



## Improving the Availability and Management of Essential AIDS and TB Medicines and Diagnostics in Uganda

*In a study titled, “Essential AIDS and TB Medicines and Diagnostics in Uganda: An Assessment of Availability and Management”, the Uganda Coalition for Access to Essential Medicines (UCAEM) has found that, on average, people on anti-retroviral therapy (ART) do not find medicines at treatment centres at least 20% of the time. This paper expounds on the study’s recommendations for not only minimising stock-outs of essential AIDS and TB medicines, but also for improving the availability of ARVs for children, HIV diagnostic kits, laboratory facilities, and of prophylaxis medicines.*

### Background

A free ARV programme implemented with support from external donors has over the past few years led to a significant increase in the number of people living with HIV/AIDS (PHAs) accessing antiretroviral therapy (ART). By 2006/7, about 105,000 PHAs were receiving ART from 313 centres. Given the relatively wide range of ARVs available for prescription to PHAs, Uganda is well into the modern trends of AIDS treatment. The substantial availability of combination ARVs brings with it the advantages of a reduced pill burden and thus, improved adherence. In addition, the availability levels of medicines at treatment centres located in rural areas is comparable to those in urban locations, suggesting the medicine distribution system is generally fair. These advances in the treatment effort however, mask the reality, extent and impact of stock-outs of the essential AIDS and TB medicines in the accredited centres.

Access to affordable medicines is a human right enshrined in the UN Universal Declaration on Human Rights, which together with subsequent UN statements, affirms people’s right to health. The reliable provision of ART to at least the people who are registered to receive it is therefore a key component of an adequate, functioning health care system that enables people to realise their right to health. As government plans to roll out ART to 80% of Health Centre IV’s by 2010, it is important to consider whether the present PHAs on ART can access treatment at the accredited health facilities.

Besides risking their lives, if treatment of PHAs is interrupted for one reason or another, they are likely to develop resistance to the medicines they are currently taking, which could lead to emergence of resistant strains of HIV among the general society if any of the affected PHAs transmits HIV to other people.

### Modern AIDS treatment will save more lives

At accredited centres, both public and private, ARVs are provided free of charge. Private facilities however, charge for consultation and treatment of opportunistic infections. The UCAEM study found a total of 26 first- and second-line drugs and combinations in both adult and paediatric formulations, indicating a fairly wide range of treatment options available to PHAs in Uganda. The Ministry of Health (MOH) needs to maintain this kind of variety – and even expand it further – to give PHAs of all profiles the safest and most effective treatment options available in the world.

Modern treatment regimes involve a combination of drugs that come in one pill (or in a single set of pills) in a ‘fixed dose’. Combination therapy ARVs are generally recommended as they improve patient adherence and thus minimise cases of drug resistance.

In line with the MOH policy of phasing out combinations containing Stavudine 40mg, combinations containing this drug were available in only about 10% of the public facilities surveyed. The Stavudine 40mg combination (Lamivudine/Stavudine/Niverapine tablet 150mg/40mg/200mg) is being phased out after studies found that the combination containing Stavudine 30mg has a reduced side-effect profile of Stavudine without being less effective. The pace of phasing out Stavudine 40mg, which was found only in a few centres, should be maintained.

### **Stock-outs of ARVs deny PHAs the right to health**

While all health facilities accredited by the MOH to provide ART are supposed to have ARVs all the time for the patients they have registered to serve, at the time of the survey, ARVs were found in only 83% of the facilities that were surveyed. In the public sector, adult formulations of first-line fixed-dose, triple combination ARVs, were found in 32 out of the 39 public sector facilities that were surveyed. A stock-out rate of 20% at any point in time implies that PHAs receiving ART at one in every five public facilities risk developing resistance to treatment or even death due to interruptions in treatment. The occasional lack of ARVs by some of the accredited facilities negatively impacts on access to ARVs by some PHAs. The MOH needs to ensure availability of these medicines in all the facilities that are accredited to provide ART by streamlining the procurement and distribution system.

There was no marked difference in availability of ARVs between the rural and urban public sector facilities, suggesting that as far as the distribution system is concerned, the stock-outs may not be dependent on distance or location. It instead points to the individual facilities, the order processing point (Deliver), or with the source (National Medical Stores).

It is nevertheless also worth noting that the non-dependence of location or distance from the source of drugs may have been influenced by the existence of parallel and apparently contrasting distribution systems. One system, run by MOH/NMS, has occasionally been associated with erratic and wrong deliveries and deliveries of nearly-expiring medicines. Another, operated by Joint Clinical Research Centre (JCRC), is seen by service providers as being more consistent with its deliveries, irrespective of the location of the centres it serves.

ARVs and anti-TB medicines are poorly stocked in the private sector. Only about a tenth of the private sector facilities surveyed had fixed dose combination ARVs. Probably, the short shelf life of ARVs and the high regulatory controls and documentation required does not make business sense for the private sector to stock these medicines. Initiatives to encourage private sector to stock ARVs are needed so that those PLWA who cannot access them from the system have an option to buy from the market.

### **Stock-outs of septrin undermine the sustainability of treatment effort**

The facilities studied had a combined total 15,971 patients registered for ART. They reported a total of 8,460 PHAs qualifying for ART each month, but their capacity being limited, most are not taken on. The problem area is the persistent stock outs of prophylaxis treatment. Cotrimoxazole tablet 480mg and Fluconazole tablet/capsule 200mg were not available in nearly half of public facilities surveyed. The shortage of drugs used in prophylaxis means more people progress to AIDS stage than is necessary. MOH should make special arrangements to ensure that there is Cotrimoxazole at least in all centres accredited to provide ARVs.

### **Paediatric ARVs a more serious rarity**

Less than half of both the public and mission sector facilities had paediatric ARV formulations though they reported having paediatric patients. Nevirapine oral suspension 50mg/5ml, the most available of the paediatric ARV formulations, was found in only one third of the public facilities surveyed and in half of mission facilities. The poor availability of paediatric ARVs implies poor care for paediatric patients, who risk over-dosing with adult tablet formulations, or are exposed to drug resistance and death at an early age. Children's systems are weak and exposing them to drug resistance at such an early stage through treatment

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interruption or adult formulations may have long-term effects on their health. Weaknesses in paediatric care are apparently deep rooted as they stem from a general gap in knowledge in the area of paediatric care and as such a critical shortage of health workers. Thus any measures to address the problem need to be broad.

### **Medicines for TB and other opportunistic infections in short supply**

It should be noted that Uganda is implementing a joint management programme for AIDS and TB. It is estimated that two thirds of PHAs have TB. The availability of TB medicines is thus, as important as that of AIDS medicines. Yet fixed dose combinations of TB medicines were available in only two thirds of public facilities. Availability of single dose anti-TB medicines was lower – less than a third of the facilities. There were no TB medicines in the private sector. Like ARVs, TB medicines do not make business sense for the private sector to stock due to their short shelf life. The MOH should strengthen the structures that are supposed to implement the policy of joint AIDS-TB management by making TB medicines available at all ART centres.

### **There a problem with HIV diagnosis**

Diagnostic kits were available in only 70% of the public sector facilities surveyed and in 59% mission sector facilities. No diagnostic kits were found in private sector facilities. With all Ugandans being urged to test for HIV, limited availability of diagnostic kits points to a problem with diagnosis. HIV diagnostic services should be available at least in all referral facilities (health centre IVs and above) irrespective of whether they are accredited to provide ARVs or not.

### **More laboratory facilities are needed**

There is limited availability of laboratory facilities that are important for monitoring the side-effect profile of ARVs and TB medicines. Less than a third of public facilities were found with laboratories capable of performing liver function and renal function tests. Liver and renal function tests are particularly important in monitoring side effect profile of Stavudine, and anti-TBs like Rifampicin and Isoniazid. Facilities capable of monitoring the white blood cell count were more available, however. First-line drugs have tendency to produce serious side effects. In the absence of the vital organ function test facilities, some of the side effects are detected from the signs and symptoms, though good laboratory facilities would help in detecting problems in early stages.

Though a relatively high number of facilities had laboratory facilities capable of performing ZN sputum tests for TB, only a few had chest x-ray services. While the ZN is sufficient in diagnosing TB, chest x-ray is required for more definitive diagnosis of the extent of TB infection.

The ability to monitor the side effect profile of essential HIV/AIDS medicine is hindered by the low availability of laboratory services in the public facilities. For proper case management of HIV/AIDS cases, there is need to improve on the number laboratories and to equip them.

### **Frequency of ordering and receiving ARVs**

Out of the facilities surveyed in the public sector, 80% determined the quantities of stock for order (pull system) compared to 70% in the mission sector. The majority of the facilities ordered for and received supplies on a bi-monthly basis. Though many facilities in the public sector place orders on a monthly basis, only a few receive supplies on a monthly basis. Given that ARVs have a short shelf life and that supply is on the basis of orders (basing on need, which changes frequently) supplies should be more frequent, that is, monthly. Stock management is evidently poor at accredited centres. The stock cards are clearly marked with words “no (consumption) report, no drugs”, but some centres still do not submit consumption reports on time, leading to delayed supply.

Stock managers of ARVs in accredited centres need to be sensitised about the recommended MIS, including consumption reports, order placement and stock management, among others. The pull system should be made to work as it matches demand with supply and minimises stock-outs and expiries. This can only be possible with a functional MIS.

### **ART centres receive medicines at varying frequencies**

Among the public sector facilities surveyed, a quarter reported receiving ARVs on a monthly basis. The

rest receive at frequencies spreading to three months after placing their orders. Since consumption reports and orders are needed monthly, it should be appropriate for supplies to be delivered monthly. There is no good reason for different ART centres to receive ARVs at different frequencies when they are supplied from the same sources. The observed disparity in lead time is not cost effective and obviously leads to unnecessary stock-outs. Given the relatively short shelf-life of ARVs and TB medicines, NMS and Deliver need to strengthen and coordinate the receiving of orders, order processing and delivery, and shorten the supply cycle to one month. In addition, MOH in conjunction with NMS, JCRC, Catholic Relief Service and others involved in supply and distribution of ARVs should work towards the convergence of the various supply systems. This should be in terms of a common lead time for delivery of medicines, and common stock levels and ordering and reporting formats. This will help iron out incidences where a particular supply programme is more prone to stock-outs, which leads to “borrowing” across programmes and in the process destabilising the balance between demand and supply within programmes.

### **The management of expired stocks of ARVs still wanting**

There is a waste management policy in place but the guidelines on how expired medicines are handled are not quite clear. The Public Procurement and Disposal Act also complicates the destruction of expired medicines in public facilities. The National Drug Authority (NDA) should be the one to handle destruction of expired medicines, but there are no guidelines on who picks the expired drugs. Out of the public sector facilities surveyed, 58% reported having expired ARVs at their premises, compared to 29% facilities in the mission sector. Some facilities store expired ARVs at their premises while others transfer them to higher facilities. A system that requires health centres to transfer expires drugs to NDA headquarters in Kampala and pay for their destruction cannot be expected to function effectively in a setting where health centres are operating under financial constraints. Only about 5% of the facilities transfer expired ARVs to NDA for destruction. NDA should be facilitated centrally to collect expired drugs from across the country and destroy them, to avoid risks associated with keeping expired drugs at facilities indefinitely.

### **Logistics management information system (LMIS) not functioning effectively**

Pharmacy technicians and nurses formed the largest percentage of cadres managing stores at ART centres. While this indicates sufficient capacity for stock management at the accredited ART facilities, there is need to train stock managers in logistics management. All facilities need a functioning logistics management information system to facilitate ordering and stock management. They need it to determines the quantities to be ordered to avoid unexpected stock-outs and for the pull system to work. More than 80% of the facilities that were surveyed had a functioning logistics management information system. Nearly all facilities reported having stock cards or the stock card were physically checked and found in place. Requisition and issue vouchers were found in fewer facilities however. It is not clear how those without a functioning MIS (20%) get their supplies.

### **Conclusion**

Many more PHAs are qualifying for ART than the system can accommodate, leading to deaths that would have been avoided if more resources were invested in increasing the availability of essential AIDS and TB medicines and expanding the capacity of the system. Well, if the system is unable to accommodate whoever qualifies for ART, then at least those who are registered for treatment should get the medicines they need when they need them. That is not happening, and the effects are not limited to the affected PHAs; they spread to the general society. From the finds of the study, it is clear any efforts to eliminate stock-outs of essential AIDS and TB medicines need to be targeted at all the levels of the system, and will range from overhauling aspects of the system that make deliveries erratic, such as parallel supply schemes, while improving the implementation of those that can improve efficiency, such as the MIS.

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