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Peter Mugyenyi, Cissy Kityo, Samson Kibende, Francis Ssali, Goeffrey Kabuye, Thomas Otim, Stefano Tugume, Rose Byaruhanga & Michael Kabugo

Scaling up antiretroviral therapy: experience of the Joint Clinical Research Centre (JCRC) access programme

Despite Uganda's success in lowering the rate of HIV infection, numbers of people already infected and progressing to AIDS continue to rise. The JCRC pioneered the use of antiretroviral drugs in Africa since 1992, and developed a successful model that incorporates drugs logistics, adherence and sustainability strategies, as well as regional referral centres of excellence and laboratories. JCRC rapidly established 35 satellite centres in the various districts, currently providing antiretroviral drugs to over 35 000 out of 70 000 patients on therapy. Increased access to treatment proceeds contemporaneously with improving infrastructure, while addressing critical human resource needs by ongoing training. This model provides data that inform a way forward for a robust, high-quality and sustainable ART programme, and aims to integrate into an improved national continuum of health care delivery.

Versnelling van antiretrovirale terapie: ervaring van die Joint Clinical Research Centre (JCRC)-toegangsprogram

Ten spyte van Uganda se sukses in die verlaging van die MIV-infeksiekoers, is daar steeds 'n styging in die getalle van diegene wat reeds geïnfekteer is en na Vigs vorder. In 1992 het die JCRC die gebruik van antiretrovirale middels in Afrika ingelui en sedertdien 'n suksesvolle model ontwikkel wat medisynelogistiek, terapietrou en volhoubaarheidstrategieë behels, asook uitnemende streeksverwysingsentra en laboratoria. JCRC het spoedig 35 satellietsentra in die distrikte gevestig wat tans antiretrovirale middels aan meer as 35 000 van die 70 000 pasiënte wat terapie ontvang, verskaf. Toenemende toegang tot behandeling gaan hand aan hand met verbetering van infrastruktuur en die aanspreek van kritiese menslike hulpbronbehoeftes by wyse van voortgesette opleiding. Hierdie model bied inligting om 'n hoë gehalte program daar te stel — 'n program wat robuust en volhoubaar is en daarna streef om deel van 'n verbeterde nasionale kontinuum van gesondheidsorglewering te wees.

Prof P N Mugyenyi, Dr C M Kityo, Dr S Kibende, Dr F Ssali, Dr G Kabuye, Mr T Otim, Mr S Tugume, Mrs R Byaruhanga & Mr M Kabugo, Joint Clinical Research Centre, Butikilo House, Ring Road, P O Box 10005, Kampala, Uganda; E-mail: pmugyengi@yahoo.co.uk & pmugyenyi@jcrc.co.ug; ckityo@yahoo.com & ckityo@jcrc.co.ug

By the year 2000 antiretroviral therapy (ART) was scarce in almost all the districts of Uganda with the exception of the capital, Kampala, where the vast majority accessed treatment.[1] The drugs cost aside, the main challenges were, as is the case in many poor set-ups, the gross infrastructure and human resource deficiencies. Systems for providing comprehensive AIDS care, including ART, needed strengthening. There was a need to prepare treatment centres, train care givers and establish drugs supplies, logistics and management systems, including monitoring and evaluation (M&E), in order to effectively expand AIDS care. During the 1990s the JCRC had demonstrated the feasibility of ART and developed an effective rapid response model, based on networking and capacity building capable of reaching the rural underserved areas and the majority of patients. The JCRC programme built capacity through a public-private partnership and the application of best practices in preparing diverse centres for the introduction of ART, handling the anticipated increase in patients, and an effective absorption of funding opportunities. JCRC addressed ownership issues by working with the centres in a spirit of partnership where the local staff remain in day-to-day control, managing their own part of the programme and yet sharing in the overall programme elements.

This article gives a brief history of the development of the model, presenting the major components and outlining the key challenges, successes and lessons learnt. The evaluation is based on service encounter information, interviews with patients and providers, and past as well as ongoing operational research.

1. Joint Clinical Research Centre (JCRC)

By the early 1990s, Uganda had the highest HIV prevalence rate in the world. However, it became the first country in Africa to reverse the HIV epidemic from the high prevalence level of up to 30% in some sentinel sites, averaging at about 17% countrywide in the early 1990s, to about 6% in 2002 (Kirungi *et al* 2006, Stoneburner & Low-Beer 2004a, 2004b). This was achieved through a vigorous preventive programme that utilised public information, education and communication (IEC),

1 Acknowledgements: all past and present JCRC staff as well as all JCRC national and international partners, especially TREAT collaboration partner.

a policy of openness, a multi-sectoral approach and committed leadership (Okware *et al* 2001, Green *et al* 2006). However, there was already a huge pool of infected people progressing to AIDS and the group was continuing to broaden. Currently it is estimated that approximately 1 to 1.5 million people in Uganda are living with AIDS. This corresponds with an escalated morbidity and mortality as more people already infected came down with AIDS. Before the establishment of the JCRC in 1991, a tiny minority of affluent Ugandan patients travelled abroad in search of therapy and monitoring tests.

The JCRC was specifically established by President Museveni to respond to a national crisis brought about by AIDS; it was charged with an urgent mission to provide a scientific approach to the AIDS crisis in the country. The JCRC was strategically planned to maximise the then very scarce local resources. It was therefore established as a joint venture of Makerere University to provide health professionals and researchers, the Ministry of Health to inform health policy guidance, and Defence to cater for the infrastructure. It was granted autonomy status to remove bureaucratic impediments, and to allow for independent policy formulation and the establishment of partnerships for expedited results. Accordingly, JCRC pioneered the use of and research on antiretroviral drugs (ARVs) in Sub-Saharan Africa in 1991, starting with a research project funded by Burroughs Wellcome pharmaceutical company to evaluate the lowest effective dose of Zidovudine (AZT).

Thereafter, self-generated funds and some funds earned from collaborative research projects with international institutions, enabled JCRC to quickly establish basic infrastructure to provide ART and acquire critical equipment for advanced diagnostic and monitoring tests, including Flowcytometer for CD4 assays. Soon afterwards JCRC expanded the provision of ART, as more drugs became available in an organised manner to include drugs logistics involving procurement and stocks, as well as laboratory supplies management. New ARV drugs were introduced as soon as they became available on the international market and stocked at the JCRC pharmacy, but unavoidably only those who could either afford them or could find sponsors had access, because of the exorbitant costs. However, the numbers of individuals on therapy continued to escalate as the cost of the drugs was reduced. By 1996 when protease inhibitors were introduced as part of highly active antiretroviral

therapy (HAART), JCRC immediately made it available, and soon afterwards introduced polymerase chain reaction (PCR) equipment to perform viral loads, in addition to the long established CD4/CD8 testing at the Centre. However, the costs of the tests were, like the therapy, too high for most patients and was therefore initially not offered to all. The early start in ART at JCRC provided a valuable opportunity for critical capacity building that proved useful for rapid ART scale-up when donor funds became available.

2. ART access initiatives

2.1 Working with UNAIDS access initiative

In 1998, UNAIDS and some pharmaceutical companies launched the Drug Access Initiative (DAI). Uganda and Côte D'Ivoire were selected to pilot the project in Africa. Others included Vietnam in Asia, and Chile in South America. DAI was designed to operate through a non-profit company, which proposed to reduce drug costs by bulk procurement of ARVs and the solicitation of subsidies by the participating pharmaceutical companies (Glaxo-Wellcome, Bristol Myers Squibb, Roche Products Ltd and Merck, Sharpe and Dohme). The Uganda Ministry of Health (MoH) supported the initiative (Zuniga 1999) and formed a partnership of Ugandan health care providers to set the minimum standards for the safe and effective use of ART and to monitor the project. The MoH also accredited new ART treatment centres, mainly within Kampala, which fulfilled the set standards for safe and effective delivery of ART. By 2000, there were six accredited centres providing ARVs in Kampala, in addition to the JCRC growing network in some main towns in the country. Although the UNAIDS initiative failed to substantially reduce the cost of ARVs, JCRC used the opportunity to expand her own programme by utilising readily available drugs within the country as buffer stock for those who could afford them, thus minimising the chances of supplies being interrupted.

2.2 Extension of ART to the districts

By 2001, more than 80% of Ugandans living in rural areas had very limited access to ART, because of the high levels of poverty and despite the desperate need. The scope of the problem involved an estimated

200 000 people who were in dire need of life-saving ART. As knowledge about the existence of life-saving ARVs became widespread across the country, a demand for the drugs increased. Most of the patients on ART accessed it through JCRC while those in the districts had to travel long distances to Kampala for therapy, thus adding to the costs of the already very expensive ART. The resources used for travelling to and paying for accommodation in Kampala could on average have been used to purchase drugs for another two to three months per year. It was therefore imperative to build capacity in the districts to facilitate access for the majority of patients.

From 2002, JCRC, as a partner with the MoH began to expand access to ART in the districts, by initially setting up two satellite clinics the Eastern and South Western Uganda, followed by an additional four clinics in other parts the country. JCRC trained staff provided generic ARVs at cost recovery, performed laboratory-monitoring tests mainly on referral basis, expanded drugs logistics, and introduced monthly M&E activities in these clinics. This resulted in a further rise in the number of patients accessing therapy and the refinement of the ART scale-up methodology.

2.3 Access through operational research

Right from its inception, JCRC planned to use operational research as one of the channels for increasing access to ART in Uganda. This was remarkable as it included three pioneering studies aimed at defining more user-friendly, more cost-effective and less toxic antiretroviral drug regimens which are still underway at JCRC as part of the multi-centre studies. These constitute some pioneer and the biggest ART trials in Africa up to this moment.

First among these was the CARE (Cohort to evaluate Access to ARVs and Education) project sponsored by PharmAccess and Roche. This was a small but important study that provided free ARVs to 50 HIV-infected patients in Uganda, and a total of 200 in Africa, who could not otherwise afford the drugs. It was a multi-site project conducted in Uganda, Kenya, Côte D'Ivoire and Senegal. This was followed by two other studies, including a multi-centre study namely: Development of Antiretroviral Therapy in Africa (DART), an Open label, randomised trial aiming at the evaluation of new approaches for management of ART and the

assessment of some ARV drugs, including Abacavir and Tenofovir, providing free treatment and monitoring more than 2 000 patients in the country.

2.4 The regional expansion of antiretroviral therapy (TREAT) programme

JCRC's ART expansion programme was accelerated when JCRC received support from the President's Emergency Programme for AIDS Relief (PEPFAR) through the USAID for a five-year project which started in December 2003. The project, named The Regional Expansion of Antiretroviral Therapy (TREAT), aimed at a rapid provision of ART in all regions of Uganda, while building nation-wide capacity for the safe and quality delivery of ART.

JCRC utilised the already established model to address the enormous challenges of infrastructure, human resources, drugs and supplies logistics, as well as the need for ongoing M&E which stood in the way of a quality and sustainable programme. There was an urgent need to rehabilitate and refurbish some critical areas in the treatment centres, train care givers, establish drugs supplies, logistics and management systems, including M&E, so as to effectively utilise these and any other additional resources. The JCRC's TREAT programme set out to work with the MoH, faith-based organisations and non-governmental organisations (NGOs) to address these challenges. TREAT set a target of establishing a minimum of 42 fully operational satellite centres in a period of five years. TREAT also undertook to provide technical support to the existing MoH accredited sites and to any future ART accredited centres in a stepwise manner. However, the programme was designed to be flexible and responsive to the needs and demands for expanded care and treatment services in any area of the country, as more funding support for ART became available and as new demands arose.

2.4.1 TREAT objectives

The primary goal of TREAT was to build capacity and establish a framework for countrywide ART access in an equitable and quality national programme based on the JCRC model, but following the MoH policy and guidelines. It specifically set out to accomplish the following objectives:

- To set up ART clinics in partnership with the public sector, NGOs and faith-based health care facilities;
- To develop an essential infrastructure, mainly through renovation and expansion of existing space, within the selected high-demand health facilities;
- To train key care providers in the provision of ART and laboratory services and to improve services;
- To establish JCRC regional centres of excellence, with quality laboratories to support the national ART programme;
- To provide free ARVs starting with the poorest of the poor, namely orphans and vulnerable children (OVC), followed by other poor AIDS patients in an equitable manner;
- To establish logistics for the efficient and accountable provision of ARVs;
- To establish a quality assurance programme;
- To develop partnerships with key players in the area of HIV/AIDS treatment;
- To conduct operational research to improve and inform the way forward.

Besides capacity building, the other main objectives of the programme included the application of the best practices in the health sector in order to build a strong base ready to address the increased treatment demand, and more efficient utilisation of the increased funding for AIDS care and treatment.

3. Implementation of model ART clinics

The programme established collaborative ART clinics linked to other services, including the prevention of a Prevention of Mother-to-Child Transmission (PMTCT) and TB programme, as an essential step in the ART expanding its nation-wide network.

The methodology involved initial assessment of prospective new treatment centres, which was carried out using the MoH accreditation criteria. The assessment tool evaluated the essential components of HIV care to evaluate the state of preparedness. The minimum requirements included an availability of clinical expertise, laboratory facilities, access

to a referral centre, counselling services and a social support system, as well as facilities to ensure drug accountability. Although the centres were all categorised as either ready or not ready to start, the JCRC developed a strategy whereby all categories were able to start immediately, if the demand and urgency mandated it, using a combination of different approaches. Basically the ready-to-go facilities were quickly facilitated by JCRC to start operating. Refresher courses were arranged for the staff, any needed renovations were carried out, and essential clinic items were provided. After a formal opening, the delivery of the drugs followed immediately. With regard to the grossly deficient facilities, a JCRC mobile clinic team runs the services while training and supervising the local staff until they are confident to take over. Clinic facilitation ranged from provision of additional equipment, renovations, strengthening of drug storage, refresher training and provision of seed ARV drugs. Clinic staff from all centres were invited to spend some period of orientation at the main JCRC campus in Kampala to observe the JCRC practice, while undergoing special training in specialised areas. Other training sessions were held on-site or at the regional level.

3.1 Infrastructure development

The initial assessment visit identified critical infrastructure gaps, including physical space as well as equipment needs that had to be addressed. Renovations under the programme were mainly restricted to improvements of existing facilities to meet the requirements for the provision of ART. The areas renovated include clinics, pharmacy space and counselling rooms. Laboratories were strengthened to undertake essential but basic monitoring tests. Equipment provided to the centres included but not limited to laboratory equipment and supplies, basic furniture, stationery, computer sets, examination couches, and communication devices. The equipment received by the centres were integrated into the general pool to be used for other services provided by the hospitals as well. This was in line with the project objective of contributing to the general improvement of the health services delivery systems. However, TREAT never allowed infrastructure deficiency to delay any critically needed services. One of the strengths has been to improvise by utilising tents or temporary arrangements, such as sharing whatever facilities existed in order to deliver critical services while more permanent solutions were found.

3.2 Human resources and training

For the successful implementation of the expanded ART access programme, JCRC brought on board about 40 essential additional staff and allocated them according to identified critical needs at the headquarters, regional centers of excellence and underserved satellite clinics with the aim to strengthen the capacity to handle the increased activities. The new cadres included, among others a full-time co-ordinator and special co-ordinators for training, logistics, adherence, M&E, a communication specialist and data personnel. As the programme is a partnership, trained employees in MoH facilities and other participating institutions work with JCRC staff at sites to provide services to the programme. The heads of the clinics/hospitals set up special ART co-ordination committees for management of the programme in their respective stations, and each identifies a key staff member to link up with the JCRC and MoH, as set out in the national ART implementation guidelines.

JCRC work in collaboration with other local HIV/AIDS training initiatives, while institutions target training to different categories of providers, including doctors, nurses, pharmacists, HIV counsellors, laboratory technologists and data personnel in order to enhance quality HIV/AIDS care and ART use.

The principles for training include an emphasis on skills transfer and local capacity development at ART sites in order to ensure quality HIV/AIDS care. A variety of training methodologies have been employed to cater for the different situations and set-ups of ART centres. These include on-the-job training by mobile teams from JCRC to satellite clinics, placement at JCRC in clinical and laboratory departments, didactic lectures and workshops, needs assessment and trainee follow-up, and preceptorship arrangements in which HIV experts from selected international institutions work with JCRC in providing training at workshops and ART sites.

To ensure consistent care for clinic patients, a core team of well-trained personnel is eventually created to staff the clinics and train junior staff as HIV care providers. All ARV clinic staff members involved in patient care receive continuing medical training to keep abreast with the latest information on HIV treatment.

3.3 Cost of ARVs

The JCRC ART programme was initially established to run on a cost recovery basis, as there was absolutely no significant international support for AIDS treatment in poor countries at the time. Established ART centres provided ART at cost and built the necessary capacity for HIV/AIDS care, until recently when subsidised and free drugs became available in the country. This, however, did not mean that the poor never accessed therapy. There were some who got sponsors, and JCRC provided some compassionate treatment for limited numbers from overhead savings. A programme under which JCRC persuaded some employers to support ART of their employees as a cost-effective investment initiative was well received by some employers, thus saving some lives.

4. Monitoring and evaluation

The M&E plan was designed to measure indicators of programme objectives, including inputs, processes and outcomes; to assess the effectiveness and impact of the entire programme, and to collect and disseminate applied and practical information to improve the implementation and outcome of the ART programme nation-wide.

4.1 Data collection

The presented data include new and some previously published results from the programme in order to present a more comprehensive picture. Evaluation was designed to use an integrated model of quantitative and qualitative data collection. Methods for data collection comprised routine health facility reports, HIV care/ART patient registers, surveys, review of service records, and interviewing of service providers and patients. In addition, special studies were carried out by use of key informant interviews, facility surveys, and population-based surveys to gather information that could not be collected through routine information systems.

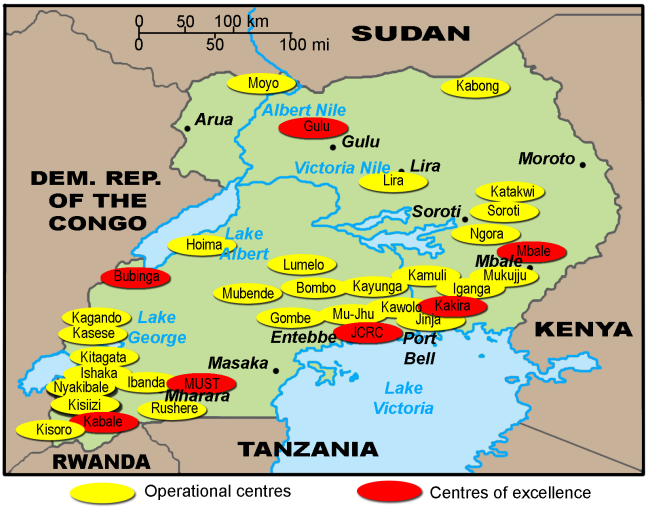
4.2 Operational ART clinics

By the end of December 2005, JCRC had successfully established a collaboration that has scaled up ART from seven clinics operational by the end of 2003 to an additional 28 clinics within public and pri-

vate hospitals in all the main regions of the country, thus bringing the total to 35 satellite ART clinics (Figure 1). Of the programme's operational sites, 24 (69 %) are based at government hospitals, eleven at private hospitals, with seven of them being faith-based hospitals.

The scaling-up of ART in Uganda has overstretched the capacity of the health sector to deliver quality laboratory services to support the programme. In its efforts to address the critical need for quality laboratory services in the country, JCRC has established six Regional Centres of Excellence (Figure 1) to ensure comprehensive laboratory support and HIV/AIDS care and treatment in the country. The laboratories also act as regional training and quality assurance centres for the smaller laboratories in the regions.

Figure 1: Scale-up: 35 TREAT operational centres, end 2005



The next phase of extension comprises sites selected to balance regional ART access, areas with high volumes in the number of patients and special requests from organisations that are already offering some HIV/AIDS services, such as VCT, and PMTCT.

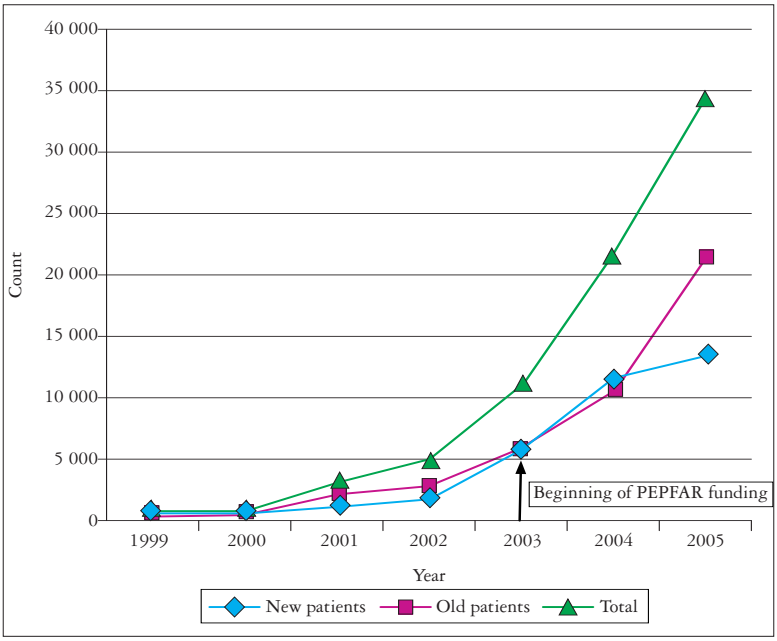
4.3 Training of health care workers

From the beginning of 2004 to the end of 2005, a total of 1 143 individuals have been trained in various areas that comprise comprehensive HIV/AIDS care. Trainees received training in more than one area in the form of workshops, placements in clinics and laboratories, on-the-job training and web-based e-Education. The cadres of staff included 314 nurses, 130 counsellors, 285 medical officers, 75 dispensers, 163 laboratory workers, 104 clinical officers, while 72 staff members attending to records and administration specialties were also trained.

4.4 Access to ART

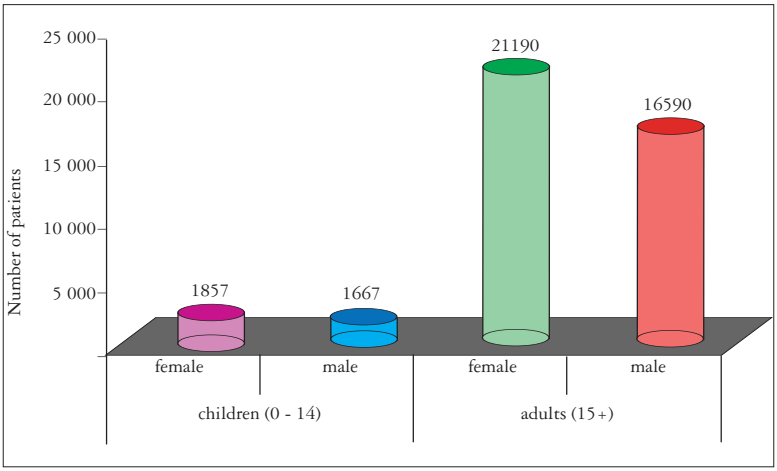
The progressive increase in the number of patients on ART could be attributed to a number of factors. These include the reduction in the prices of drugs, opening of new upcountry ART centers, sensitisation workshops and radio talk shows, increased access to laboratory services through a national referral network for screening HIV-infected patients, and emphasis given to ART provision. Since 2004, the provision of free drugs through the PEPFAR grant to JCRC led to a threefold increase in the number of patients on ART (Figure 2). By the end of 2005, JCRC and satellite clinics were providing ART to more than 50% of all patients on treatment in Uganda.

Figure 2: Patient recruitment at JCRC and satelite clinics



As the exorbitant cost of ARV drugs was a major factor for adherence, price reductions and free treatment helped patients to significantly improve on compliance with their treatment regimen. By implication it also reduced on potential risk of drug resistance. In addition, fixed dose combination formulation tablets promised to improve adherence and reduce the risk of drug sharing. The high cost of drugs mainly denied access to children and women. The majority of patients (over 65%) accessing cost recovery drugs were men, with just over 5% constituting children. However, more women and children were able to access treatment as drug prices dropped. Currently, with free drugs also being available, the distribution of patients on ART has shifted to 45% men, 55% women and 8% children aged 0 to 14 years (Figure 3).

Figure 3: Patient numbers cumulatively on ART, March 2005

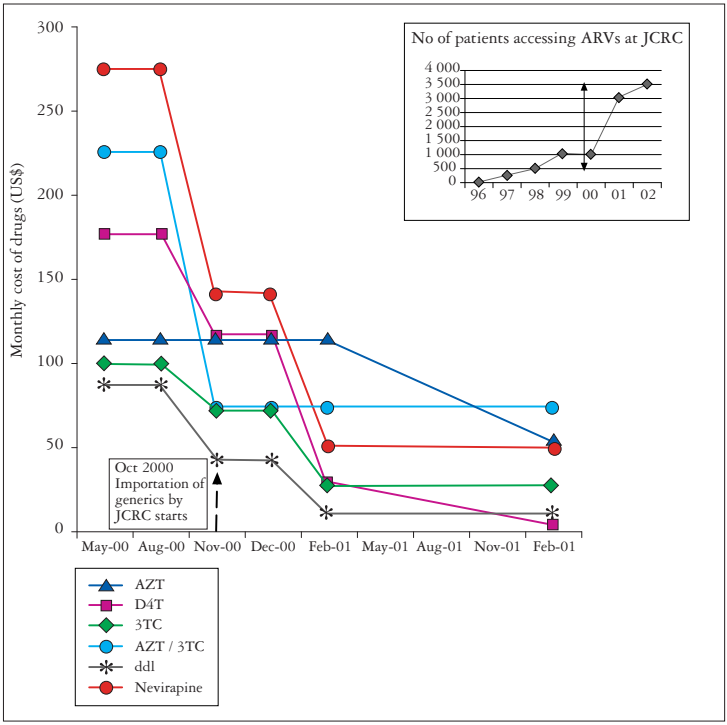


4.5 Impact of low cost ARV drugs

The JCRC strategy to reduce the cost of ARVs so that more people could afford them, included drugs market surveillance and intelligence to identify sources of quality; but low-cost drugs and supplies, bulk importation of generic ARVs, and advocacy for global drugs offered access to the poor. The turning point in drug costs for Uganda only came about when JCRC unilaterally imported low-cost generic ARVs from an Indian Company (Cipla) in October 2000 (Figure 1). For the very first time in Uganda the introduction of more affordable generic drugs made it possible for the middle-class people, including teachers, middle-grade civil servants and well-paid artisans, to access therapy at their own cost.

For the first time this was followed by an appreciable fall in the cost of brand-name drugs, which by December 2000 had decreased by a range of 22%-70% of the May 2000 prices (Figure 4). Correspondingly the numbers of new patients taking on ARVs doubled from 1 000 in 2000 to 3 000 in 2001 — a 200% increase in the number of patients taking ARVs. JCRC experienced an influx of AIDS patients from all over Uganda and some neighbouring countries, because of the ready availability of low cost ARVs and the advanced monitoring tests.

Figure 4: Impact of introduction of generic drugs on prices of ARVs



JCRC also started a strategic initiative to urge employers, including businesses and institutions, to provide ARV to their employees as a humanitarian and highly cost-effective way for the success of their businesses. With the availability of low-cost ARVs, it was explained that there would be substantial cost saving for companies and better work morale if they sponsored life-saving ART for their ill employees (Forsythe 2002). As a result, an increasing number of private companies developed HIV/AIDS policies at the workplace and accepted to provide ARVs to their employees directly through JCRC and in some other private clinics. However, even with the substantial reductions, the costs remained unaffordable for the vast majority of patients because of wide-spread poverty.

Responding to the increased demand, JCRC started providing medicines at cost recovery to private clinics, some government regional hospitals and health facilities in the regions.

4.6 ART treatment outcomes

To address concerns about treatment outcomes in poor-resource settings, preliminary data from JCRC is reassuring, while more studies are in progress to better define the issue. In one retrospective analysis of therapeutic response to the combination of Zidovudine, Lamivudine and Efavirenz in ART administered to naïve patients with advanced HIV, the disease reflected significant efficacy comparable to responses previously described in the western world (Kebba *et al* 2002). Response to generic fixed-dose combination ART, one of the commonest in use, was associated with improved compliance promising better treatment outcome (Oyugi *et al* 2004). Other studies are being conducted to inform better treatment strategies and regimes in circumstances of poverty.

4.7 Sexual behaviour among patients on ARVs

Negative effects of ART on HIV-risk behaviour have so far not been a significant factor among JCRC patients. Initial data from a cross-sectional study among 723 respondents comparing sexual behaviour in the prior six months between ART-experienced and ART-naïve patients in face-to-face structured interviews (Bateganya *et al* 2005) did not reveal any significant differences. Receipt of ART was not associated with a significantly higher likelihood of being sexually active (adjusted odds ratio [OR] 2.0; 95% confidence interval [CI] 0.3–9.9). Reporting one or more casual sexual partners in addition to a main partner was not different in terms of ART status. The ART-experienced respondents were more likely to report consistent condom use with their spouses than were ART-naïve respondents (OR 2.82; 95% CI 1.74-4.6). This finding is similar to experiences from South Africa where a *Médecins sans Frontières* project to provide ARV therapy has found higher rates of condom use with a main partner (Levy *et al* 2005). Future studies will assess the durability of this finding as access to ARV therapy expands.

4.8 Adherence to ART

The challenges associated with insurance of sustainable high adherence levels to ART over time in big numbers of patients are immense. In the past, the potential for resistance to ARVs was cited as a reason for denial of access to ART use in developing countries (Stevens *et al* 2004). However, early studies among those with moderate levels of poverty and purchasing their own antiretroviral drugs indicated that adherence was better than those in most industrialised countries. (Byakika-Tusiime *et al* 2005, Oyugi *et al* 2004). These studies found adherence near 90%, and this high level was consistent as would be expected with the high rate of viral suppression. However, these estimates have some selection bias and are likely to change as the duration on therapy and free drugs access increase. The level of adherence observed in Uganda is consistent with studies in South Africa (Bekker *et al* 2003) and Senegal (Vergne *et al* 2003).

Inability to pay for ART was the single most important barrier to adherence to therapy, especially for patients who earned less than US$50 per month. Future studies will continue to examine the trends and changes in adherence over a prolonged period and changing circumstances.

5. Challenges and discussion

5.1 Increased demands for ART services

Numerous organisations in different stages of preparedness have requested JCRC to provide expertise to help them extend HIV services to their clients. These include government health service sector and providers, NGOs and faith-based organisations. As donor-driven ART access programmes have been established among organisations without prior ART experience, some of them face operational and logistical problems, especially pertaining to uninterrupted drugs supplies and need for monitoring tests. In some cases JCRC has provided emergency supplies of ARVs to fill such gaps, while others have requested that their clients be taken over by JCRC altogether. So far JCRC has coped well with the demands, but this has necessitated increased manpower and the need for a more flexible and responsive logistics system.

To meet the challenges, JCRC has responded by seeking more resources to stock emergency drugs, strengthen the logistics sector, and provide referral laboratory services. JCRC has established a centre of excellence in each region of the country within two hours by bus accessible to over 70% of centres providing ART throughout the country. A memorandum of understanding to provide PMTCT programmes with neonatal PCR DNA HIV diagnosis, and some others with CD4 and viral loadtests have been signed, thus making such advanced tests accessible throughout Uganda for the first time. However, the level of utilisation will depend on the availability of resources. This is one of the fastest, most cost-effective and best practices for general access to quality HIV services in resource-constrained countries.

5.2 Donor factors

All donor agencies require regular reports to justify the funds they provide for the programmes. Some of them, including PEPFAR, have complicated reporting systems, causing care providers to divert from the crucial life-saving services in order to meet time deadlines. Some require establishing a cadre of staff for this kind of work. Likewise, the donor programmes do not always release funds on a timely basis, thus risking interruptions in drugs supplies.

As many organisations often provide services in the same health care facilities, and are funded by the same donors, there has been some scramble for patients in order to "account for" or justify the donor funds. Yet, it is not always possible to allocate patients to specific programmes, because the majority of patients share the same facilities and are taken care of by the same personnel. In response the JCRC has emphasised the partnership and shared-ownership of her TREAT programme as an important policy that donors could take in account when designing the next donation rounds. In addition, most donor programmes have a time limit, despite AIDS being a life-time chronic disease! Donor programmes' sustainability is yet another challenge that needs to be addressed in good time.

While providing funding for ARVs, PEPFAR initially ignored opportunistic infections (OIs). Yet, AIDS and OIs are inseparable, and one cannot be treated without the other. There have been some moves by the donors to address this situation, but it is further complicated by

the wide range of OIs, and their precise definition raising the issue of what to include.

5.3 Equity issues

The most serious equity issue is a lack of universal access to ART. Until this is achieved there will always be many more problems related to compliance, which would in the long term contribute significantly towards drugs resistance. To mitigate the effect of this issue, when increased funding became available to JCRC from PEPFAR, the poorest of the poor were prioritised to access free ART first, as an affirmative action to address equity. Therefore AIDS orphans and vulnerable children were the first, followed by their caretakers, pregnant women in advanced stages of immune-suppression, and poor widows, followed by all poor women and their poor spouses. The full package aims at universal access that includes a full cost recovery strategy by those able to afford the drugs, including those sponsored by their employers or insurance, leaving free treatment for the poor. At the same time more affordable generic drugs were made more accessible to those who could afford them. However, this still left a significant number of people in need underserved.

Other important equity issues include balanced geographical access of ART services. The northern region of Uganda, which has been a war zone for a long time, remains underserved.

5.4 Quality and sustainability

A quality and sustainable programme is dependent on adequate human resources and critical infrastructure, including quality laboratory services and supportive robust logistics, competent service supervision, and monitoring and evaluation. It was fully justified that our life-saving ART services did not wait to address these crucial factors in such a dire AIDS catastrophe. However, side by side with increasing access, these issues now need to be addressed, otherwise initial treatment success will at best be short-lived.

It is however, not possible for a parallel ART programme to succeed while the rest of the country's health services remains in quandary. In recognition of this fact JCRC has as far as is possible always linked the improved ART services to improvement of the general health care sector.

Often no additional costs are involved, and yet the improved services positively contribute to staff morale and improve the general care of patients. For instance, improved communication, laboratories, stand-by power supplies, some crucial staff and patient easements, and some supplies have been shared at little, but highly cost-effective additional expense. Moreover, new extensions and venues renovated by JCRC for ART services have been made available for sharing with some other deficient services. One of the glaring deficiencies identified, is a lack of child-friendly clinics. Where some are being established for AIDS-infected children, they will, whenever possible, be used for other out-patient children. This approach will form a basis for future integration of ART services into the continuum of care.

Addressing human resources, on-going training and the improvement of work conditions for health care providers so that they can stay at their jobs, are keys to building a critical mass of care providers. This, however, is constrained by many donor programmes ignoring or marginalising the human resource needs.

M&E is emphasised for donor use, but needs to be more geared to informing programmes for continuous quality improvement. JCRC has strengthened the M&E section and introduced computerised data for better patient tracking and improved services. This will be linked to the nation-wide adherence agenda in expansion stages.

The responsibility for donor-supported infrastructure and human resource capacity building, maintenance and sustainability will in the long term transfer from donors to the government. It is therefore imperative that adequate planning will ensure a smooth transition. The government needs to allocate some resources to AIDS in the national budget and, as poverty and AIDS are linked, so are the ultimate solutions for both.

6. Lessons learnt

6.1 Infrastructure constraints present no hindrances to ART programmes

In any state of emergency a lack of infrastructure is *never* an acceptable excuse for inaction. JCRC decided that poor health system infrastructure should not prevent life-saving interventions. It demonstrated that

only minimum infrastructure is needed for HIV testing and for starting ART. In dire situations, JCRC improvised by pitching tents, but nevertheless provided the therapy. For critical laboratory services JCRC in Kampala undertook to do the tests and return the results to the clinics. In the meantime, a long-term strategy aimed at building quality laboratory services started with the establishment of regional centres of excellence by JCRC for a quicker, more efficient referral system. Although it is important to address other permanent infrastructure shortcomings, these are secondary to relieving the humanitarian emergency.

6.2 The success of the initial cost-recovery programme

A cost recovery approach for ART access was established by JCRC long before AIDS treatment funding materialised. It has since been regarded as an important component of an ART sustainability strategy. It also helped JCRC to develop its capacity and expertise in the management of an ART programme, which later paid dividends as JCRC led the way in scale-up of ART in Uganda. In a cost-recovery ART programme, the most important determinant for success is the cost of drugs. For far too long pharmaceutical companies resisted any reduction in the cost of ARVs, with devastating results for the poor. However, from 2000, the prices of ARV drugs started dropping fast as a result of competition from generics and mounting international pressure (JCRC communication, Rojo 2001). Although a month's antiretroviral therapy cost more than many families would earn in a year, an increasing number of patients and employers were able to pay for ARVs as the prices went down, thus sustaining the JCRC programme since the early 1990s without any outside financing. The JCRC cost-recovery programmed grew to become one of the largest ART provision and AIDS research programmes in Africa. It also provided early evidence that ART was feasible in Africa at the time when there was widespread belief that it was impossible. However, the major set-back was equity concerns, since the poor could not access therapy. It is for this reason that JCRC prioritised the poor for free drugs in the spirit of affirmative action.

Our experience shows clearly that lower cost generics saved some lives and forced the cost of ARVs down, thereby increasing access. This is a key message to inform better World Trade Organization rules to avoid future tragedies for poor people.

6.3 Public-private partnership for rapid ART scale-up

The JCRC scale-up model demonstrated how an autonomous organisation working in partnership with various public and private sectors developed a successful model for quick and effective scale-up of ART access in Uganda. With appropriate adjustments to suit local conditions elsewhere, such an approach is applicable in any other resource-constrained circumstances.

National and international partnerships, including collaboration with international academic and research institutions and foundations, also augmented the JCRC to develop into a leading research centre capable of researching on a wide range of HIV/AIDS and health-associated conditions.

6.4 HIV prevention benefit from ART expansion

VCT remain the cornerstones of prevention. Testing for HIV represents an acknowledgement of one's personal vulnerability, and is often a first step towards taking responsibility for self-protection as well as for protecting others. Until treatment centres were opened in the districts, many people felt there was little they could do if they were infected. When ART became more widely available, people had a strong incentive for VCT, as evidenced by numbers reporting for VCT jumping three to four times in areas where treatment clinics were newly opened. The AIDS Information Centre (AIC) communication VCT branches that were associated with ART clinics realised sharper increments in VCT attendance, as compared to others that had not yet provided ART.

7. Conclusion

JCRC has demonstrated a successful programme and furnished evidence on the feasibility of scaling-up ART nation-wide in a low-resource setting, using existing facilities, while training critical manpower and making systematic improvements that include a cost-recovery component as part of a sustainability strategy. Therefore, fully autonomous organisations in resource-constrained countries working in partnership with government and NGOs can play a major role in setting up a quality national AIDS treatment programme.

Uganda and other developing countries need a national commitment and a strategy for eventual self-sustainability in the management of AIDS and other emerging diseases. It is also imperative that donor agencies take moral responsibility to sustain and expand aid to poor countries in the face of this humanitarian emergency, and not to abandon them for whatever excuse until such a time when their governments can take over. This of course means tackling poverty as a root cause of the dire situation of AIDS in poor countries. Therefore, the alleviation of poverty, better patents law to allow quick and unrestricted emergency life-saving drugs, good governance, and a more compassionate and fair world order would help minimise the likelihood of a repeat of such a catastrophe that AIDS has been to mankind, and especially the poor, over and above bringing an end to this very epidemic.

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