinicians from all RCEs and Kampala were trained in Good Clinical Laboratory Practice and Good Clinical Practice.

Training for strategic information to support the HIV program; Data management:

Data collection and management is very crucial for efficient ART delivery. With the introduction of new data collection and electronic patient tracking systems like Clinic Master at the RCEs and TREAT data base at the satellite sites, staff from 25 ART supported TREAT sites were trained and reviewed use of clinical tools and data collection for M&E. This involved training on use of the two data bases that are facilitating patient data capture in the clinics.

Logistics management: JCRC full aware that logistics are a critical component in running National ART and Laboratory support programs,

organized appropriate training to equip staff with skill and required software to support this program function. 21 Laboratory technologists, Laboratory logistics, stores and staff from Finance from all RCEs, 2 satellite clinics and Kampala attended a Laboratory Logistics training of trainers' workshop which was designed to equip trainers in all RCEs with skills to roll out the new laboratory logistics system. This system is being used improve laboratory supply provision and services. This workshop was followed by site specific training as a measure of ensuring that the system is rolled out efficiently. 36 laboratory technologists and administrators were trained from 5 RCEs

Systems support - 27 staff from various departments were trained in Advanced Navision support, a system that supports improved systems that facilitate better care. **Safety-** 125 staff from all the departments at JCRC Kampala were trained in clinic and laboratory safety with particular emphasis on fire. This is one of the cross cutting areas that was identified as crucial and important for staff.

Community based training: 67 Community Liaison volunteers (CLVs) from Mpigi health centre, Mubende and Gulu RCEs were trained. The training equipped the CLVs with knowledge on various aspects like Volunteering, Community mobilization, HIV/AIDS, Stigma and Discrimination, Healthy Living, ART, ART Adherence, Pediatric AIDS, PMTCT, Opportunistic Infections, Palliative Care, Record keeping and support services.

INTERNATIONAL CLINICAL OPERATIONAL AND HEALTH SERVICES RESEARCH (COHRE):

This is a training program based at the JCRC but collaboratoryorated between Uganda's institutions (Makerere University College of health sciences, MUST, NTLP) and the Case Western Reserve University (CWRU) of USA. The goal of COHRE training program is to conduct training, research and mentorship as well as operationalize research findings in order to strengthen the national capacity to address the public health and scientific challenges of the evolving HIV and TB

epidemic in Uganda. The program supports short and long term training arrangements relevant to the priority training needs as identified by the COHRE faculty.

This year the program enrolled 9 students in its high degree program at the two collaborating universities in Clinical and public health related fields. The non-degree training carried out in 2009 included the training of Gulu Health Workers **in implementing HIV/TB Collaborative Activities**. This was a 5 day training that targeted 32 trainees and equipped them with skills to enable them implement TB/HIV Collaborative activities in the most appropriate way

The program was also able to equip 56 workers in health settings, researchers and other providers in Uganda, with skills and processes involved in **Dissemination, Implementation and Operations Research** in order to optimize the effectiveness and efficiency of interventions.

The year saw the renewal of the COHRE program for another five years through a competitive process to build on the successes of the first phase of the program. This extension will enable the program to continue extending support to very promising Ugandan young scientists pursue high degrees in medicine and public health. Next year will also see us strengthening and streamlining our mentorship and coaching program, emphasizing bioethical and human right related training, and addressing issues of quality improvement and assessments through our short and targeted non degree training.

JCRC PROFESSIONAL DEVELOPMENT PROGRAMS

JCRC as an institution organizes various programs and supports staff to attend course as ways of providing opportunities to build professional capacity of staff. JCRC further has a well established an internship/ placement program that targets national and International students/ trainees.

The placement program: This program was established to offer expository learning to talented upcoming health professionals in field of advanced clinical care and general health care using close mentoring as a method of capacity building. The training takes place in Kampala or any of the established RCEs. The program targets national and international students from a number of universities some of which include, Makerere, Kyambogo, Mukono and Mbarara University of Science and Technology, Uganda. Students from International Universities that have been trained in 2009 include, University of Wisconsin – Madison, Acardia University and New Castle University. In 2009, 16 students were trained in the laboratory service provision for HIV/AIDS care, 13 in counseling and adherence support for patients under HIV care, 4 clinical management of patients on ART and 1 in M&E for ART programming. The program has established syllabus for each component, students are examined through pre and post placement methods and close supervision and support from their supervisors helps impact skills. Several health care providers from partner institutions have visited JCRC for practicum placement training on the wards, clinics and in the laboratories.

Training of Trainers: Staff got capacity building to support the training function at JCRC in the following areas: **GCP:** Two members of staff were trained as trainers for GCP by INTERACT. The training needs of the JCRC staff and other implementing partners will now be properly addressed. **TB:** 6 staff received training on Management of TB/HIV co infected patients with support from TB CAP and Uganda Nurses association and another staff member received training on control and management of MDR TB. Trainers based in Mbale RCE were able to roll out this training and they targeted 23 health workers from the districts of Mbale, Soroti and Tororo. The TB/HIV collaborative has been made possible under the TBCAP program.

Palliative care management: A team of 3 staff from each of the 4 RCEs have been trained this year by Hospice Uganda as a trainers for palliative care integration. RCEs have formed PC teams

and trainers have conducted CMEs to facilitate integration palliative care into the continuum of care for persons affected by HIV/AIDS and their families.

Counseling: Staffs have been trained as a trainers for couple counseling, counselling children and adolescents for HIV testing and positive prevention all supported by SCOT. They will support their colleagues in the counseling department strengthen related aspects and later roll out best practices to RCEs.

FOGARTY INTERNATIONAL CENTRE (FIC) INTERNATIONAL CLINICAL RESEARCH SCHOLARS (ICRS) AND FELLOWS (ICRF) PROGRAM:

Working in collaboration with the Case Western Reserve University (CWRU), JCRC submitted an application and successfully became one of the international sites that was competitively selected by the Fogarty to act as a training site for international Clinical Research Scholars (ICRS) and fellows (ICRF). This is a research capacity building program. This fellowship addresses global health challenges through innovative and collaborative research and training programs, supports and advances the NIH mission through international partnerships. The Ugandan scholar was matched with a fellow from CWRU to undertake a one year (July 2009-June 2010) full time clinical research program based at JCRC and partner institutions. The opportunities provide new insights to upcoming clinical leaders. The fellows are expected to develop and implement their own projects, in addition to attending tailored short courses organized by JCRC. Fellows on this program benefit from highly qualified and experienced mentors who help scholars advance their educational and professional growth. Samar Mehta, PhD, MD candidate from SUNY Downstate Medical Center; and Juliet Akao, MBChB, MMed from the Joint Clinical Research Center. They are currently working at the Joint Clinical Research Centre (JCRC) under the mentorship of Peter Mugenyi, MBChB, ScD, FRCP.

WHO Knowledge Hub Program:

The Knowledge Hub is WHO collaboration with the Regional Knowledge Hubs for Capacity Building on Scaling up ART which include JCRC, IDI, Mildmay, TASO, AIC and MoH Uganda. It is based at the JCRC and together with WHO AFRO, WCO, MoH and other HIV Implementing partners; the KH accomplished activities for 2009 are as listed below.

Support within Uganda: Supervised and participated in updating and adaptation of Uganda IMAI materials and M&E materials. As a result currently multiple aspects of care are compiled in one HIV ART card and the registers. TB, PMTCT, paediatrics and related information can be recorded on one card which has helped streamline data collection for M&E. Subsequently, KH has worked with MoH and HCI to train 74 HWs from Eastern region in the use of the updated M&E tools.

The program also reviewed and facilitated 48 HWs in the pretest of the updated IMAI TB Co-management materials, and further pre-tested the materials on IMAI Quick check respiratory distress management materials. An HIV Monitoring tools training was held for 40 Health Workers in Hoima region while 70 health workers in Karamoja region were trained in IMAI.



Support within the African Region: WHO AFRO, WCO and HQ focused on getting IMCI scaled up in AFRO region thus organized trainings targeting

several African countries. Uganda had 78 participants, 7 countries sent 24 HWs (TOTs) from Ethiopia, Eritrea, Namibia, Zambia, Zimbabwe, Kenya and Swaziland. Facilitation was done by WHO AFRO, HQ, WCO and Uganda IMAI team. An IMAI Resource Network Workshop & Introduction to New IMAI/IMCI and Related Community Tools was further organised in Harare for 9 countries to share experiences since scale up of ART activities. This generated supportive and guided discussions for countries.

The KH reviewed the updated HIV Community package materials in Harare.

The KH further facilitated in IMAI PMTCT training for 34 HWs from 8 countries Yemen, Tanzania, Nigeria, Yemen, Mozambique, Ethiopia, Malawi and Kenya. In Uganda a similar training was organized for 20 Tutors from 15 nurse and Clinical Officer schools in Uganda.

13 health workers from Yemen gained experience through KH support, visiting ART sites and communities including Masaka referral hospital, JCRC, IDI, TASO, Kitovu Mobile amongst others.

Other activities have included, field testing of the Operations manual, Mentoring of health workers and supporting implementing partners like IDI to develop an in service training curricular which adapted some of the IMAI materials and processes of training.

5.0 Extending services across Uganda

5.1 The TREAT Program

Coverage: The period under review marks part of the first year of the TREAT Program transition. The JCRC TREAT program consolidated services in the 46 ART sites and 25 outreaches. The cumulative number of people accessing ART was 99,233 by end of December 2009. This includes patients supported by MOH under Global Fund and PEPFAR. The current number of patients receiving ART was 51,930 and of these 15,719 were new patients. 1,852 new Orphans and Vulnerable Children (OVCs) were enrolled on ART. Target populations include OVCs, OVC care takers, pregnant women,

widows and the poor communities in hard to reach areas including IDP camps, West Nile, Karamoja and fishing communities in Kalangala district. As the TREAT Program is in a transition with limited capacity to enroll new patients, JCRC has worked closely with MOH facilities to strengthen MOH logistics system and capacity to enroll new patients.

Program activities

Health Infrastructural support: JCRC TREAT program has greatly contributed to infrastructure strengthening in health facilities in Uganda. Kapchorwa district hospital and Kalangala HCIV were renovated and extended. Kalangala ART clinic was officially launched. This has greatly improved the working environment and quality of care in health facilities. The seven Regional Centres of Excellence (RCEs) are strategically located across the country in Gulu, Mbale, Kakira, Fort Portal, Mbarara, Kabale and Mubende. RCEs have continued to act as regional hubs for laboratory support and clinical HIV/AIDS services for a number of ART sites in the country.

Laboratory Support to the National HIV Care programs: TREAT has continued to provide quality laboratory services to MOH and other HIV/AIDS programs in Uganda, through the 7 RCEs. State of the art laboratory services are available in JCRC Kampala and RCEs. They offer state of the art laboratory services including OI diagnosis, ELISA, CD4s, DNA and RNA PCR and toxicity monitoring.

For the period under review, 143,728 CD4 tests were done, 21,629 Viral load tests and 38,712 DNA PCR tests. JCRC has consolidated the provision of DNA PCR services to the MOH Early Infant Diagnosis (EID) Project through the RCEs in the country. Specimen referral system from lower health facilities to RCEs has been strengthened. RCEs capacity to support lower level sites in their regions has been strengthened to offer training, laboratory support, monitoring and quality assurance. Collaboration with EGPAF, UWESO and PMTCT sites encourage a family based approach to link all family members into care and treatment services.

Capacity Building: Health workers capacity to provide care and treatment has been enhanced through training. Training involves a purposive mix of scheduled workshops, CME seminars, placements in clinics and laboratories, and on-the job training. The program built skills of 1,716 unique individuals in various areas that support the ART program implementation. JCRC mobilized expertise from within and outside the country to include the University of Wisconsin, USA, and Case Western University. Training has been decentralized to the Regional Centres of Excellence (RCEs). ACE Project continued to support capacity building and organizational strengthening at JCRC, where management and leadership training was offered to JCRC management team, to enhance performance. Details of the TREAT training program are on page..

Strategic Information- M&E: TREAT has strengthened the M&E system with more training and support supervision to lower health facilities. With support from ACE Project Data collection from high case load clinics has been improved with the roll out of a database from RCEs to more clinics. This has resulted in; timely and efficient generation, storage, and use of strategic information across the ART sites. NAVISION software has been up graded and a number of critical departments have been computerized, to generate timely reports. Internet connection has been consolidated in over 22 ART sites including the hard to reach areas. MOH is able to get timely reports from the hard to reach sites.



One of the Data rooms at Mbale RCE

Transitioning of sites: Six formerly TREAT supported sites have been smoothly transitioned to new USAID district based HIV/TB programs and other Implementing partners. The sites include Kapchorwa and Iganga district hospitals, Kamuli mission hospital, Apac district hospital and Patong HCIII, Pader district (Plus Kayunga).

Laboratory and Drug Logistics Support: The robust drug logistics system has ensured uninterrupted supply of drugs and laboratory supplies to all the TREAT sites, thus increasing clients' satisfaction and trust and also meeting the program objectives. Quantimed software was introduced, which has improved forecasting, compared to the past when drug procurement was based on estimating needs based on experience. Quantimed software uses ARV regimen information directly from health facilities, hence providing more accurate forecasting and quantification. A new laboratory reagent logistics system has been developed to forecast and quantify laboratory reagents. Training was offered with support from SCMS

Information Education and Communication activities: JCRC TREAT program has enhanced ART knowledge levels through the TREAT For Life campaign, which combines social marketing, community mobilization, health promotion and ART treatment literacy. Patients have been empowered with ART related information. In partnership with Health Communication Partnership, JCRC implemented a campaign aimed at increasing awareness of HIV testing, care and treatment services for children. Distribution of IEC materials including posters, flipcharts, paediatric booklets, CDs and DVDs with the HIV testing for children campaign messages.

Strategic Partnerships: JCRC has strengthened linkages and partnerships with a number of organizations, including Clinton Foundation Initiative, Inter-religious Council of Uganda (IRCU), TASO, Uganda Prison Services, Pace, Compassion International, NUMAT, STAR-E and STAR-EC, Hima Cement Factory, MSF, PREFA, Hospice, Baylor College Uganda.

6.0 JCRC REGIONAL CENTRES OF EXCELLENCE

The seven JCRC Regional Centres of Excellence (RCEs) located strategically to serve the country in Fort-Portal (the far West), Kabale (South-western), Mbarara (West-central), Kampala (Central), Mubende, Gulu (North-central), Kakira (East-Central) and Mbale (Eastern) continued to serve as HIV/AIDS care and treatment points for the hospitals where they are located. The RCEs laboratory network ensured that the laboratory services were provided to clients and collaborators without much disruption.

Cross section of some RCEs



Mubende RCE



Mbarara RCE



The transition arrangements commenced with cessation of initiation of ART in March 2009 which meant that even for clients who were already enrolled in the TREAT program but were pre-ART, could not access ART when they became eligible. This was the major set-back in this reporting period.



Kabale RCE

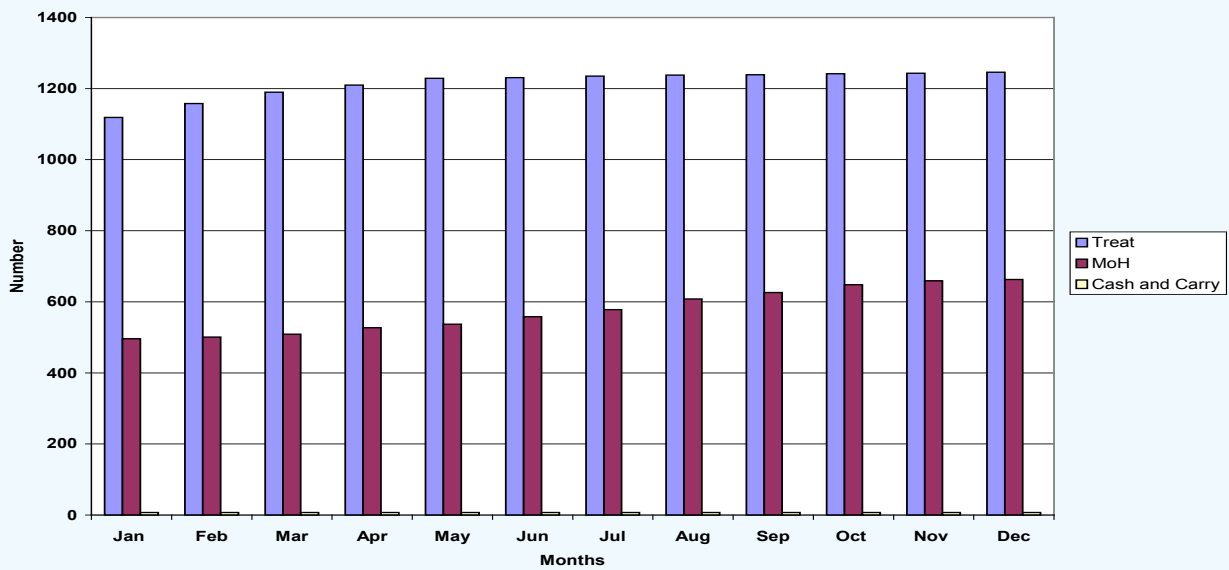


Kakira RCE

Gulu Regional Centre of Excellence

Gulu REC HIV clinic is jointly managed by JCRC core staff and Gulu RRH scoded staffs. The RCE team is committed to providing high quality comprehensive HIV and laboratory services to the disadvantage population of northern Uganda. The center acts as the reference laboratory for northern Uganda and it supervises several other ART sites in the region. In the last quarter of 2009 the center successfully handed over one of its satellite site at Patongo to NUMAT our partner in the region. The clinic that is collaboratively run with the Gulu RRH is currently looking after a total of 5153 active clients 59% of which are exclusively supported by the JCRC's TREAT program while the reminder get partial support (including laboratorys and buffer drugs) from the program.

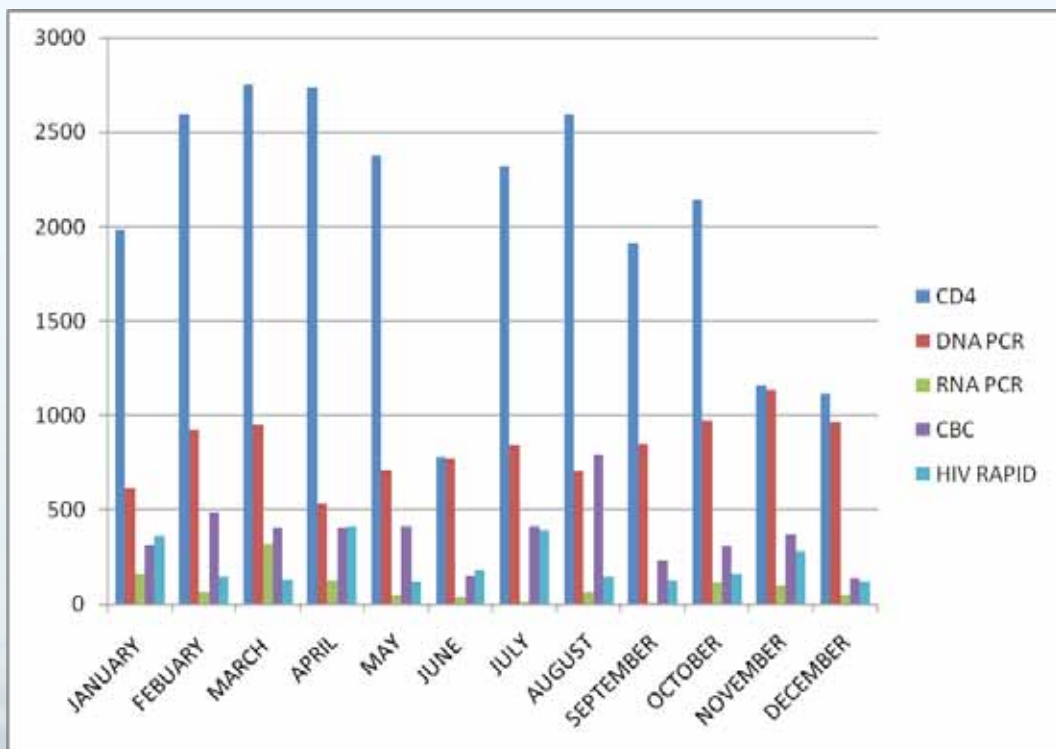
CUMULATIVE NUMBER OF PATIENTS ON ART BY PROGRAM –GULU RCE 2009



However, with peace prevailing again in northern Uganda, most clients are returning to their rural places. Some of the clients who have returned to their villages find it hard to return to the clinic, ending up discontinuing the service or transferring to nearby service provider without formal referrals from the clinic.

The RCE house a core laboratory that offers a number of compressive laboratory services ranging from CD4 analysis, DNA PCR, Chemistry viral load, and other basic laboratory test. This year the laboratory saw an increase in the workload of more than 50% compared to 2008 mainly because of increased confidence in our services by partners.

MAJOR TESTS RUN IN THE YEAR 2009



Kabale RCE



A cross section of Kabale RCE staff with the JCRC Chairman of the Board.

Kabale Regional Centre of excellence is located in Kabale Regional Referral Hospital in Kabale district, south western Uganda. Kabale R.C.E. has been operational since June 2002. The centre also serves as the ART department of Kabale Regional Referral Hospital and collaborates with the hospital chronic care clinic (Kabale Hospital mini TASO) to offer HIV/AIDS services at the hospital.

In the year 2009 Kabale RCE has witnessed improvement in the quality of care through the streamlining of systems and processes. This has been done using learning processes and guidance from the support supervision team from Kampala JCRC.

Stake holders in the region have played a great role in the treatment outcomes of our clients through supporting of service provision at both the HC IV levels where the clients come from, referrals and also at the RCE where some laboratory tests are paid for.

Our influence in the HIV/AIDS activities in the region has been strengthened through regional supervision done at both the TREAT and none TREAT sites with the mandate from the District Health teams and HCI. In these supervisions district teams have been mentored to do supervision hence sustainability of the process

will be guaranteed.

The tireless effort of a dedicated and hard working RCE team has helped improve the quality of services offered at the centre despite the challenges that have been faced through out the year. We have observed an increase in the number of clients enrolled into care and a big proportion of these being retained in care. Also the centre income has gradually improved despite the introduction of costing for non TREAT clients. The laboratory is also able to support stake holders from within the Kabale Region.

The World AIDS Day celebrations for Kabale District were held at Kamwezi - Kabale District on 1st December 2009. The Chief Guest was the Kabale Resident District Commissioner, Mr. Cox Nyakairu. Kabale RCE participated in the planning and implementation for the activities to make the day a success. Various stakeholders in HIV/AIDS care had stalls showing activities /services they provide to the community. The RCE had a stall displaying all our activities using different media that included progressive charts. The RCE's drama group also participated with their educative songs, sensitising the communities about the theme of the World AIDS Day.

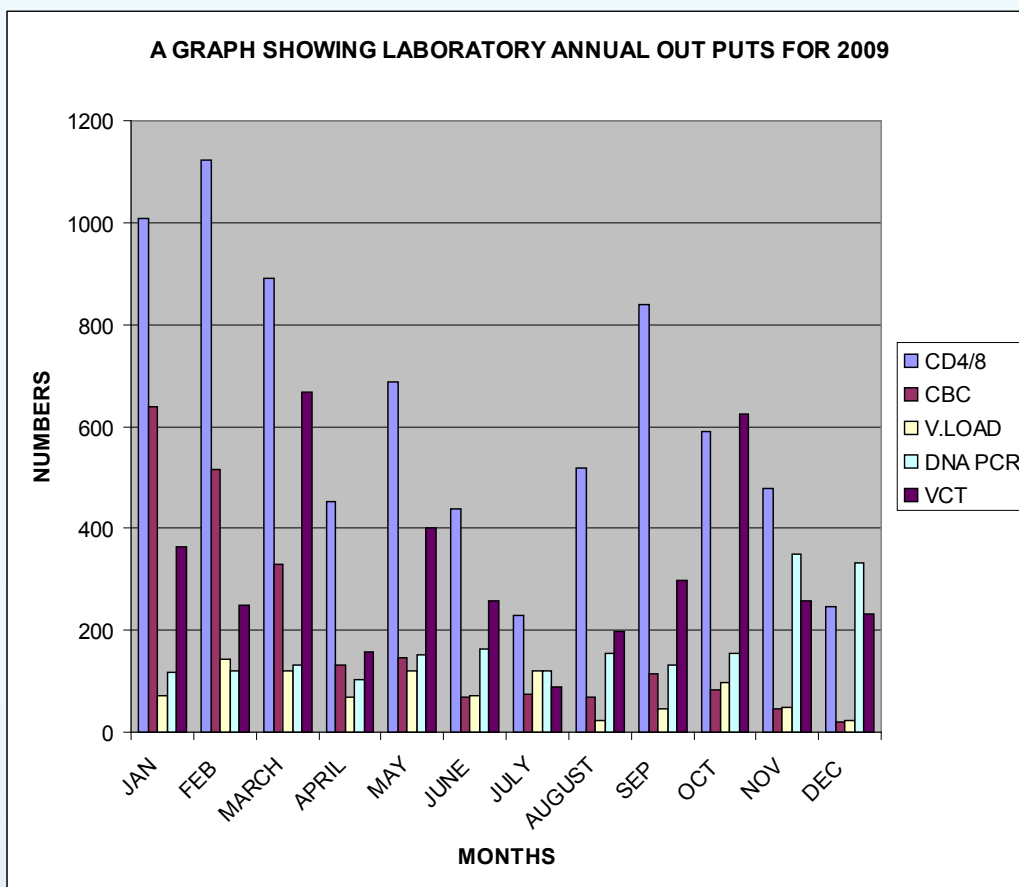
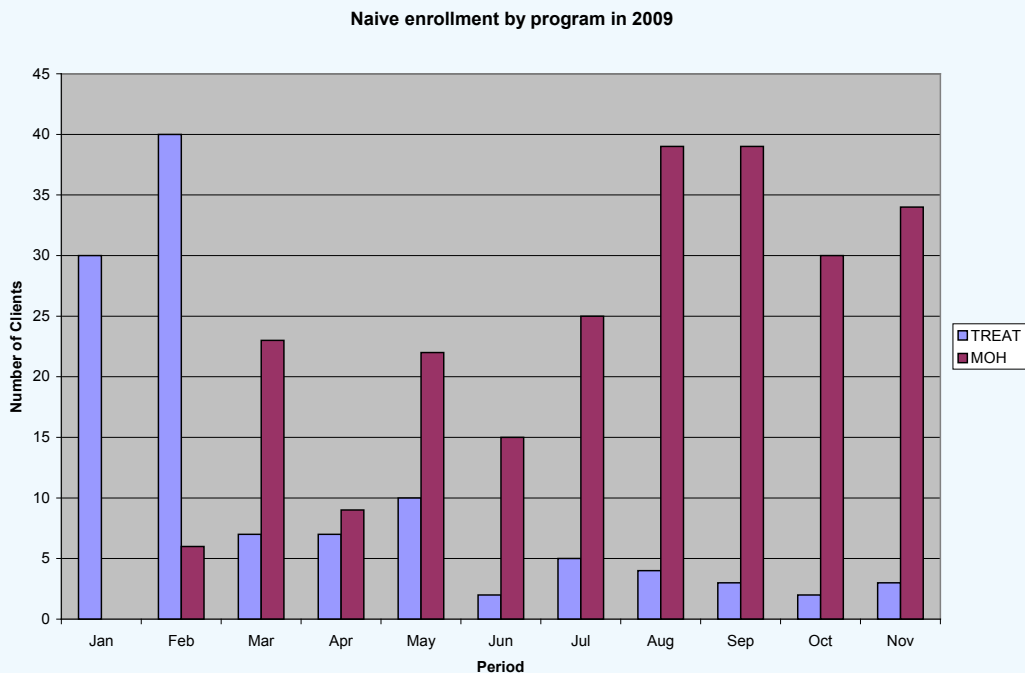
CLINICAL CARE

Kabale RCE serves both the TREAT clients and the MOH programmes hence serving as the Kabale Regional Referral Hospital ART clinic. The number of clients enrolled on ART continues to increase in the clinic. However the number of children enrolling into care remains low. Only 15% of all new clients on ART are children.

LABORATORY SERVICES:

The RCE continues to house the region's reference laboratory supporting HIV/AIDS treatment and research programs in the region. Tests ranging from microbiology, haematological, and virological tests are done at the laboratory.

NAIVE ENROLLMENT BY PROGRAM IN 2009



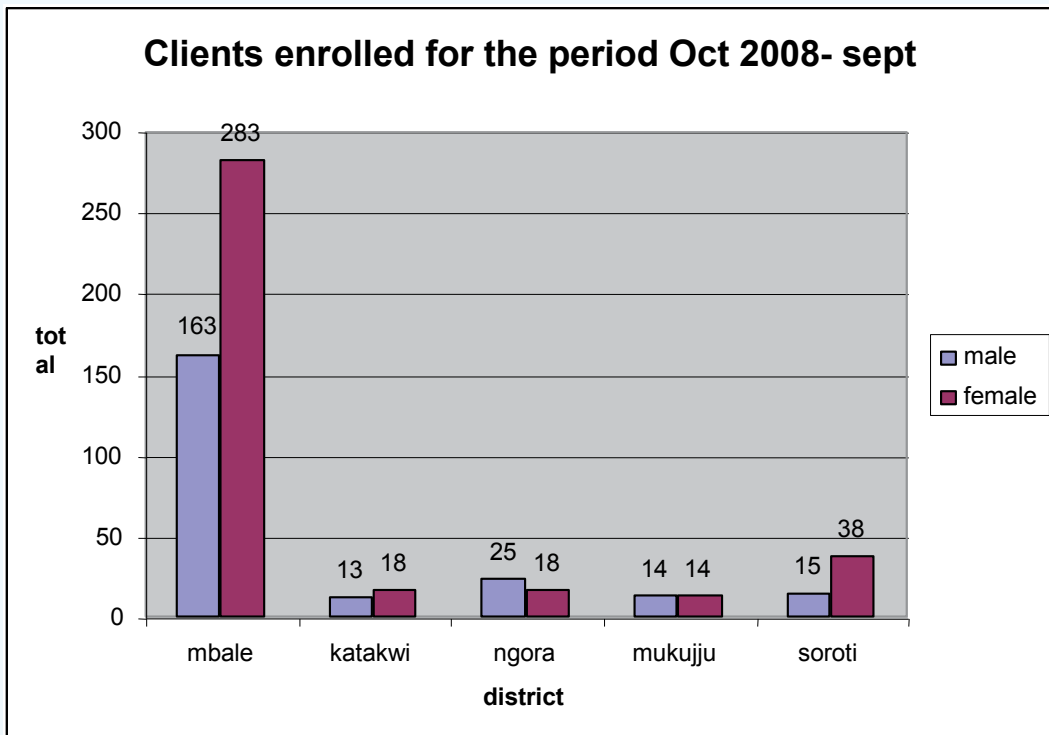
Mbale RCE

The centre is located in Mbale town at the municipal council dispensary building on Pallisa road. The centre currently serves as the regional control unit for six TREAT sites viz; Mbale regional referral hospital, Mukujju health centre IV Tororo, Kapchorwa hospital, Ngora Freda Carr hospital, Soroti regional referral hospital and Katakwi hospital.



Health Education talks at Mbale RCE

Since the beginning of the new year, the number of new clients (adults) enrolled into the clinic has gone down because of the current freeze. The centre however has continued to enrol children into care and even started those who require antiretroviral drugs (ART), on drugs.



Like the rest of the RCEs, Mbale houses the regional laboratory that supports the ART program in the region. Our laboratory also supports a number of research programs including clinical trials conducted as part of international networks. Currently the RCE is actively involved in the EARNEST trial, the PASER program, PROMOTE, PROMISE and many other smaller studies either as a participating site or as a reference laboratory. This has seen the sample load at the laboratory shooting up progressively during the past year as shown in the table below.

SUMMARY OF THE TESTS DONE ANNUALLY

Month	CD4	CBC	VL	DNA PCR	CHEM	TB	PREG	ELISA	HIV RAPIDS
Dec	1234	952	88	79	37	14	3	143	190
Jan	2284	1064	102	204	77	16	5	168	551
Feb	2963	1072	119	358	118	0	7	72	195
March	3196	769	150	330	121	0	7	14	56
April	2208	733	102	420	113	7	5	16	37
May	3070	1097	145	457	105	10	3	12	56
June	1768	519	58	271	47	10	3	12	52
July	2043	565	103	383	52	9	4	11	27
August	2109	687	165	501	68	13	5	25	34
Sept	2599	647	110	488	69	15	0	18	47
Oct	2854	678	160	469	151	14	5	12	32
Nov	2371	594	145	664	117	15	6	20	35
TOTAL	28699	9377	1447	4624	1075	123	53	523	1312

Kakira RCE

Kakira Regional Centre of Excellence which started in the confines of the Kakira Workers hospital relocated to its current location near the Kakira Town council offices in May 2008.

The Kakira R.C.E. continued to provide Antiretroviral Treatment to slightly over 1,000 clients from the districts that make Busoga region and, a few from beyond. The RCE state-of-the-art laboratory provided haematology, microbiology, virology and immunological tests for the TREAT clients and specified tests for over ten health facilities in the region some of which are supported by projects such as STAR –EC. Our influence in the HIV/AIDS activities in the region has been strengthened through collaboration with STAR-EC and other partners to provide laboratory services and technical assistance (TA).

The adherence department at the RCE has put in place adherence support measures that have ensured that less than 10 % clients have sub-optimal adherence. The psychosocial support clubs that are age-specific continued to be operational at the RCE.

On the scene of public relations, Kakira RCE collaborated with Kakira Town Council to host the World AIDS day commemorations for Jinja district. The function which was held in the RCE compound was very colourful and purposed increasing publicity for the institution. The RCE also provided bi-annual support supervision to Jinja, Kawolo and Kakira hospitals.

Fort Portal RCE

JCRC activities in Fort Portal begun with a partnership with GTZ PMTCT program in 2001 with the intention of supporting the program to focus on the broader programming and challenges faced by the fight against

HIV/AIDS and providing a more comprehensive HIV/AIDS Prevention, Care and Treatment services. The geographic coverage of this RCE is Fort Portal (Rwenzori region) of Kabarole, Kyenjojo, Mubende, Hoima, Kasese, Bundibugyo and Kamwenge). The centre is located in Fort Portal Regional Referral Hospital and houses the regional laboratory that meets all laboratory services needed to support efforts to fight HIV both in a clinical and research settings.



A cross section of clients waiting to be served at Fort Portal (Left) and Mubende (Left) RCE

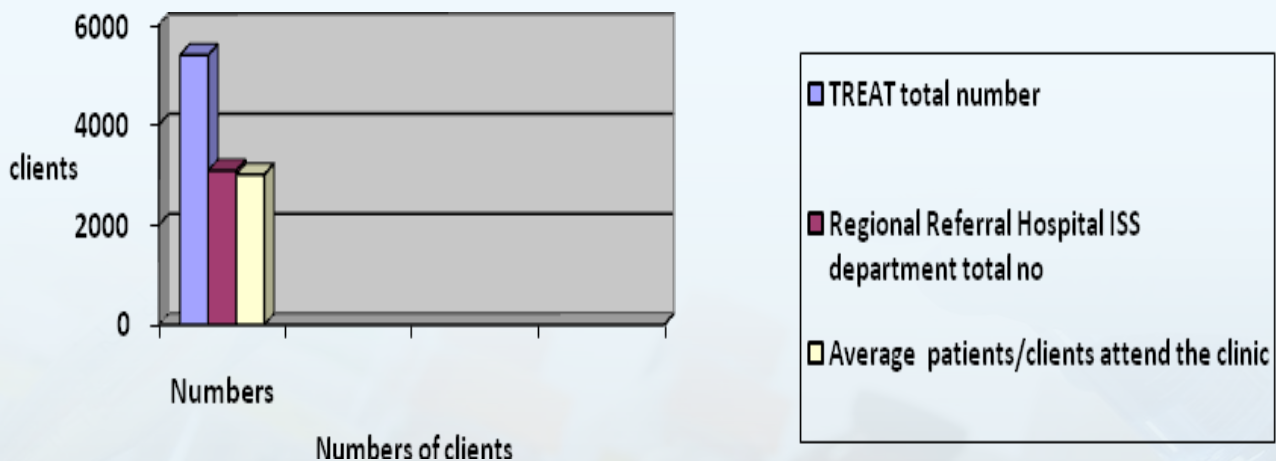
Clinical care

The RCE has throughout the year provided Prevention Care and Treatment to a total of up to 5385 TREAT clients. In addition 3080 clients under the MOH programme are seen within the JCRC Fort Portal premises. The clinic runs daily and has a private clinic established to increase patient enrollment on the ART programs. New clients are also enrolled in the MOH ART program given the scaled down enrollment of TREAT.

The average numbers of patients attending the clinic per month are 3000 as represent in diagrams below.

Graph showing Client seen at the RCE for TREAT & MOH 2009

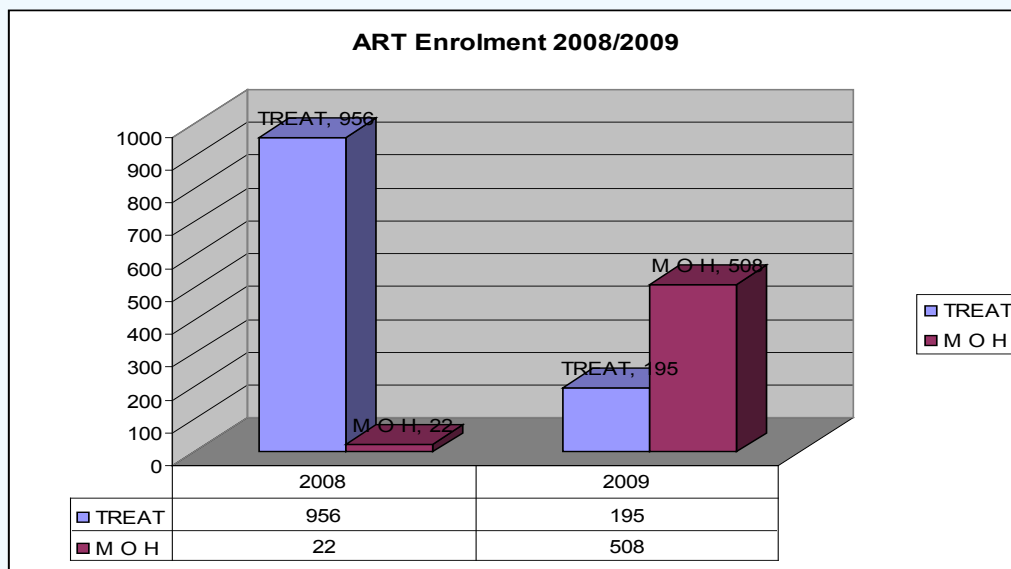
Figure 2.0.1



The graphic representation shows that the TREAT project is the larger Contributor in ART service provision compared to MOH programme in the Fort Portal regional referral hospital

A graph showing the number of new clients enrolled for the TREAT & MOH program between 2008-2009

Figure 6.03



The above graph shows a progressive decline in recruitment of clients to the TREAT project. The numbers still being recruited are children under age 14.

Psycho social support:

The is able to measure and know the level of adherence of 4624 clients assessed in the year 2009, 95% (3493) were adhering above 95%, 5% (231) clients have adherence below 95%. More than 48,208 clients attend health talks at the clinic, 3800 clients have attended adherence counseling sessions and more than 20,000 have been sensitized in the communities. 50 Community Liaison Volunteers were recruited and trained. 20 active CLVS were trained in Nutrition program with the collaboration of Nulife and Ministry Of Health in November 2009. More than 200,000 people have been sensitized in the communities especially in markets, churches, schools and local council meetings. Drama clubs continue to support clients.

Research: There are a number of trials and studies that include, EARNEST TRIAL, PASER study-Pharm Access Studies and JCS study-JCRC Children’s Study that are being conducted at the RCEs.

Laboratory Services:

The laboratory has performed an increased number of tests especially HIV DNA PCR compared to the previous years from 2006 that registered 46 tests, 2007 ,717 tests and 2009 recording the highest numbers of 4057 clients. There is currently routine external quality monitoring Programme for CD4 (UK NEQAS) and HIV DNA PCR (CDC GAP). The laboratory receives samples from the following districts; Kabarole, Kyenjojo, Kamwenge, Kasese, Bundibugyo sometimes Kibaale and Mubende (for DBS samples). Apart from the samples received from JCRC Fort Portal RCE clinic i.e. TREAT and private patients, the Laboratory also receives samples from centres funded by several partner organizations



The graph clearly shows a sharp increase in from 2006 through 2007 and reaching an apex in the year 2008, of 17531 clients, and a reduction by more than 500 clients in 2009 to 15148. This can be explained by the costs that were attached to the tests in 2009 leading to a decline in the number of tests conducted.

Support to lower sites and capacity building

The 2009 annual clinical JCRC Regional training took place at the RCE. The continued medical education is facilitated with good internet connection, at the RCE.

Support Supervision was done to all satellite sites under the jurisdiction of Fort Portal RCE.

Partnerships

The RCE participated in the Kabarole District and Agriculture Trade in support of good nutrition for HIV/AIDS clients.

In April 2009 Fort Portal Regional Referral hospital acknowledged the JCRC (HIV) clinic as the most hospitable department in the hospital.

The centre (RCE) participated in the World AIDS day which was held on 8th Dec 2009 at Buheesi Sub County. Kabarole district, flagged by the American Embassy and other stake holders namely; JCRC, CRS, RTI and TASO .

The nutrition program in September 2009 under the NuLife initiative of the USAID. To date the intervention has supported up to 5856 clients.

The Laboratory processes samples from the following partners: Catholic Relief Services (CRS) , Baylor college of Medicine, Research Triangle International (RTI), Ministry of Health facilities, Hima Cement Factory and Kasese Cobalt Company

7.0 Finance, Administration and Human Resources

Human Resources

JCRC expanded in terms of Human Resources. A cross section of staff were hired to fill various positions at JCRC's head offices in Mengo and its Regional Centres of Excellence across the country.

Recruitment to address increased demand for JCRC services countrywide

To maintain our vision of being a vibrant self sustaining centre of Excellence in Medical Research, Training and Health Care Services, JCRC seeks out the highly skilled and talented professionals. In 2009, a total of 35 staff was recruited to join the JCRC workforce, including 7 medical doctors and 6 laboratory technologists.

Capacity development

JCRC recognizes the need to provide opportunities to staff to advance themselves in their careers as a way of personal growth and to improve job satisfaction. As a result, the HR department worked closely with the Training department to organize in-house trainings for staff and also facilitates staff to attend short courses. The Human Resource department works closely with the administration to ensure that staff are allowed time off to undertake advanced courses. Currently, 9 staff members are pursuing bachelors' degrees, 11 are at masters' level and 2 are pursuing PhD programs. 7 staff members successfully completed their masters' degrees and 6 completed their Bachelors degrees. We congratulate them all.

Financial Report:

The financial year for JCRC is 30th June and so this calendar year report cuts across two financial years. 2009 was a year of growth for JCRC with a rise in income of 12.5% compared with 2008 while, expenditure rose by 15%. This trend was consistent with the growth in research activities undertaken and volume of patients treated by JCRC.

Looking ahead to 2010, there will be challenges as a result of the global reduction in donor

funding to HIV treatment and a greater emphasis on prevention and training. However, JCRC shall continue to play her role as a leading centre of excellence in research and care while at the same time seeking to be more efficient and cost efficient. JCRC will continue to attract new research and other grants and explore income generation activities for services rendered to other projects, corporate and private clients.

Welfare:

Bereavement: The department makes efforts to create a motivating work environment and support staff in times of joy and in times of sorrow. On a sad note, 2009 was a sorrowful year for some of our staff who lost their dear ones, and JCRC shares their grief with them. Dr Mary Abwola (Head RCE Mbale) and Dr Grace Najjuka (Laboratory Technologist & MO) lost their husbands; Mr. Disan Mulima (Laboratory Assistant) lost his wife, while the others lost close relatives to include their dear parents. JCRC joins all those who lost their dear ones and at this moment say “May their souls rest in eternal peace”.

Weddings: On a happy note the year saw 2 staff members getting married, and we wish them all the best as they take this new road.

Extra curricula activities: Football tournament: This year we participated in a football tournament organized by the African Palliative care Association. We performed quite well and hope for better performance next year. Further still, 76 JCRC staff participated in the MTN marathon and this was a great time of exercise, team building and bonding. Performance was good with 3 JCRC staff making running time below 1 hour in the 10 km race.



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