

Logistics And Procurement Decisions And Issues For Consideration For Introducing And Expanding Access To ARVs In Uganda

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Executive Summary

Of the 2 million PLWHA in the country, the Government of Uganda estimates that at any one time, about 100,000 are in need of anti retroviral therapy (ART). ART has been available in Uganda since 1998, but provided mainly through the private sector, some employers and a small number of research or pilot projects. With the recent availability of low-cost, high quality generics, often in fixed dose combinations, the government is now able to explore the feasibility of public sector access to ART.

To guide and facilitate the expansion process, the AIDS Control Program in the Ministry of Health has set up a cross-disciplinary, multi-sectoral ARV Task Force with five subcommittees, with the aim of producing policies and guidelines within the areas of clinical care, finance, logistics and procurement and advocacy, which will feed into the National ARV Policy. The primary purpose of the documents is to provide a consistent framework for implementers to use while expanding ART availability in the public sector. The policy and guidelines will also enable MOH to access US\$ 3 million dollars worth of funding for procurement of ARV drugs through the World Bank MAP Project, and assist the MOH/GoU in preparing their proposal to the Global fund for AIDS, Tuberculosis and Malaria (GFATM) in round three, anticipated in April 2003.

The purpose of the consultancy was to assist the Logistics and Procurement sub-committee of the ARV Task Force to:

- Finalize quantification of \$3 million worth of ARVs to be procured with World Bank MAP funding,
- Document existing logistics and policy decisions,
- Identify outstanding issues requiring further decision making, and
- Assist in planning for the additional activities that the logistics sub-committee must complete.

During the process of finalizing the quantification, members of the logistics subcommittee worked with those from the clinical care committee to select the final standard treatment regimens, based on clinical criteria as well as taking into account financial and logistics implications of clinical decisions.

The results of the quantification demonstrated, that based on the lowest cost estimates for drugs, it will cost approximately \$519,000 to treat 1000 ARV cases per year, or \$520 per patient per year. This figure is slightly higher than the cost of the lowest combination regimen on the market (which costs \$350), because estimates were done for 1000 cases, and capture the costs associated with switching from first to alternate lines of therapy and for treating paediatric AIDS cases. The figure of \$520 only includes the cost of ARVs and does not include costs for laboratory tests or treating and preventing opportunistic infections.

There were nine issues that the logistics subcommittee identified as requiring further decision making and consideration. The subcommittee recommended development of policies for:

- Ensuring that Uganda is legally able to import generic drugs into Uganda,
- The extent of subsidies for patients purchasing ARVs, and when and if drugs will be provided free,
- Eligibility criteria for enrolling patients, given that there will not be enough ARVs to treat all who need them,

- Financing procurement, storage, distribution and a logistics management information system for ARVs,
- Standardizing and coordinating procurement approaches for ARVs, and
- Confirming the institution responsible for overseeing management of laboratory equipment, reagents and supplies to support ART expansion.

In addition to policies, there were a number of areas in which the logistics subcommittee members and other relevant partners require further action for implementation. Recommendations from the consultancy include:

Introduction

The consultant visited Uganda in February and March 2003 to assist the Logistics and Procurement sub-committee of the ARV Task Force to:

- Finalize quantification of \$3 million worth of ARVs to be procured with World Bank MAP funding,
- Document relevant logistics information and key policy decisions available to date,
- Identify outstanding critical issues and gaps in implementation that have yet to be addressed, and
- Assist in planning for the additional activities that the logistics sub-committee must complete

The consultancy was funded by USAID through the JSI/DELIVER Uganda project. The consultant was in Uganda from February 23 – March 4 and March 17-28 (see Annex I for the Scope of Work).

The approach taken during the consultancy consisted of information gathering, advocacy for decision making through individual and group interviews/discussions, official meetings and reviewing background documentation. A site visit to Masaka Regional Hospital's ARV clinic was also made to record practical, field-based observations and challenges. The consultant prepared a draft report for discussion, which was presented to Logistics Subcommittee members on March 14 for comments. The detailed schedule of activities is presented in Annex II.

The report is divided into 8 sections. Chapter 2 presents the Current Situation and includes a summary of ART service provision and a brief description of procurement and logistics system operations for drugs and laboratory supplies. An overview of key logistics considerations for an expanded ART program is presented in Chapter 3, and Chapter 4 documents decisions that logistics and other subcommittees have made that are pertinent to logistics system implementation. In Chapter 5, the decisions that have already been made are translated into results, in the form of a one-year quantification for ARV drugs using World Bank MAP funding. Chapter 6 presents issues and questions for the MOH that still need to be addressed before the National Policy and Guideline documents are finalized. The final chapter identifies recommendations and next steps for implementation of a logistics system for ARVs.

2. Current Situation

2.1 Background

The government of Uganda estimates that of about 2 million PLWHA, 100,000 are in need of anti retroviral therapy (ART). Although ART has been available in Uganda since 1998, to date, it has not been provided widely through the public sector, primarily because of lack of funding for these high-cost drugs. A secondary factor that has also been cited is the fear of poor compliance due to the high pill burden, strict timing intervals and numerous side effects. Currently, ART is provided mainly through the private sector, some employers and a small number of research or pilot projects. With the recent availability of low-cost, high quality generics, often in fixed dose combinations, the government is now able to explore the feasibility of public sector access to ART.

Uganda is in the process of developing a national policy and guidelines for introducing and expanding access to ART in the public and private sectors. The Ministry of Health, through the AIDS Control Programme (ACP), is leading the process, under the mantle of the ARV Task Force and its subcommittees. The five subcommittees consist of: Policy, Advocacy, Clinical Care, Logistics & Procurement, and Financing. Representation on these subcommittees is cross disciplinary and involves members from private, civil society and public sector partners implementing ART in the country. The ARV Task Force -- chaired by Dr. Peter Mugenyi of JCRC - - and its subcommittees were established in November 2002.

Currently, all the subcommittees are in the final stages of developing their respective sections of the national policy and guidelines. The primary purpose of the documents is to provide a consistent framework for implementers to use while expanding ART availability in the public sector. Furthermore, the development of policy and guidelines will also enable MOH to access US\$ 3 million dollars worth of funding for procurement of ARV drugs through the World Bank MAP Project, and assist the MOH/GoU in preparing their proposal to the Global fund for AIDS, Tuberculosis and Malaria (GFATM) in round three, anticipated in April 2003. For this submission, it will be necessary to include both proposed policies and procedures for ART treatment, as well as quantification for commodities to be requested under the GFATM project. The GFATM proposal includes about \$6 million of funding for ARVs over 3 years.

2.2 Current Practices in provision, procurement and supply chain management of ARVs

Currently ARVs are procured mainly through the private sector, by Medical Access Uganda Limited – a not-for-profit company that was started under the Drug Access Initiative – and the Joint Clinical Research Centre¹. Three wholesaler pharmacies – Star Pharmaceuticals, Shurik and Surgipharm – also import ARVs as does one retail pharmacy – Rene Pharmacy². Health facilities that are currently providing ART, purchase drugs from various importers described above and stock small quantities which can be purchased by patients.

¹ “Implementation Guidelines for ART in Uganda.” Prepared by the ARV Task Force, MOH Uganda. March 2003.

² National Drug Authority. “List of Accredited Centres and Pharmacies authorized to distribute antiretrovirals.” February 21, 2003.

Costs for the drugs vary significantly depending on whether they are branded or generic. Although branded drugs are generally more expensive, this is not uniformly the case. Currently, there are 46 registered ARVs, including 16 from 4 manufacturers in India, 2 from South Africa and 28 from Europe and the U.S. Sixteen ARVs are pending registration.

Twenty-two sites in Uganda have been accredited to provide ART, of which 18 are in operation. This includes 7 of the 11 regional hospitals: Arua, Mbarara, Mbale, Kabale, Lira, Masaka and Gulu as well as Mulago National Referral Hospital. The majority of the private and NGO sites providing ART are in or around Kampala. It is estimated that about 10,000 people in Uganda are currently on ART, about 1000 of which access these services through public sector facilities. The full list of accredited centers and pharmacies can be found in Annex III.

JCRC is the largest ART service provider in the country, providing approximately 50% of the care to adult patients on ARVs. In 2002, about 1070 patients accessed ART from JCRC, of which 48% were female and 52% male.³ Mildmay International Center, which has a specialized center for paediatric HIV/AIDS care and support, has the highest number of children on ART – 105 or just under 50% of children known to be receiving ART in Uganda.

There is not an existing supply chain that stores and distributes ARVs below the central level that can be used to manage drugs for an expanded ART programme. Medical Access is currently a major supplier, but it operates on a cash and carry system and sells only branded drugs. Obvious choices for consolidating procurement and logistics are the National Medical Stores (NMS) and Joint Medical Stores (JMS), currently the largest providers of all other essential drugs to the public and NGO sectors. Both NMS and JMS are licensed to import ARVs, although neither have begun doing so. These organizations could potentially conduct procurement, storage and distribution of ARVs for an expanded programme, although details on procedures and financing must first be worked out.

Data management for ART has been identified as an area that requires significant improvement.⁴ The majority of ART centers use manual methods of data management, including for patient monitoring. A few sites that have computerized systems use either a database developed by CDC or their own systems. Nonetheless, data retrieval and analysis for the rapid assessment was difficult, and most centers identified this as a challenge. Logistics data for ARVs is not routinely collected or reported, thus it is likely a new LMIS will have to be developed.

2.3 Current Practices in provision, procurement and supply chain management of laboratory items

Central Public Health Laboratory Services (CPHLS) – based in Kampala – has the mandate for procurement, logistics management and oversight for quality assurance and management of laboratory equipment and supplies for all regional, district, HC IV and HC III labs in the country. Initial screening for HIV in Uganda at the beginning of the epidemic (1987-1990) was done at CPHLS, which also had oversight for HIV related lab supplies and equipment. Uganda Virus Research Institute (UVRI) – based in Entebbe – took over the mandate for HIV tests and supplies while CPHLS was undergoing renovation in the early 1990s. Although this was initially only a

³ Akol, Z, E. Namagala, E. Aceng and J. Serutoke. “Draft Report on Rapid Assessment of Access to ART in Uganda.” November 2002. MOH and WHO, Uganda.

temporary arrangement, partly as a result of funding constraints, CPHLS is no longer involved in procurement and supply of any HIV related lab equipment and supplies. UVRI currently provides the MOH procurement committee with advice on HIV equipment and supplies to purchase, while CPHLS does so for all other lab equipment and supplies. CPHLS has fairly significant funding constraints and receives the majority of its funding from WHO, with smaller amounts from MOH/U and CDC. Quantification of non-HIV related laboratory requirements is budget based rather than related to actual needs, and CPHLS is able to purchase about 80% of requirements locally, through Joint Medical Stores. UVRI quantifies HIV related equipment and supply needs and provides these figures to MOH for procurement.

Medical supplies (including laboratory supplies) imported into Uganda are usually subject to a importation duty of 0.8% of the pro-forma value. However, any drugs or medical supplies directly involved in HIV/AIDS prevention, care or treatment are exempted from importation duties. When lab supplies or reagents are imported, NDA notifies UVRI, which performs any quality control tests before authorizing NDA to allow them to be imported into the country.

No systematic means of distribution for lab supplies exists in the public sector. Delivery from the central level to lower levels is either by CPHLS or UVRI vehicles, depending on the type of lab item, but this is not necessarily done on a regular basis or according to needs. When CPHLS is able to purchase supplies, distribution is done on an allocation system based on the essential tests required at each level. Mainly due to funding constraints, most labs at district and HC IV and III levels experience chronic shortages of required reagents. Although districts are supposed to be including purchase of lab supplies in their budgets, most districts are not doing so at present.

3. Overview of Key Logistics System Considerations for National ART Programmes

3.1 Requirements of an Effective Logistics System

The capacity to reliably, consistently and securely supply the commodities needed to support ART service delivery is indispensable to the success of HIV/AIDS programmes. In both the public and private sectors, program planners are increasingly aware of the importance of effective supply chains, because logistics improvements bring important, quantifiable benefits. Strong supply chains benefit programs in four important ways:

- Increased program impact through the consistent and reliable supply of essential products;
- Enhanced quality of care through the delivery of high quality products;
- Improved accountability through reduction of loss and wastage;
- Increased support of critical stakeholders by ensuring the integrity of the supply chain

These benefits are of particular importance in ART implementation at a national level in resource constrained settings. Much of the caution by governments and donors in introducing ARVs on a wide scale in these settings has been due to the fear of potential negative outcomes associated with delivering these expensive, highly potent medications. The following are some examples of these outcomes that can be prevented or minimized through implementation of an effective logistics system:

- Emergence of widespread drug resistance associated with an interrupted supply or poor quality drugs.
- Leakage from the public sector into the unlicensed private sector or to other countries, thus disrupting global pricing patterns and, and again, increasing the likelihood of resistance.
- Increased expense to programs, which have insufficient funds for buying drugs for essential health problems. Even though logistics cannot expand the total resource envelope, it can ensure that available resources are used efficiently and wastage is minimized.

3.2 Logistics Management Issues in scaling up ART delivery in Uganda

It is important to keep in mind that although much of the focus in the following section is on the immediate logistics considerations for implementing a national ART program, ultimately the decision making process must take into account the larger geo-political context.

Uganda, Kenya and Tanzania are moving towards the creation of an East African community with “no borders.” In practice, there is already significant cross border movement with minimal restrictions and sharing of health services next to border areas. Thus, especially in an environment in which generic importation or local manufacturing of ARVs is enabled in one or two countries, but not in all, **harmonized legislation, registration and quality control standards and pricing policies are considerations for long term goals for ART programs in each of these countries.**

3.2.1 **An integrated approach is required** to examine the logistics implications of HIV/AIDS. Although ARVs are the single most expensive commodity, **HIV/AIDS prevention, diagnosis, counseling, and treatment programs require more than 120 distinct products to operate effectively.**

3.2.2 The role of the public and private sector in drug procurement and logistics needs to be carefully defined. **If the public sector wants to take the lead, it will have to carefully consider incentives that encourage the private sector to participate as partners in the programme.** Public- private partnerships including NGOs and civil society organizations are essential

3.2.3 **A supportive policy and legal environment must exist for all of the logistics functions to be able to operate effectively and efficiently.** The National Drug Authority is willing for generic drugs to be registered and imported into the country and two local Ugandan pharmaceutical manufacturing companies have applied for permission to begin local production of ARVs. As long as there are no legal barriers for importation and local production, this will likely bring the price for ARVs down even more than they currently cost. **Policies are also required for determining how candidates for ART are selected, provider qualifications, treatment sites and referral systems and ARV prescribing and dispensing guidelines.**

3.2.4 ARV Product Selection for first and second line regimes as well as specific sub groups, such as TB patients and PEP for health workers, should provide clear guidance for program managers and implementers. In addition, because fixed dose combinations often offer a significant benefit to enhancing adherence, the guidelines should address preferences for specification of the regime in terms of pill burden. **ARVs should be included on the Essential Drugs List and user-friendly standard treatment guidelines developed for service providers.**

3.2.5 Complimentary to the ARV product selection will be supplier selection consistent with the selected products. **Supplier Selection should be undertaken based upon the country's past experience with manufacturers as well as reference to WHO list of pre-qualified suppliers** whose products have been evaluated and recommended by WHO as high quality efficacious drugs appropriate for resource limited settings⁴.

3.2.6 **A balance needs to be struck between thoroughness and speed in the registration of all new products for initial and ongoing quality control.** This applies both to imported and local manufacturers. Delays in registration should not become a source of protecting local monopolies.

3.2.7 **Financing and ability to pay is an issue that will greatly impact demand of ARVs and thus, the distribution of the products.** While the importation of generics into Uganda has and will continue to significantly reduce the cost for first line therapy down to \$1 a day – or \$350 per patient per year – this is the equivalent of the average annual per capita income of Ugandans (\$360). Although the official government policy is that there is no cost-sharing for medications in the public sector, discussion is still ongoing as to when to provide ARVs free or at a subsidized cost. If for example there is a 50% subsidy, even the cheapest (first line) regimen is likely to

⁴ WHO. February 2003. Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality. Suppliers whose HIV-related products have been found acceptable, in principle, for procurement by UN agencies.

be unaffordable for the majority of Ugandans. Another issue to be addressed is the cost of the required diagnostic agents for laboratory testing to monitor and manage treatment, which still remains high and is potentially a major constraint to expanding implementation of ART.

3.2.8 Drug Quantification. Due to the fact that currently there are insufficient funds to procure ARVs to treat everyone who needs them, quantification initially can only be done based on available funding, and for a defined target population. **A crucial input for ARV quantification is the need for clear guidelines for service providers about criteria for providing first and second line and alternate treatment regimens for those eligible to receive ART.** Following an assumption based quantification methodology, data on actual consumption and stock levels at the service delivery site to accurately estimate commodity requirements must be collected and reported, generally through a LMIS.

3.2.9 Procurement. The need for quality management throughout the supply chain of these items makes open market procurement a greater than ordinary risk for ARVs. This is especially important given the fact that there are likely to be multiple procurement agents buying the drugs, depending on the funding source, e.g., MAP, GFATM etc. **The ideal solution would be to use a single procurement agent. If, however, procurement itself cannot be harmonized through one agent, the procurement procedures – including options such as prequalified tendering and use of identical specifications – can be standardized.** Furthermore, coordination of quantities to order and procurement cycles amongst various donors and procurement agents will help reduce duplication and enhance supply chain management of ARVs.

3.2.10 Inventory Management, Storage and Distribution. The value of ARVs in terms of cost as well as life-saving potential, create an incentive for mismanagement and pilferage if appropriate inventory control procedures and systems are not designed. Therefore **strict monitoring of inventory levels and secure transportation and storage facilities will be needed.** A decision has been made to distribute and store the ARVs through the existing system, using NMS. New procedures for handling ARVs should be as consistent as possible with existing procedures for handling high cost or classified drug items at hospitals or facilities.

3.2.11 A well functioning Logistics Management Information System (LMIS) is required if the logistics system is to operate effectively and ensure the availability of quality products at service delivery points. **Close monitoring of ARV drug consumption and stock levels is particularly important for ensuring adequate supply of quality drugs, responding to changes in demand, managing increased volumes of commodities and minimizing pilferage and misuse.** The LMIS should be designed and in place before distribution of ARVs begins.

4. Decisions recommended by the Logistics Subcommittee

4.1 Policy and Legal Issues

In the interests of enhancing access, the subcommittee encourages procurement of lowest cost ARV drugs – including generics – as long as drug quality is assured

NDA has decided to take a neutral position on importation of generic ARVs – as long as quality of imported drugs is assured, NDA will not concern itself with patent issues⁵. Furthermore, three local companies – KPI, UPL and Rene Pharmacy – have applied to begin manufacturing ARVs in Uganda. NDA has issued a position paper on local production to provide guidelines to these companies. While the companies are gearing up for local manufacture, they will import bulk finished drugs from their sister companies in India and repackage them locally. This stance on purchasing either generic or branded ARVs is supported by the MoH Policy on ART, which states that low cost, high quality drugs will be purchased – regardless of patent status – in order to support GoU's strategy on enhancing equitable access to ARVs by all Ugandans. Uganda is also in the process of developing a law that will allow importation and use of generic ARVs, as per WTO Doha agreements.

Innovator companies have registered patents for 7 ARV drugs in Uganda,⁶ 5 of which are included in the recommended standard treatment regimens. GlaxoSmithKline has registered patents for Combivir, Lamivudine and Zidovudine; Boehringer Ingelheim for Nevirapine; and Agouron for Nelfinavir. GSK also has patents registered for Abacavir and Amprenavir (neither of which are currently included in the STGs).

The subcommittee recommends that all ARVs – particularly those bought through the public sector – should be channeled through either accredited pharmacies or dispensing centers, both within health facilities or at retail outlets

Treatment using the new supply of ARVs will begin at 12 regional hospitals in 2003, some of which are already providing ART. In 2004, services will rollout to 50% of district hospitals, and expand to the remaining district hospitals in 2005. The MoH policy is that only accredited treatment centers will receive drugs procured and distributed through the public sector. Ideally ARVs should only be available at accredited centers or through accredited physicians, but it is recognized that this will be difficult to regulate in the private sector. NDA, however, does have the mandate to only accredit a limited number of private sector pharmacies to stock and dispense ARVs, thus controlling the drug supply in the private sector is a feasible approach.

The existing accreditation criteria for treatment centers do not include comprehensive or sufficient measures to assess pharmacy, drug and logistics management capacity. Subcommittee members, led by NDA, are in the process of reviewing and improving criteria that can be used for accreditation of pharmacies or dispensing centers. The committee considers it important to accredit dispensing sites within public sector treatment sites as well as dispensing pharmacies in the private sector, both to assure quality within the private sector, but also to broaden access in case of stockouts or shortages within the public sector sites. The development of revised accreditation

⁵ National Drug Authority “Draft Position Paper on Antiretroviral Drugs.” September 2002.

⁶ Attaran, Amir and Lee Gillespie-White. “Do Patents for Antiretroviral Drugs Constrain Access to AIDS in Africa?” JAMA October 17, 2001—vol. 286 (15) 1886-1892

criteria for pharmacy, drug and logistics management will be in-depth and include elements on training, storage, inventory control, record keeping and reporting and measures to re-assess accredited sites to ensure standards are maintained over time.

4.2 Product Selection and the Essential Drugs List of Uganda

All ARVs recommended for use by the clinical care committee will be considered essential drugs and added to the EDLU during the next revision

The Clinical Care subcommittee of the ARV task force has finalized standard treatment regimes for first and second line therapy, treating TB/HIV patients and PEP for occupational exposure in health workers. The Logistics subcommittee has also determined that ARV drugs in the standard regimes are considered essential drugs and will be included on the Essential Drugs List of Uganda, either in the next revision or as an addendum to be published immediately.

4.3 Drug Registration

To minimize delays related to drug registration, a position paper on procedures for registering ARVs – including generics – has been published by NDA

NDA has well established, clearly defined processes for companies to apply to register any new drugs, formulations and strengths for the Ugandan market. Nonetheless, in recognizing the importance of ensuring availability of high quality, low cost ARVs on the market, NDA has issued a position paper clearly outlining procedures to be followed for registration of ARV drugs, particularly generics.

Currently, NDA estimates that it takes a minimum of 3-6 months from the time of a drug application to the time of registration. Generally, due to delays in documentation and communication, the average duration for new drug registration is about a year. Every time a new drug application is received, NDA must inspect the factory producing that product for GMP (depending on the country of manufacture) for each different product category. For example, if a generic manufacturer in India has antibiotics registered for the Ugandan market, but has applied to register an ARV, NDA must re-inspect that manufacturing site for the category of ARVs. If however, the manufacturer already has one or more ARVs registered for the Ugandan market, and is applying for a third, inspection is not necessary. NDA generally only conducts factory inspection visits twice a year. Following factory inspection, a full evaluation of the application dossier is conducted.

To enhance access, NDA and the subcommittee have agreed to fast-track registration of ARVs

Because the registration process can be lengthy, ARVs are treated as a high priority and NDA has instituted a fast tracking registration process to be applied for new drug applications for ARVs. The average duration for registration in this instance is 1-3 months. It is important to note that each new strength of a drug requires a separate application. For example, there are already several strengths of ddl tablets registered in Uganda (100mg, 25 mg), Merck & Co. must submit a separate application for registering the new strength of 200mg tablets.

4.4 Quality Assurance

To minimize delays in receiving and distributing ARVs, NDA will carry out routine analysis rather than mandatory analysis for this category of drugs

As part of its efforts to assure quality of all imported drugs, NDA requires each batch of incoming drugs to be accompanied by a certificate of analysis from the manufacturer (rather than the supplier). However, for certain categories of drugs (TB and anti-malarials), mandatory analysis is also conducted, which means that a sample of drugs is taken from the incoming shipment, and tested for quality. The products are held under customs control while the testing takes place, which could be anytime from 3 to 14 days.

All other drugs are subject to routine analysis, which essentially means certificates of analyses are assessed and the drugs are released to the program without any testing at the port, as long as all documents and physical attributes are compliant with NDA's statutory requirements. Quality assurance for these drugs is conducted through post market surveillance sampling by drug inspectors. NDA will keep its eye on this situation, however, and if in the future, quality for ARVs is not meeting expected standards, NDA will switch from routine to mandatory analysis for imported ARVs.

In an effort to beef up NDA's capacity in post market surveillance, drug inspectors have been trained in evaluation of ARVs for quality by WHO. NDA will also expand its regional presence to 7 regions, from 3 currently, and is intending to set up a Drug Information Pharmaco-vigilance Center, funded by WHO, which is anticipated to be operational from July 2003. Information will be collected on adverse drug reactions, quality tests both at the time of importation and also during post market surveillance. Relevant information will also be shared with health professionals. A data bank will be developed so NDA can track quality deterioration, either to the manufacturer or due to storage and handling during distribution.

4.5 Inventory Management: Storage and Distribution

NMS will store and distribute ARVs procured for use in public sector health facilities and a vertical system for storage and distribution will not be set up for this category of drugs

The logistics subcommittee has decided to take a long-term view in terms of logistics management of ARVs. Thus ARVs procured through the public sector (MAP, GFATM etc) will not bypass the existing storage and distribution systems. They will be stored at the NMS warehouse and distributed through an agreement with NMS. Again, this decision is reflected in the MoH Policy on ART⁷, which states that all ARVs destined for public health facilities will be purchased or ordered through NMS. In order to ensure that drug flow is assured during the period in which NMS builds up its capacity in the area of ARVs, the policy has a clause that allows facilities to obtain ARVs elsewhere if ARVs from NMS do not meet quality standards or are not available.

It is thought that having a limited number of importers/suppliers of ARVs in the country will greatly facilitate quality and low costs of these items. It is the MoH's view that NMS can be a significant supplier of low cost, high quality ARVs that are available for purchase by public, NGO and private facilities in Uganda. By providing a reliable and consistent supply of low cost, high quality drugs, NMS can in effect

⁷ "Antiretroviral Treatment Policy for Uganda." Ministry of Health, March 2003.

help to squeeze out small, unlicensed ARV drug sellers, thus minimizing the risks of counterfeit or low quality drug availability on the market and reducing the regulatory burden of the government.

Imported ARVs must be received with a minimum of two years or 75% of their shelf life remaining, to minimize the risk of expired stock

The shelf life for the majority of ARVs falls between 18- 36 months. Consistent with the policy for other drugs imported into Uganda, ARVs will have a minimum requirement of shelf life when they arrive in country, to reduce the risk of expiry. Particularly during the initial expansion period when demand and uptake is uncertain, especially at new sites, ARVs may not be dispensed as rapidly as expected and thus it is prudent not to accept drugs with less than the required shelf lives.

ARVs for second line treatment, and option B of first line treatment, will be maintained at NMS and distributed to lower levels on an “as needed” basis, both to reduce inventory holding costs and assure rational use of ARVs

Another important decision made by the logistics subcommittee was geared at maximizing use of resources by reducing the amount of buffer stock required at ART treatment centres. This decision pertains mainly to the ARV supply for adult cases receiving option B of first line treatment and second line ARVs, which will not be required in large quantities or by all patients during the first year. Option B of first line treatment is intended for those patients who develop toxicity for Option A, or the fixed dose combination of D4T+3TC+NVP. Rather than assuming that every site will require these drugs, and estimating an average quantity per site that is likely to be inaccurate, ARVs for these two purposes will be centrally maintained and sent out on an “as needed” basis. Courier services that serve the majority of the country, can be used for rapid distribution of these drugs. Although these services are likely to be costly relative to NMS distribution, such contracts will ensure timely and consistent deliveries and are still likely to cost less than maintaining higher buffer stocks of the drugs at each site.

Although such an approach might result in a 3-5 day delay in patients being able to start treatment with these regimes, there are two significant benefits to this approach. First, the quantities required to maintain a buffer stock only at the central level are significantly lower than those required for buffer stocks at every site (in other words, the program has less money tied up in inventory levels of ARV drugs). Thus, both in terms of relative volume and absolute cost, funds are freed up to treat more patients. Maintaining a central stock of these items will also minimize the risks of loss through pilferage and expiry, by facilitating tracking of inventory levels.

Second, the ART programme manager within MOH will be better able to track information on drug substitution and regime switching since they will be closely involved in authorizing distribution of these drugs. This information can then be rapidly fed back into adjusting forecasts, particularly until a routine LMIS is developed and implemented.

4.6 Logistics Management Information System

The subcommittee recommends implementation of a LMIS for ARV tracking, which will begin as a vertical system but will be designed to integrate other commodities at a later date

A well functioning clinical records/reporting/monitoring system and LMIS for ART is critical for providing routine feedback from clinical and pharmacy records so that toxicity, resistance, drop outs and stock status can be detected and reported monthly, the forecast of needs adjusted, and the shipment quantities and product formulations changed as needed. Similarly, given highly mobile populations, tracking patient treatment as they move will be critical to maintaining as many patients on first line therapy as possible.

The logistics subcommittee agreed unilaterally that without an effective and timely LMIS, the logistics functions of distributing ARVs to sites that need the drugs would be impossible. Although the committee was extremely reluctant to propose development of any vertical system, there was general agreement that given the high costs associated with ARVs, initially the LMIS for managing these drugs might have to start out on a vertical basis but should be designed to be integrated with other health commodities at a future date. Although no concrete decisions were made on the design of the LMIS, the consultant was encouraged to provide more information on the feasibility and cost of three different approaches: manual, semi-automated and fully automated (using technological innovations such as bar coding, smart cards and hand held devices).

4.7 Laboratory Requirements

Procurement and logistics management of laboratory equipment and supplies required to support a national, expanded ART program is a critical but overlooked area that needs to be addressed

Some key basic decisions regarding the role of laboratory tests as they pertain to ART have been made. The clinical care subcommittee has determined that viral load and CD4 counts are not critical requirements for initiating ART in the public sector and has recommended a short list of basic minimum tests for ART. Essential and desirable tests recommended by the Clinical Care Subcommittee are presented in Table 2 below.

Table 2: Recommended Tests for patients accessing ART through the public sector

Level Available	Investigation	Test and equipment requirements
All levels	Absolute minimum tests HIV antibody test Haemoglobin or hematocrit	Rapid tests
	Basic recommended tests Total WBC + differential	Heamatology Analyser
District hospitals	Basic recommended tests LFTs: alanine or aspartate aminotransferases Serum creatinine and/or blood urea Serum glucose	Clinical chemistry analyser
		Pregnancy test Urine sticks
	Desirable test Bilirubin	Clinical chemical analyzer
Referral hospitals	Desirable test Serum lipids	Clinical chemical analyser

		CD 4 cell count	Flow cytometer/Facs count
Research centres	Optional tests	Viral load count	Viral load machine

It is clear that the Logistics and Procurement subcommittee must play a similar role for laboratory requirements as it does for ARVs, namely it will provide advice on quantification and procurement of equipment, reagents and supplies and guidelines for logistics system implementation. However, the Logistics subcommittee only co-opted a member with laboratory expertise in March 2003. Partly as a result of this, the issues related to procurement and logistics of laboratory supplies to support an expanded ART program have not been discussed or developed with the detail that is required for effective implementation.

The MOH, through MAP, is procuring equipment and reagents in readiness to support an expanded ART program. Selection of the equipment and reagents included input from UVRI and the laboratory at Mulago Hospital, but not CPHLS.

5. Quantification Of ARV Drugs For Public Sector Health Facilities Using World Bank MAP Funding

5.1 Background

The World Bank through the MAP project has allocated US\$ 3million to the Ministry of Health for the procurement of antiretroviral drugs for a one year period. This is the first time that the MOH will procure ARV's for use in the public sector.

5.2 Objectives

To quantify national ARV requirements for treating patients in the public sector to be procured under the MAP project for 2003-2004

5.3 Approach

Given the lack of data that exists to guide such an exercise, the quantification relied heavily on assumptions of treatment and service utilization patterns developed in conjunction with key informants. Key informants that provided critical information included Dr Elly Katabira, Chairperson ARV clinical committee, who provided data on service statistics for ARV treatment in adults and Dr Philippa Msoke, a committee member responsible for paediatric AIDS at Mulago Hospital. Dr. Peter Solberg of CDC also provided valuable information on dosages and prices and reviewed initial drafts of the quantification.

Information was collected on:

- Standard first and second line treatment algorithms recommended by the Clinical Care Sub-committee of the ARV task force
- Pricing information from Joint Clinical Research Centers; Medical Access, the largest importer of ARVs in Uganda; CDC; and international prices for generic drugs (for which local prices are not available)
- Estimated percentages of patients that will receive first and second line drugs for both adults and children

The quantification was conducted concurrently with the process of finalizing the clinical care guidelines. In order to enhance accuracy and build consensus, after each draft quantification was produced, it was shared with various members of the Clinical Care subcommittee for comment and further clarification. One advantage of the interaction between the two processes was that the logistics consultants were able to provide the clinical care subcommittee members with an idea of the financial – and thus access – implications of certain drug choices and service utilization assumptions. When finalizing decisions on care, the subcommittee was able to make more informed choices about program reach based on preliminary quantification results.

5.4 Assumptions

1. This quantification was conducted using a combination of morbidity and data on target number of patients to be treated. A logistics-based forecast was not conducted because of the lack of historical consumption data from the public sector, and because the program cannot provide a full supply of ARVs for public sector requirements.

2. The quantities estimated assume that standard treatment guidelines for first and second line ART will be strictly adhered to in the public sector. These are described in Table 1 below.

Table 1: Standard Treatment Regimes for ARV drugs recommended by the Clinical Care Subcommittee of the ARV Task Force, March 1, 2003

Regimen	Drug Combination	Fixed dose combinations	Pill burden / patient / day
ADULTS FIRST LINE			
Option A	D4T(30mg) + 3TC + NVP (i) and D4T(40mg) + 3TC + NVP (ii)	D4T+3TC+NVP	(i) = 2 (ii) = 2
Option B	AZT + 3TC + NVP (i) or EFV (ii)	AZT + 3TC	(i) = 4 (ii) = 3
ADULTS SECOND LINE			
Option A	AZT + ddl + Kaletra	None	(i) = 10
Option B	D4T+ ddl + Kaletra	None	(i) = 10
CHILDREN FIRST LINE			
Option A < 5 yrs	AZT SYRUP 3TC SYRUP NVP SYRUP	N/A	5-8 bottles per month per drug
Option B > 5yrs	D4T/3TC/NVP	½ tab of D4T+3TC+NVP	(i) = 1
CHILDREN SECOND LINE			
Option A	D4T+ ddl + Nelfinavir	None	8
Option B	AZT + ddl + Nelfinavir	None	8
OTHERS			
TB patients (CD4 <50-200)	D4T + 3TC + EFV (i) or AZT + 3TC + EFV (ii)	AZT + 3TC	(i) = 5 (ii) = 3
PEP	AZT + 3TC + Kaletra	AZT + 3TC	8
PMCT	Single dose NVP for mother and syrup for child	N/A	N/A

3. All adult and paediatric AIDS cases eligible for ART and targeted for drugs through the public sector will receive ARV's free or subsidized in the public sector. However, it was assumed that the majority of patients beginning treatment in the public sector would be ARV naïve, and thus eligible for the first line treatment regime. In other words it was assumed that patients currently accessing ART through the private sector – and undoubtedly receiving very different ARV regimes – would not switch to access free or subsidized public sector ARVs. If such a situation were to occur on a widescale, first line treatment is likely to fail for these patients and the funds spent on procuring ARVs (the majority of which are first line drugs) would be wasted.
4. Uganda's total population was assumed to be 24 million, based on recent census results. A national HIV prevalence rate of 6% was used based on the most

recent surveillance report⁸. ACP/MOH estimates that there are 100,000 adult AIDS cases in Uganda, or approximately 7% of HIV+ individuals in the country.

5. Quantification has been done per 1000 cases treated on an annual basis. The MOH anticipates more funding for ARVs through MAP and the GFATM for the next few years, so rather than quantifying for a limited number of patients for several years, MOH requested a quantification for ARVs to cover as many patients as possible for a one-year period. Using the factor of 1000 cases provided in the quantification, program managers will be able to determine how many patients can be treated based on available funding levels, and adjust target population figures accordingly.

The following assumptions and percentages were provided primarily by Dr's Katabira and Musoke from the Clinical Care subcommittee:

6. Of 1000 AIDS cases per year, 90% will be adults and 10% children between 1-12 years.
7. It is assumed that a very limited number of patients currently on ART, and paying for drugs through the private sector, will switch to access this supply of ARVs. The assumption is that the majority of patients who will access ARVs through the public sector are currently not receiving therapy. It is also assumed that very few of the patients that receive first line drugs will need to switch to second line drugs due to treatment failure during the first year.
8. Of 900 adults, 90% will receive first line therapy (see sheet A, annex I). Of this 90%, the majority (95%) will receive option A or the fixed dose combination (FDC) for D4T+3TC+NVP. The quantification will refer to the most well known FDC for this regimen on the market (Triomune), which comes in two dosages, 40mg of D4T and 30mg of D4T. It is recognized, however, that Triomune may not be purchased, but rather an equivalent formulation. Because the majority of patients presenting for treatment initially are below 60kg, the assumption was that 40% of the 770 patients on option A will receive 30mg Triomune for the whole year, while the remaining 60% will start on 40mg. In reality, some individuals will switch to the higher dosage after 6 months, which is why a slightly higher percentage of 40mg Triomune will be quantified for.
9. Option B is reserved for the very small percentage that experience peripheral neuropathy from D4T, and for which single drug substitution will be required (AZT). Patients on Option B will receive Combivir (AZT+3TC) and either nevirapine or efavirenz as loose drugs. Pill burden for EFV is a consideration, given that a new strength of 600mg has just been released on the market, which would greatly enhance compliance by reducing the number of EFV pills from 3 to 1 a day. The small percentage of patients that experience peripheral neuropathy is likely to increase in year 2, although this is not factored into this quantification.
10. Of the 10% on second line therapy, half will receive D4T plus ddl and Kaletra, while the remainder will receive AZT instead of D4T. The assumption was that of patients starting second line therapy, as with first line therapy, the majority will be below 60kg, and will be started on a lower dosage and switch to the higher dosage after 6 months. Thus as in #8 above, quantification was done for 40% of patients receiving 250mg of ddl and 30mg of D4T, and 60% receiving 400mg of ddl and 40mg of D4T. Pill burden is a consideration here. Although 200mg and

⁸ Uganda HIV/AIDS Surveillance Report. June 2002.

50mg tablets of ddl are available, neither strength is registered in Uganda, only 100mg and 25mg are registered. Using registered strengths of ddl, the pill burden for adults >60kg just for ddl is 4 pills daily compared to potentially 2 daily. For adults <60kg, the ddl pill burden is 4 pills daily compared to potentially 2.

11. Of 100 children, 90% will receive first line therapy. Of those receiving first line therapy, 70% will be under 5, divided between 18-24 month-olds (20%) and 2-5 year olds (80%). The remaining 30% will be between 5-12 years. Dosages for children are calculated by weight, with specific formulas of dosage per kilo. For the purposes of quantification, a standard dosage has been used for each subgroup of children, and this assumed children were at the top weight of that category.
12. The under 2's will receive five bottles of each syrup a month, while 2-5 year olds will receive eight bottles of each syrup per month (see sheet C, annex I). It is assumed that all 5-12 year olds weigh less than 60kg, thus quantification was done for the 30mg FDC (e.g, Triomune). Most (90%) of the 5-12 year olds will receive half the adult dose of 30mg Triomune (1/2 tablet), while 10% will weigh enough to qualify for the full adult dosage of 30mg Triomune.
13. The proportions of children receiving second line therapy correspond to those for first line. The majority of first line therapy consists of AZT, so 70% of children will receive D4T/ddl/NFV for the second line regime and 30% will receive AZT/ddl/NFV. Again, it was assumed that all children under 12 weigh less than 60kg, so D4T of 30mg and ddl of 250mg dosages were used in the quantification. For children, half the adult dosages of each of D4T and ddl were quantified for. Similarly, half the adult dosage of NFV was used for quantification of needs.
14. Consideration for ARV drugs for TB/HIV patients was included in the numbers of patients who will receive option B of first line and second line drugs. It was assumed that, as stated in the National ART Policy, the majority of patients will complete their TB therapy before starting ART, and thus receive option A of first line drugs. Only those with CD4 counts of less than 200 will receive the TB specific regime.
15. Quantification for mothers receiving MTCT intervention of a single dose of nevirapine was not conducted, since this supply is already being provided through UNICEF and the Boehringer Ingelheim donation programme. Mothers who have received a single dose of NVP and have developed resistance are included in those patients accessing second line treatment.
16. Quantification of drugs for PEP amongst health workers was also not conducted. It is the government policy that PEP will be provided, however, the clinical care committee decided that it was not prudent to order drugs for PEP until such a time that all sites are able to conduct rapid testing of both patient and health worker at the time of exposure, so as not to misuse ARVs for PEP purposes.
17. For this first round of quantification, primarily because so little data is available on toxicity/intolerance and failure rates, issues such as patients switching from NVP and EFV due to rashes were not included in the quantification. These should be addressed for quantification under GFATM.

Table 2: Estimates for Number of Adults and Paediatric AIDS Cases that will receive ART through the public sector

Total population for 2002	24,000,000	A
Total number of people living with HIV/AIDS (A x 6 prevalence)	1,440,000	B
Total number of AIDS cases (B x 7%)	100,000	C
Total number of adult AIDS cases eligible for ART	TBD	D
Total number of adults AIDS cases eligible for ART that will access public sector health services	TBD	E
Estimates of treatment based on 1000 AIDS cases a year		F
Adult AIDS cases (F x 90%)	900	F1
Adult AIDS cases on first line drugs (F1 x 90%)	810	F2
- Adult AIDS cases on option A of first line drugs (F2 x 95%)	770	F2a
- Adult AIDS cases on option B of first line drugs (F2 x 5%)	41	F2b
Adult AIDS cases on second line drugs (F1 x 10%)	90	F3
Paediatric AIDS cases (F x 10%)	100	F4
Paediatric AIDS cases on first line drugs (F4 x 90%)	90	F5
Paediatric AIDS cases <5 on first line drugs (F5 x 70%)	63	F6
- Paediatric AIDS cases <2 on first line drugs (F6 x 20%)	13	F6a
- Paediatric AIDS cases 2-5 on first line drugs (F6 x 80%)	50	F6b
Paediatric AIDS cases >5 on first line drugs (F5 x 30%)	27	F7
Paediatric AIDS cases on second line drugs (F4 x 10%)	10	F8

18. To maximize use of resources, and reduce the amount of buffer stock required at ART treatment centres, it is assumed that the supply for adult cases receiving option B of first line treatment and second line drugs will be centrally maintained and sent out on an “as needed” basis. Nonetheless, a 5% wastage rate was included in the quantification.
19. It was assumed there would be a zero stock balance of any of the ARVs upon delivery of the drugs to the warehouse.
20. The MOH anticipates that more MAP funding and GFATM will be available before December this year for more ARV drug purchases. However, until the financial flow and procurement systems are fully developed and clear, it was considered prudent to quantify for a buffer stock of four months (see sheet B, D, annex I). Although a six month buffer stock is ideal, this was considered unaffordable in terms of the lost opportunity cost for treating a greater number of patients.
21. For EFV, a new strength of 600mg branded tablets has just been put on the market by Merck & Co. This will reduce the patient pill burden from 3 tabs a day of EFV to just 1 tab a day. Furthermore, the price of the 600mg tablet is significantly lower than the generic cost for 200mg tablets, by approximately \$100 per patient per year. Although the 600mg strength of EFV is not registered in Uganda, NDA has received the Merck application to register the new strength and expects the process to be complete well before the product will arrive in the country. Thus, quantification was done for the 600mg strength tablet.
22. For ddl a similar situation occurs where strengths of 200mg and 50mg tablets are not registered. However, although 200mg is not registered it has been used in the country and there is reason to believe its registration is pending. Thus the quantification for adults used 200mg instead of 100mg, reducing the pill burden for the second line regime from 12 to 10 pills daily. Because there is no record of the 50mg product being used or pending registration, quantification was done using 25mg strength which is registered, to reduce potential delays in

procurement. There was some discussion about the fact that if enteric coated (EC) ddI was not ordered, and the dosage was twice a day, then 100mg pills would be required to provide sufficient buffer for absorption. However, the conclusion was that if 200mg was dosed once a day, which does not compromise drug efficacy, this problem could be avoided.

23. Although local prices in Uganda shillings were preferred for costing purposes, only JCRC provides prices in local currency and these are retail prices. Thus, the price list of Medical Access Uganda Ltd (August 2002) was used for the majority of branded products, while generic prices were obtained from MSF's December 2002 document entitled "Untangling the Web." The annual price listed in the MSF document, was divided by 12 and used to provide a comparison generic cost to branded products available locally. If prices were not available from the MSF document, the branded price was listed instead. Generic prices were used even if the generic product is not registered in Uganda, to give committee members an idea of potential cost savings. The JCRC prices (February 2003) were also used as a reference. Detailed costs are presented in sheet E, annex I.
24. Cost comparisons were done for branded drug prices and generic drug prices. In some cases (EFV and Kaletra) branded drugs were significantly cheaper than generics, although in most cases, generics were lower cost. A comparison was also done for total costs for the following two scenarios:
 - a) Scenario 1: for first line drugs in adults, 70% are on option A (FDC for D4T+3TC+NVP) compared to 30% on option B of treatment (Combivir + NVP or EFV)
 - b) Scenario 2: for first line drugs in adults, 95% are on option A (FDC for D4T+3TC+NVP) compared to 5% on option B of treatment (Combivir + NVP or EFV)

The results of adopting a less flexible prescribing scenario (95% limited to FDC for D4T+3TC+NVP) demonstrated approximately \$50 cost savings per patient annually, or the ability of the program to reach approximately 10% more patients (comparing lowest prices for treating 1000 patients annually).

25. No quantification was conducted for the lab supplies that will be required to complement initiation and maintenance of patients on ART.

5.5 Results

The final quantities to order are presented in Annex IV, along with cost estimates. A cost comparison was done for branded and generic/lowest costs for total quantities required to treat 1000 patients per year.

Based on lowest cost estimates (either generic or branded) for each drug, it will cost approximately \$518,723 to treat 1000 ARV cases per year, or \$519 per patient per year.

Although the lowest combination regimen on the market is estimated to cost \$350, calculating treatment costs for 1000 patients captures costs associated with switching from first to alternate lines of therapy, as well as costs for treating paediatric AIDS cases.

It is important to note that this is just the cost of drugs required to provide ART and doesn't factor in any other commodities, including lab supplies or drugs for OI treatment or prophylaxis.

6. Policy Issues Defined by Logistics Subcommittee Requiring Further Consideration

6.1 Statutory Basis for importation of generic drugs into Uganda

The subcommittee discussed the importance of ensuring that Uganda is legally able to import generics and referred clarification of this issue and advocacy for final decision making to the Policy subcommittee.

Although NDA and MOH have adopted supportive positions for importation of generic ARVs into the country, there is nonetheless a need to ensure that, as the program expands, Uganda is legally able to freely import generic ARV drugs, specifically with regard to application of TRIPS under World Trade Organization (WTO) agreements. Currently Uganda law provides protection for patents registered in Uganda and 5 drugs recommended in the STGs have patents registered in Uganda. A law that would pave the way for legal importation of generics, under the conditions outlined at the WTO Doha meetings, is currently under development. At Doha, WTO members affirmed that TRIPS should be interpreted and implemented so as to protect public health and promote access to drugs for all. Countries were given the option to declare a state of emergency and issue compulsory licenses to generic manufacturers without previous negotiations with the patent owner. On 27 June 2002, the WTO TRIPS Council approved a ten year extension of the transition period, from 2006 until 2016, during which time less developed countries are not required to provide patent protection for pharmaceuticals.

The “Proposed Industrial Property Bill 2002,” is under development and is intended to create a legal means for Uganda to import generic drugs, based on recent WTO developments. Developed in consultation with a wide array of stakeholders, the draft document must first be presented to the Cabinet and then be passed by Parliament. A special Parliamentary subcommittee has been established to address TRIPS related issues for drugs. In the meantime, several institutions and pharmacies are importing generics and NDA has developed a position paper, in which it has stated it will not bar importation of generic ARVs.

To capitalize on these developments, and ensure optimal use of resources, especially for the \$3 million of MAP funding for ARVs, the subcommittee recommends that MOH, through the Policy Subcommittee, should advocate for timely passage of the bill, and ensure that a clearly stated policy is in place to allow legal importation and use of generic drugs for ART. The current draft of the Policy document states unilaterally that MoH will source from both generic and innovator manufacturers for ARVs during procurement. This is a continuation of past policy, where Uganda – through JCRC – has been importing generics for several years, and has been able to reduce ARV prices significantly.

6.2 Free versus subsidized ARVs in the public sector

The policy regarding pricing of ARVs to patients in the public sector that is currently being finalized by the Policy Subcommittee should ensure the guidelines implemented limit those who can pay from accessing free or highly subsidized drugs

The subcommittee identified two issues for consideration in this regard. The first issue relates to the need for a consistent policy regarding payment or non payment of

these drugs. Currently, the draft Policy includes the following decisions regarding free and subsidized drugs:

- ARVs for prevention (e.g., PMTCT and PEP services) will be provided free to patients;
- A sliding scale of fees for patients receiving ARVs for treatment, including free or highly subsidized drugs for those who cannot afford drugs and even full payment for those who can pay.

The policy statement highlights the fact that equity is a driving goal for the MoH and recommends that clear criteria be developed to determine how health workers and patients will be guided on the level of subsidy required, to ensure that equitable access is achieved.

Another issue to consider is the implication of providing free ARV drugs through the public sector. From a logistics perspective, a major issue to consider is whether a large population of patients currently on treatment will move from paying for drugs and services through the private sector to accessing these free or at highly subsidized costs through the public sector. If this happens on a large scale, the quantities estimated for procurement in Chapter 5 will become significantly less useful. This is because the quantification was conducted on the assumption that a large proportion of patients starting ART in the public sector would be ARV naïve. If patients currently receiving different ART regimens through the private sector switched to free treatment through the public sector, there is a high likelihood of treatment failure for these patients. Regardless of the pricing policy selected, safeguards against such situations should be put in place to pre-empt wastage of resources.

6.3 Eligibility Criteria for enrolling patients

The Logistics Subcommittee recommends that the Clinical Care and Policy Subcommittees develop clear eligibility criteria for patients receiving ARVs procured for the public sector.

Currently, there is not enough money under MAP to procure ARVs for 100,000 PLWHA who are estimated to need the drugs. Combined MAP and GFATM funding levels will not even be sufficient to treat a “low” scenario of 10,000 patients. Although the policy document provides some guidance on policies around free and subsidized provision of ARVs, there are no clear selection/eligibility criteria for service providers to use when enrolling and treating patients.

Clear criteria for patient eligibility for ARVs are necessary for multiple purposes: to enhance equity and service provision and ensure effective logistics management of ARVs. In developing these guidelines, one consideration that the subcommittees should keep in mind is accounting for changes in patient behaviour as ARV prices become more widely available at lower costs through the public sector. For example, one scenario is that a significant number of non ARV naïve patients – or patients receiving drugs through the private sector – switch to accessing drugs in public sector. This could potentially result in high failure rates for the ARVs quantified under MAP and used to treat majority of public sector patients. Both subcommittees acknowledged that developing eligibility criteria that addressed this specific issue will

be challenging, given the lack of data available on patients currently receiving ART, but that it must be addressed in the criteria.

6.4 Revision of NDA Statute

The subcommittee recommends that the Policy Subcommittee support and provide input into the revision of the drug classification section of the NDA Statute to schedule ARVs as a subclass under Class A to enhance drug quality and monitoring

Currently there is no provision for ARVs within the system of classification of drugs. Class A drugs are usually highly controlled items such as narcotics and psychotropics. Class B is the broadest category and includes the majority of prescription drugs, including anti-infectives, anti-biotics etc. Class C are over-the-counter preparations. For the moment, until this issue is resolved, ARVs are classified as Class B items. Opinion in the logistics subcommittee was divided about whether ARVs should be classified as Class A or B. NDA is recommending Class A given the high level of abuse of many Class B drugs. The resistance to this suggestion is because committee members are worried that placing them in Class A will restrict their access and thus expansion of the ARV program. NDA has suggested reclassifying ARVs under Class A, but as a sub class that is not as restricted as narcotics, although it still allows sufficient control to ensure quality and reliability of the drugs. The recommendation is that the NDA statute pertaining to reclassifying ARVs be revised to ensure stricter control of these items.

The draft policy does not address this issue specifically, because the statute is currently undergoing review and revision, and it is anticipated that this will be addressed by the time the policy document is complete. There appears to be no resistance to the idea of classifying ARVs as a sub class under Class A, as long as equity of access is not compromised. Immediate expansion plans include the regional hospitals and high volume district hospitals, and eventually HC IV's, all of which have medical officers for prescribing ARVs, which is a basic requirement for Class A drugs.

6.5 Financing Logistics Management Costs: procurement, storage, distribution and LMIS

The Logistics subcommittee and financing committee must identify and develop mechanisms to assure there is a continuous flow of funds for procuring ARVs, and for paying for logistics functions to ensure their uninterrupted supply through the in-country pipeline

Assuring the financing flow for ongoing procurement of ARVs once patients have been enrolled for ART will be critical to ensuring a consistent flow of ARVs into the country, and thus down to the clients, especially given that the program has decided to maintain only a four month buffer stock for these items. Even a two month delay between the funding cycles for MAP and GFATM could have serious ramifications for ARV availability and stockouts in Uganda, given the low level of buffer stock that has been provided for.

Setting up guidelines for a similar mechanism at all implementing ART sites is also critical. Regardless of whether or not drugs will be provided free to patients, ART sites should establish separate accounts for procuring ARVs to minimize the risk that funds will be diverted to cover other expenses, thus leading to ARV stockouts.

Furthermore, despite available funding for procuring ARVs, and a decision that the drugs will be stored and managed through the existing systems such as NMS, no mention has been made of how the logistics management functions will be financed. The current practice is for NMS to include a 6-10% markup on the value of the drugs, which covers storage, handling and distribution to district levels. If this model is followed, then it is important that the value of the markup be carefully negotiated, given the high cost of ARVs. Although NMS has results from a study demonstrating that 10% does not cover their total costs, in the case of high value items such as ARVs, this will obviously not be the case. Also important to keep in mind is the significant price reductions in ARVs that have occurred over a very brief time period, mainly due to increasing availability of generic drugs. Thus, any price negotiation based on value, should take into account possible devaluations in the price of ARVs over time. The price negotiation should take into account extra measures NMS will have to institute to ensure security of the supply.

One extra logistics cost that has not been addressed for other essential medicines is that of developing/maintaining a LMIS for ARVs. Although the need for a tracking system for logistics information for all essential drugs has and continues to be expressed, lack of resources and political support for its development have prevented implementation of an LMIS for the majority of essential drugs. In contrast, because of the many enumerated risks related to expanding ART access in Uganda, including high cost of drugs and risks of drug resistance, an LMIS is considered a critical intervention in ART implementation. Although it is too early to know the costs of developing such a system, nevertheless the issue of allocating financial resources for its development and maintenance must be addressed. Without funding for this purpose, experience with the STI and other projects has shown that even once ARVs arrive in the country, they will likely not reach the ART centers on a regular and timely basis.

6.6 Standardizing Procurement Procedures and Coordinating Donated Products

Guidelines and a decision on aligning procurement procedures and ensuring coordinated procurement by several donors for ARVs will ensure that funding is used effectively, ARVs arrive regularly and duplication of orders and wastage is minimized

Due to the potential risks of overstocking and understocking of ARVs associated with multiple sources of funding and procurement agents (each with different operational cycles), ensuring that there is a consistent approach in procurement procedures and that identical drugs are procured is also critical. Ideally approaches for promoting procurement of quality drugs without limiting competition should be adopted, such as limited competitive bidding using prequalified suppliers and use of uniform drug specifications by each procurement agent. NDA has suggested the following criteria for prequalifying suppliers that are eligible to respond to tenders for ARVs:

- Manufacturers currently registered by NDA; and
- Manufacturers of drugs prequalified by WHO or other internationally recognized bodies, such as MSF.

The policy document supports such an approach and recommends limited competitive tendering, based on WHO's prequalified list. The goal is both to ensure that high quality drugs are procured and minimize delays in the procurement process.

Although limiting the procurement procedures that can be used for ARVs is a necessary first step, a further complementary step required to reduce the risks of stockouts or overstocks is ensuring there is a mechanism to coordinate needs requirements, procurement and shipments from multiple donors, given the fact that new donors and procurement agents are likely to emerge over time. One approach is to use the MOH's policy on target numbers of patients to treat over a specific period of time together with eligibility criteria to prepare a 3-5 year forecast for ARVs. This can then be used to develop a long term procurement plan, to coordinate procurements amongst various donors. One advantage of this approach will be that the MOH can be proactive about advocating for resource mobilization, since they will have a clear estimate of costs for treating more patients. Another advantage is that if more donors come on board, MOH has clearly defined estimates of needs and timing for when commodities are required, so the new donors can align their purchases with whatever is on hand or being purchased.

A further consideration over time relates to aligning procurement for ARVs with the procurement policy for all other essential drugs. At a Pharmacy Section/MOH and UHSSP-sponsored workshop on "Procurement of Medicines and Health Supplies" on March 19th, the MOH and stakeholders agreed to begin the process of operationalising integration of procurement by contracting NMS as its primary procurement agency for drugs & health supplies.⁹ A framework agreement (Memorandum of Understanding) that will define responsibilities and fee structure to enable NMS procure, store and distribute on behalf of donors, programmes and projects will be developed. The MOU will ensure competitive pricing and performance against agreed benchmarks. If procurement of ARVs is aligned with MOH policy for other essential medicines, this will overcome the problem of multiple agents with different procedures and cycles. Evidence has shown that without clear MoH direction and guidance on a preferred procurement agent, donor projects generally make their own individual and diverse procurement arrangements. There is little documentation on the performance of these arrangements. Overall, it appears that lead times are usually long, and irregular or interrupted supply is common due to inefficiencies in the tendering process, including award of contracts for unregistered drugs.¹⁰

6.7 Implementation of uniform and comprehensive approaches to data collection and management

The Logistics and Clinical Care subcommittees should identify and combine minimum essential data elements required for patient and drug monitoring and develop a strategy for routine data collection, reporting and analysis to assist with ongoing program management

Although each subcommittee individually has discussed the importance and need for data collection, the two have not yet worked together to determine data elements, and implementation guidelines for the system. For many programs, Health Management Information Systems (for service utilization data) and LMIS (for logistics data) operate side by side as two separate, unlinked systems. In the case of ART there are several benefits that could be achieved through linking or merging the two systems. Benefits include: enhancing accountability of drugs consumed,

⁹ "Main recommendations of the health supplies procurement meeting held on the 19th march 2003." MOH. March 2003.

¹⁰ "Health Supplies Procurement Meeting: In the spirit of SWAp." Prepared for 19th March meeting by MOH Pharmacy Section and UHSSP.

identification of irrational prescribing and dispensing patterns, monitoring of toxicity and regime changes which will thus inform quantification of future supplies and feed into resupply of drugs to each site. Ideally, all minimum essential data requirements, including those for financing, monitoring and evaluation etc should also be identified and collected along with service statistics and logistics data.

The clinical care committee has started working on a list of minimum data items that are required for ART monitoring of patients and similarly the logistics subcommittee has begun the same process for logistics data required. It will be important to have a decision made as to whether to implement one integrated system or to have two separate systems.

Depending on the decision made as to how to collect, organize and analyse patient and drug flow information – whether together or separately – a decision can then be made regarding implementation of an LMIS. Options for LMIS implementation are presented in Annex V.

6.8 Procurement and supply chain management of laboratory equipment and reagents

The role of each subcommittee – and specifically the Logistics subcommittee – in determining laboratory requirements and assuring supplies of laboratory equipment and reagents should be clearly defined, including a decision on financing mechanisms for these commodities

The issue of laboratory supplies has not received the same focused attention that ARVs have, and thus there are gaps in decisions in this area that require further clarification. Beyond the primary decision about which basic minimum tests are required for ART, detailed thinking has not progressed further, to the level of policy decisions on which organization will oversee laboratory requirements and supply chain management for equipment and reagents (CPHLS or UVRI). Similarly, key implementation guidelines – particularly regarding use and distribution of laboratory tests – need to be reviewed and enhanced. Mirroring the lack of clarity regarding institutional leadership for these items, there also appears to be a lack of priority within subcommittees as to what needs to be done for lab supplies and which subcommittees should provide leadership and guidance. It is particularly important to clarify this given that currently the logistics and clinical care subcommittees have limited laboratory expertise represented in their membership.

If laboratory supplies are to be integrated within the overall health care system, then in theory NMS should have the mandate for storage and distribution, under oversight from CPHLS. Furthermore, if a framework agreement for procurement is developed, then NMS will be the MOH's designated procurement agent, and also responsible for procuring laboratory supplies. Currently, there is no relationship between CPHLS and NMS in terms of procurement, handling or storage and distribution. NMS does have the capacity to store and distribute these items, although obviously a MoU regarding the percentage markup for these items will have to be negotiated and developed, assuming funding is in place.

The two pressing questions that need to be addressed before further decisions on logistics system design and implementation can move ahead include:

- Which organization has the mandate for selection and oversight of supply chain management of laboratory equipment and supplies for ARVs and other HIV needs – CPHLS or UVRI?
- Where will funding for upgrading CPHLS to resume these responsibilities, including overseeing management of these supplies and training laboratory personnel, come from?

6.9 Integrating donated ARVs into the supply chain management system for ARVs purchased by the public sector

The Logistics and Policy Subcommittees should develop the policy and procedures for how donated ARVs will be integrated into the supply chain for ARVs purchased through the public sector

Although the majority of ARVs that will be used in the public sector will be procured by the public sector, there will nonetheless be small quantities of ARVs donated for specific purposes or projects. In such cases, will donated ARVs be subject to the same policies as public sector procured ARVs, or will they follow the procedures that have been developed for all other donated drugs?

Issues to consider regarding donated ARVs include quality assurance, consistency with recommended standard treatment regimes for the public sector, financing for any logistics costs and any potential costs of these donated drugs to patients. If donated drugs enter in large amounts for specific geographical regions or sites, this could potentially disrupt existing trends in consumption and distribution through NMS and ACP, which should be taken into account when developing procedures for logistics management of these items.

7. Recommendations for Implementation

7.1 Program Issues

Recommendation 1: Improve supply chain management and procurement of associated HIV/AIDS commodities, including HIV testing, which is critical to expansion of ART nationwide

Action Items

1. Ensure that types of HIV test kits selected for procurement for VCT and PMTCT program expansion are user friendly and practical for lower level health facilities, thus enhancing ACP's ability to rapidly expand VCT and PMTCT service expansion
2. Determine how HIV test kits – especially rapid tests that do not require refrigeration and that are destined for VCT and PMTCT service expansion – will be stored and distributed
3. Develop an agile supply chain management system for HIV test kits that will ensure that tests are distributed on a timely and regular basis to implementing sites so that they can be used prior to their expiry date

Recommendation 2: Revise national accreditation criteria for ART treatment centers to improve section on pharmacy, drug and logistics management for public and private sector dispensing centers

Action Items

1. MOH and NDA and other relevant subcommittee members should revise the pharmacy, drug and logistics management section of the accreditation requirements to expand criteria related to training, record keeping and reporting, inventory control and storage
2. Criteria for private sector dispensing sites for ARVs should include a requirement for general data on number of patients to which ARVs were dispensed and quantities of drugs dispensed every six months
3. Include professional organizations in the development of the criteria and develop a role for them in ongoing re-certification or re-accreditation to ensure standards are maintained over time

7.2 Product Selection and Registration

Recommendation 3: Any further product selection decisions should be shared with logistics subcommittee representatives to ensure that costs, storage and distribution issues are considered

Action Items

1. Ensure there is regular representation of the logistics subcommittee on the clinical care subcommittee to facilitate information sharing and so that clinical care subcommittee members are aware of logistics implications of product selection decisions

Recommendation 4: Implement procedures to minimize delays related to registration of new ARVs

Action Items

1. Encourage companies that win tender awards to submit importation documentation to NDA four weeks prior to product arriving at the port to expedite importation process and minimize delays
2. Include a member of NDA on procurement committee for ARVs to minimize potential delays related to registration and importation
3. Continue to strengthen capacity of NDA for inspection, quality control and registration with an overall goal of reducing delays in registration and enhancing availability of data on drug quality. Specifically, capacity is required for training and evaluation in inspection of ARVs

7.3 Quantification, Forecasting and Procurement

Recommendation 5: Develop a 3-5 year forecast for ART and a corresponding procurement plan to allow for donor coordination once new funding sources become available and frequent shipments of small quantities of ARVs

Action Items

1. Standardize procurement procedures such as limited competitive tendering and specifications to be used across different procurement agents.
2. The MOH and its partners should use decisions about targeted number of patients to treat and number of implementing sites to develop a forecast for 3 year ARV needs. The forecast should include a low, medium and high scenario
3. Once the forecast and cost is known, develop a procurement plan, to ensure that even if funding is not available, resources can be mobilized to ensure that patients already started on treatment do not stop because of lack of funding
4. Determine the mechanism for coordinating procurements and financing amongst various donors

Recommendation 6: If uncertainties of funding are likely to cause bottlenecks in procurement, consider creating a fund for ARVs and other high value public health commodities, such as TB drugs. This type of mechanism can be implemented at both the national and treatment levels

Action Items

1. Logistics subcommittee members to work with financing committee to develop a mechanism to assure continuous flow of funds for ARV drug purchase for 5-10 years. Different approaches should be explored: a mini-basket for ARV drug purchase, a drug fund for high priority drug purchases e.g. ARVs, TB and anti-malarial drugs etc
2. Assign an institution, section or body responsible for coordinating donor inputs into this mechanism
3. Develop recommendations for implementation of the mechanism, including financing, administration and management procedures, and ownership by the MOH or GoU
4. Determine the mechanism for procurement coordination and decision making. Select an institution or body that is able to engage in dialogue and coordination between donors, procurement agencies and programs within MOH
5. The institution to work with the pharmacy section in MOH and donors to determine whether NMS can be the appointed agent for ARV drug procurement using all sources of funding.
6. If a single procurement agent is not feasible, institution to develop consensus on standard procurement procedures and specifications for ARV drugs, including consideration of limited competitive tendering using prequalified suppliers

7. At lower levels, given a possible subsidy for patients to pay for drugs, determine how payment money will be collected and channeled towards repurchase of ARVs.
8. Determine financing mechanisms at implementing site levels to ensure that sites do not stock out of drugs due to lack of funds or interruptions in financing sources

Recommendation 7: Determine and clarify procedures for procurement and logistics management of laboratory supplies to support expanded ART service provision

Action Items

1. MOH to confirm decision that CPHLS will resume mandate for operational management and supervision of laboratory equipment and supplies for HIV items, including those to support an expanding ART programme
2. Define roles and responsibilities for CPHLS and UVRI regarding these items
3. Conduct advocacy amongst development partners to solicit resources (financial and technical) to upgrade capacity of CPHLS to support new responsibilities
4. As part of guideline development for CPHLS in the area of HIV lab supplies, ensure procedures for logistics management are defined and documented

7.4 Logistics Management Information System

Recommendation 8: Ensure that a functioning LMIS and inventory control system is in place prior to the arrival of ARVs

Action Items

1. Determine list of essential logistics and other data elements that must be collected to facilitate logistics system functioning. Ensure this is coordinated with the data requirement list currently under development by members of the Clinical Care subcommittee
2. Decide on the scope of the information system or systems that will be implemented, either jointly for collecting all ARV related data or individually for different components (i.e. clinical, logistics, financing etc)
3. Explore cost, feasibility and buy-in for three different models: manual, semi automated or fully automated. Include consideration of locally available technological innovations (e.g., smart cards, palm pilots etc).
4. Once design of system has been determined, define procedures for information gathering, reporting and analysis and document them in a procedures manual for each level and site. Procedures should also be developed or refined for inventory management at all levels, aimed at ensuring secure storage and distribution throughout the supply chain.
5. Begin system implementation by pilot testing it in sites already providing ART. As part of system rollout, develop job aids to enhance daily workload of health workers in using and maintaining system
6. Ensure that final system is owned by and closely linked with all other MOH systems (HMIS, NMS etc)

7.5 Inventory Management, Storage and Distribution

Recommendation 9: Develop mechanism for ARVs to be stored and distributed through NMS

Action Items

- 1.** Develop a service agreement with NMS to outline performance measures for storage and distribution of ARVs through NMS. Agreement should include consideration of: storage criteria to ensure security and quality, frequency and mode of transportation, mechanisms for responding to requests from implementing sites and mechanisms for obtaining allocation lists for distribution from MOH counterparts, along with all other components of the agreement
- 2.** Conduct a rapid analysis of what markup should be agreed on for NMS to store and distribute ARVs. Currently most programs pay 10%, while MAP pays 6.5%. Given the high value of ARVs, a much lower percentage will need to be negotiated, although not so low as to prevent NMS from effectively providing the service
- 3.** Another issue to consider in developing the service agreement is how NMS will be payed, both for storage and distribution but also for drugs themselves by implementing sites

Annex I

Scope of Work

ARV Logistics Technical Assistance

February 24 – March 4, 2003

March 17 – March 28, 2003

Anti-Retroviral Task Force - Technical Assistance Consultancy

Background

In November 2002, the AIDS Control Program within the Uganda ministry of Health established a multi-sectoral and cross-discipline Anti-Retroviral Task Force in order to guide the Government of Uganda and the Ministry of Health on introducing and expanding Anti-retroviral therapy (ART) in both the public and private sectors. The Task Force reports to the ministry of Health and is chaired by Dr. Peter Mugenyi of JCRC. The Task Force consists of five sub-committees; Policy, Clinical Care, Advocacy, Logistics, Finance, and Coordination. Steve Wilbur of DELIVER is chairman of the Logistics sub-committee and DELIVER staff participates in the Policy and Finance committee meetings.

The various sub-committees have been quite active and have met regularly over the past three months. Key decisions are in the process of being made. With preliminary recommendations on key policy issues emerging from each new meeting.

The Logistics group has collected most of the available material on ARV services currently in the country. It has also actively challenged the other sub-committee to define and finalize key policy issues that must be decided before final decisions and final quantification can be done.

One immediate goal of this process to define ARV national policy is to assist the MOH/GoU in the preparation of a major project proposal to be submitted to the Global fund for AIDS, Tuberculosis and Malaria (GFATM) in round three, anticipated in April 2003. For this submission, it will be necessary to include both proposed policies and procedures for ART treatment, as well as quantification for commodities to be requested under the GFATM project.

In addition to an anticipated request for ARV commodities from the GFATM, there is an immediate opportunity for the MOH to acquire several million dollars worth of ARV drugs through the MAP Project. The MOH and DELIVER are presently doing quantification for these drugs, with commodities possibly arriving in Uganda by July/August 2003.

Yasmin Chandani has worked with HIV/AIDS and ARV logistics for the DELIVER Project for the past several years. She has recently participated as the logistics specialist on the Kenya ARV Assessment reviewing, working with Peter Mugenyi or JCRC to produce a comprehensive policy issues document for NASCOP/Kenya. She has also worked closely with the ACP section in Uganda on HIV test Kit, STI and OI quantification, so knows the MOH program in Uganda well.

General SCOPE of Work

To assist the ARV Logistics and procurement sub-committee to document relevant logistics information and key policy decisions available to date , to identify outstanding critical issues that still must be addressed and help plan additional work that the logistics sub-committee must complete. This assistance is needed because the sub-committee individual members do not have sufficient unplanned time to accomplish these tasks, which needed to be completed within the coming month.

Specific Scope of Work

1. Meet with the Logistics sub-committee members and relevant participants to gather and verify key logistics information and decisions already made.
2. Help define other logistics information that is needed to design an ARV logistics procurement and distribution system.
3. Help the sub-committee define whether a specific logistics assessment is needed or whether a larger review including logistics issues would be more appropriate.
4. Prepare a written document addressing the above issues and de-brief the sub-committee.
5. Collect information on HIV test Kit procurement and planning and PMTCP Nevirapine planning as it might effect ARV distribution.
6. Help finalize MOH quantification and purchasing requirements to be made to the MAP/WB Project for ARV commodities.
7. Help plan the TOR for a subsequent logistics assessment or for a logistics component in a larger countrywide ARV readiness assessment if required.
8. Participate in a planning session with AIM, the Services Project, CMS and USAID on logistics issues and coordination at the district level, with particular reference to ARV introduction on March 4th.
9. Prepare a draft report and de-brief the sub-committee and USAID.

Annex II Schedule of Activities

Monday 24th February

Owen Smith, PHR+ Abt Associates, Consultant to Finance Subcommittee

Tuesday 25th February

ART General Task Force Meeting

Wednesday 26th February

Dr. Catherine, PHR+ Abt Associates, Consultant to Policy Subcommittee
Marty Makinen, PHR+ Abt Associates, Consultant to Policy Subcommittee
Dr. Elizabeth Madraa, Programme Manager, ACP/MOH
Dr. Zainab Akol, VCT Manager, ACP/MOH
Dr. Elizabeth Namagala, ARV Manager, ACP/MOH

Thursday 27th February

Dr. Elly Katabira, Consultant Physician/Mulago Hospital and Chair of Clinical Care Subcommittee
Dr. Phillipa Msoke, Chief Paediatrician, Mulago Hospital/Johns Hopkins University Clinic
Martin Shiere, TASO Private Sector Consultant
Logistics Subcommittee meeting

Friday 28th February

Suzanne McQueen, USAID
Dr. Elizabeth Namagala, ARV Manager, ACP/MOH
Sailesh Savani, CEO, The Lynx Group (by phone)

Saturday 1st March

Clinical Care Subcommittee Meeting
Marty Mackinen, PHR+ Abt Associates, Policy Subcommittee consultant

Monday 3rd March

Kate Kikule, NDA
Francis Otim, NDA

Tuesday 4th March

Dr. Peter Mugenyi, Head JCRC, Chair/ARV Task Force (by phone)

5th March – 16th March (not included in consultancy)

Monday 17th March

Dr. Elizabeth Namagala, Secretary, ARV Task Force all subcommittees

Tuesday 18th March

Dr. Elly Katabira, Consultant Physician/Mulago Hospital and Chair of Clinical Care Subcommittee
Dr. Phillipa Msoke, Head Paediatrics Dept, Makerere University and Head Paediatrician Mulago Hospital/Johns Hopkins University Clinic (by phone)
Constance D, Head of Labs, Mulago Hospital, Johns Hopkins University Clinic
John Omiat, Procurement Officer, UAC HIV/AIDS Project, MAP
Dr. Alex Opio,

Wednesday 19th March

MOH meeting on "Health Supplies Procurement Meeting: In the spirit of SWAp."

Thursday 20th March

Mrs. S. Okui, Acting Chief Laboratory Technologist, Central Public Health Laboratories

Friday 21st March

Dr. Elizabeth Namagala, ARV Manager, ACP/MOH
Dr. Zainab Akol, VCT Manager, ACP/MOH

Monday 24th March

Joseph Mwoga, Regional Pharmacist, Pharmacy Section, MOH
Dr. Elizabeth Namagala, ARV Manager, ACP/MOH (by phone)
Mr. Joseph Serutoke, Logistics Advisor, WHO (by phone)
Raveena Chowdhury, Technical & Logistics Advisor, Reproductive Health, MOH

Tuesday 25th March

Tom Brown, Crown Agents
Logistics Subcommittee meeting

Wednesday 26th March

Field visit to Masaka, "Uganda Cares" HIV/AIDS clinic (provides ARVs, VCT and other HIV support services)
Annik Hamel, Global Coordinator for Access to Essential Medicines, MSF
Catherine Hamel, Country Rep, MSF

Thursday 27th March

Finance Subcommittee meeting
Dr. Elizabeth Namagala, ARV Manager, ACP/MOH (by phone)
Dr. Zainab Akol, VCT Manager, ACP/MOH
Suzanne McQueen, USAID
Vastha Kibirige, Condom Coordinator, ACP/MOH

Friday 28th March

Annex III
LIST OF ACCREDITED CENTERS AND PHARMACIES
AUTHORIZED TO DISTRIBUTE ANTIRITRIVIRALS

LIST OF AUTHORIZED PHARMACIES AS OF FEBRUARY 2003

Importers

1. Medical access
2. National medical stores
3. Joint medical stores
4. Joint clinical research center
5. Star pharmaceuticals
6. Shurik
7. Mednet (U) LtD
8. Surgipharm (U) Ltd

Retailers

1. René pharmacy
2. City pharmacy

Accredited Center

1. Public health institutions
2. Mulago national referral hospital
3. Mbarara university teaching and referral hospital
4. Mbale regional hospital
5. Gulu regional hospital
6. Arua regional hospital
7. Kabale regional hospital
8. Masaka regional hospital
9. Soroti regional hospital
10. Makerere university hospital
11. Kalongo hospital

PRIVATE AND NGO HEALTH INSTITUTIONS

1. Joint clinical research center
2. Midmay international center
3. Nsambya hospital
4. Rubaga hospital
5. Mengo hospital
6. Lacor hospital
7. St.joseph kitgum
8. International medical center
9. Case medical center
10. Victoria medical center
11. Kololo hospital
12. Kadic medical center
13. Africa air rescue (AAR)
14. Bank of Uganda staff clinic
15. The surgery

Annex IV

Results of ARV Quantification

Annex V
Options for Implementing a Logistics Management
Information System for ARVs, as part of an expanded ART
Programme for Uganda

To come later....

Annex VI
Report from site visit to Masaka Regional Hospital ARV
Treatment Center
March 26, 2003

Masaka hospital ART center

Masaka hospital is a regional hospital with accreditation to provide ART services. It has a center, which is as a result of partnership of various NGO's, MOH, District local council. The center treats 100 patients both adults and children. It has got two medical doctors, one nurse who handles the store, dispenses and keeps the records, one laboratory staff employed by AIC. The center has one PC for data management. The clinic runs twice a week and patients get laboratory tests three times a year.

The partners have got different roles they play; AIC carries out VCT and recommends the individuals to TASO, Nsanbya hospital and other local NGO's. The NGO's then identify and recruit patients. Patients are thereafter screened for eligibility based on clinical criteria after which treatment commences.

Criteria for eligibility:

Cd4 count of less than 150

Masaka based

Strict adherence to schedule

The center stores the ARV's on site under tight lock and key with only one person in charge of keys (Nurse) and the same person dispensing the drugs. In order to avoid leakage, the nurse keeps records of the patients who receive the drugs, which is crosschecked by the prescribing medical officer one the same day. Thereafter a physical inventory is conducted.

In order to follow up on the habits and adherence to taking the medications, patients are required to return the empty bottles of the drugs. This is deemed useful in two ways.

1. To see whether the patient actually swallowed all the medicine and if some is remaining then ascertain what actually happened and avoid reoccurrence
2. To ensure that the medicine is not ending up elsewhere

Overall there were no stock outs of drugs reported and adherence was reported over 90%

The Masaka Hospital situation is a good example of a successful program for ART that could be emulated.