Rapid Assessment Report- Uganda

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August 13-19, 2005

PRESIDENT'S MALARIA INITIATIVE

In late June 2005, the United States Government (USG) announced a new five-year, \$1.2 billion initiative to rapidly scale up malaria prevention and treatment interventions in high-burden countries in sub-Saharan Africa. The goal of this Initiative is to reduce malaria-related mortality by 50% after three years of full implementation in each country.

This will be achieved by reaching 85% coverage of the most vulnerable groups---children under five years of age, pregnant women, and people living with HIV/AIDS---with proven preventive and therapeutic interventions, including artemisinin-based combination therapies (ACTs), insecticide-treated bed nets (ITNs), intermittent preventive treatment (IPT) of pregnant women, and indoor residual spraying (IRS).

The Initiative will begin in three countries in 2006: Angola, Tanzania, and Uganda. In 2007, an additional four countries will be added, and in 2008 another four will join. Funding will begin with \$30 million in FY06 for the initial three countries, increase to \$135 million in FY07, \$300 million in FY 08, and reach \$500 million in FY10, with the aim of covering a total population of 175 million in up to 15 countries by 2010.

In implementing the U.S. Government component of this Initiative, the U.S. is committed to working closely with host governments and within existing national malaria control plans. Efforts will be coordinated with other national and international partners, including the Global Fund to Fight AIDS, Tuberculosis, and Malaria, Roll Back Malaria, the World Bank Malaria Booster Program, and the non-governmental and private sectors, to ensure that investments are complementary and that Roll Back Malaria and Millennium Development goals are achieved.

A. General Background: Uganda

Epidemiology of Malaria in Uganda: Malaria is endemic in 95% of Uganda. The remaining 5% of malaria transmission lies in the highlands of the South West and East, which are epidemic-prone. Malaria is the leading cause of morbidity and mortality, accounting for 39% of out patient's visits at health facilities, 35% of all hospital admissions and 14% of all hospital deaths. Nearly half of hospital in-patient deaths were to children under 5. Current estimated annual numbers of deaths from malaria range from 70,000 to 100,000. Cases of malaria have been increasing in recent years, with fever cases in 2004 estimated to be 65 million.

Health System Infrastructure and Service Delivery

While there has been some progress made in treatment and prevention efforts, timely treatment for malaria remains a problem. The first course of action for nearly half of caretakers is self-medication, with only a quarter of caretakers seeking treatment at a health facility. To address this problem, Uganda has been implementing the Home Based Management of Fever (HBMF) program, which is designed to put malaria treatment into the hands of caregivers. Community volunteers in the implementation districts distribute prepackaged, age-specific, "Homapak" malaria treatment kits to mothers/caregivers of young children, with

instructions on proper use. A 2003 evaluation of the HBMF program found an increase from 7.3% in 2001 to 39.2% of children receiving treatment within 24 hours in the 9 districts receiving the HBMF intervention¹. The NMCP in April 2005 reported a further increase to 55% of children nationally. Home based management of fever has been scaled up and is now being implemented at community level in 47/56 districts, greatly increasing access to early and correct treatment for malaria. IPT is being implemented in all health facilities that offer antenatal care services, reaching national coverage of about 30%². While household ownership of any type of net has increased over the past five years from 13.2% to 25.9%, and the proportion of children under 5 sleeping under a treated net also increased to about 15%, there is still clear need to increase coverage, particularly of insecticide-treated nets (ITNs) and long-lasting insecticide-treated nets (LLINs).³ Indoor Residual spraying has not been implemented in Uganda for a number of years, however there is a plan to begin a spray program targeting the highland districts at risk of epidemic malaria using GFATM funds.

Government: Within the formal government health sector, preventive and curative malaria interventions have been incorporated as part of the Minimum Health Care Package delivered at the primary health care level. Primary health care centers have responsibility for delivery of malaria services through IMCI and mobilization of communities and other partners to address malaria locally. At the district level, primary duties include planning, resource allocation and management, as well as oversight of all facilities in the district, including those operated by NGOs (mainly FBOs) and the private sector. Districts are decentralized to a large degree and make their own health plans and budgets. The MOH and RBM partners strengthen the existing referral structure to improve access to treatment for severe malaria at higher level facilities. The National Malaria Control Programme at the central level supports implementation through policy formulation, setting standards and quality assurance, resource mobilization, capacity development and technical support, malaria epidemic control, and monitoring and evaluation. Health comprises 8% of GOU's national budget.⁴

NGOs and private sector: NGOs receive significant funds from the government through Primary Health Care Grants to provide outreach and preventive services at hospitals, district and local health care facilities. [2002] Health Facility Survey NGOs, including FBOs, distribute ITNs at subsidized prices or even free to vulnerable target groups, women and children.

The private sector plays a significant role in expanding access to effective treatment for malaria through direct service provision, pharmacies and drug shops, providing 70-80% of all malaria treatments. Private sector manufacturers and distributors produce equipment and supplies and serve as a source for ITNs to NGOs and to the rapidly growing retail market (total sales of ITNs in 2004 was 565,000).

Research and teaching institutions build pre and in-service training courses for personnel involved in malaria control interventions and promote evidence-based practices through focused operations research.

Major partners in malaria control:

In addition to government resources and funds channeled by international partners through budget support as part of the health SWAP, major direct contributors to the funding of the national malaria control strategy include multilaterals such as (WHO, UNICEF) and bilaterals including Department for International

¹ Fapohunda, B.M; Beth, A.P., et al (2004). The home based management of fever strategy in Uganda; survey report 2004. BASICS II/MoH/WHO/USAID, Kampala

² Achievement, Challenges and areas of Concern for National Malaria Control Programme for HSSP I, JB Rwakimari, April 2005.

³ UHAIS, 2004/5

⁴ Malaria Control Strategic Plan, 2001-2005.

Development/United Kingdom (DfID), USAID, Development Corporation of Ireland (DCI), and other health development partners, NGOs and the Global Fund.

Uganda has received two Global Fund awards to support malaria control and prevention programs⁵. The 2nd round GFATM grant in the amount of \$23 million contributes to scale up of home-based management of fever to all districts in the country, organization of a first round of free ITN distribution and net re-treatment, and start up of an IRS program in 3 districts (planned for 2005/06). Adding to this, the \$66 million 4th round GFATM grant will allow Uganda to introduce ACTs first at health facility levels and eventually also in the community and to sustain the ACT supply until 2009. GFATM funds will provide 1.8 million ITNs which are earmarked for free distribution.

USG partners and agencies in Uganda

USAID/Uganda has a long-standing malaria program in Uganda and has also been the largest bilateral donor for malaria in Uganda since 2000. USAID's implementing partners in malaria activities in Uganda include John Snow International (JSI), Johns Hopkins University Communications for Change Project (JHU/CCP), Netmark Project (AED), the Malaria and Childhood Illness Secretariat (MACIS) hosted by Africare, and in the recent past, Population Services International (PSI) and Research Triangle Institute (RTI). Through its contract for the UPHOLD project via JSI, USAID/Uganda also has sub-contractual relationships to the Malaria Consortium.

CDC has an office in Uganda based in Entebbe at the Uganda Virus Institute. CDC/Uganda works primarily in HIV under the President's Emergency Plan for HIV/AIDS Relief (PEPFAR). CDC supports a number of programs through NGO's. As part of their home based care program, CDC is delivering ITNs to HIV/AIDS infected individuals. Presently, CDC has engaged the services of AMREF, an NGO, which is conducting a refresher training for laboratory personnel to improve their technical competencies in doing malaria, HIV and tuberculosis diagnosis as well as managerial skills in data management to improve their estimate of laboratory reagents ordering.

Other donors and international partners: DfID is one of the major donors with contributions to malaria programs, working largely through direct funding to the "basket", in addition to some project funding via the Malaria Consortium. The DCI also supports malaria programs, again via the Malaria Consortium. Although GTZ has made contributions to research work in the past, current support remains limited. WHO is funding training of trainers for Indoor Residual Spraying, and has been an active participant in supporting Uganda's malaria efforts. UNICEF contributes to some ongoing activities related to malaria, although this has not been a major focus for them in Uganda recently. World Bank funding is available to the government for malaria control within their IDA funding envelope.

National policies, strategic plans and guidelines:

The National Malaria Strategic Plan and the Health Sector Strategic Plan II prioritize two main areas of intervention; i) Improving case management of clinical malaria through highly effective, artemisinin-based combination therapy delivered at health facilities as well as at the community/household level through homebased management of fever; and ii) malaria prevention using a combination of insecticide treated nets (ITN), indoor residual spraying (IRS) and environmental management (where feasible). This approach is

⁵ In early September 2005, the GFATM temporarily suspended implementation of these grants, pending reorganization of the Project Management Unit within the Ministry, which had been charged with implementing the grants. As of this date, the Government has taken concrete actions to resolve this issue, and it is likely that the grants will get back on track.

complemented by prevention and treatment of malaria in pregnancy, forecasting and prevention of malaria epidemics, and sound monitoring & evaluation of implementation and impact.

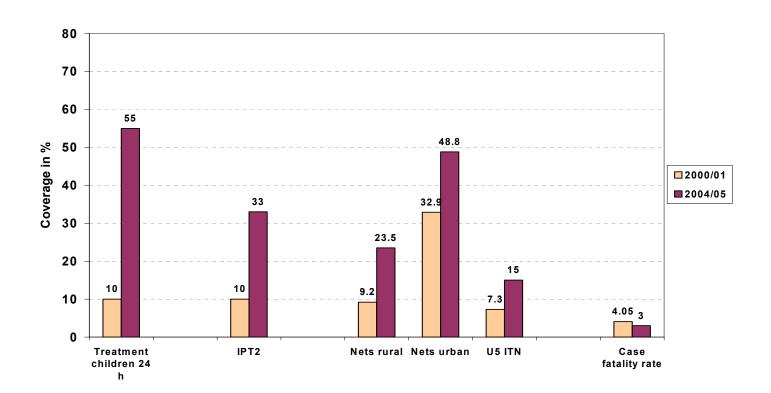
Five targets have been set by the Uganda National Malaria Control Program as part of the five-year national malaria control strategy:

- To increase the proportion of the population at risk of malaria who receive appropriate treatment for malaria within 24 hours of recognition of symptoms
- To increase the proportion of pregnant women receiving IPT to 60%
- To increase the proportion of children aged less than five years regularly sleeping under ITNs to 50%
- To reduce malaria case fatality rate at hospital level from 4.05% to 3%.

Uganda has several strategy documents that support treatment and prevention of malaria: Antimalarial drug policy change from CQ/SP to Artemisinin Combination Therapy (2004); Malaria in Pregnancy Control (2000); Home Based Management of Fever (2002); Policy and Strategy for Insecticide Treated Nets (2003); and Policy and Strategy for Indoor Residual Spraying (in final stages).

In April 2005 the NMCP prepared a summary table of results to date in terms of the major malaria indicators, which is reproduced below.

Figure 1 **Progress of Key HSSP I Indicators: 2000/2001 to 2004/2005**



Coordinating mechanisms:

Roll Back Malaria: As a signatory to the Abuja Declaration, Uganda has established country-specific objectives which focus on increasing treatment access for children and pregnant women, expanding the number of persons at-risk sleeping under bed nets and improving detection and response to malaria epidemic. RBM partners have supported interventions, operations research, and monitoring &evaluation, including two surveys to establish baseline data from which to build interventions and a country assessment to evaluate progress towards achieving Abuja targets.

Inter-Agency Coordination Committee for Malaria (ICCM): The ICCM provides a forum at the national level for all stakeholders to coordinate malaria control plans and activities and monitor progress against objectives and set targets. Members include the major donors (USAID, DfID, DCI, WHO, UNICEF), NGOs, Ministry of Health representatives, and the private sector. Five technical working groups have been established as part of the ICCM; vector control/ITNs; malaria case management; information education and communication; malaria in pregnancy; monitoring, evaluation and research.

Monitoring and Evaluation:

A survey supported by Roll Back Malaria partners was conducted to establish baseline data for interventions and a country assessment was carried out to evaluate progress towards achieving Abuja targets. A round of efficacy studies on antimalarial medicines were conducted in 7 sentinel sites. Insecticide susceptibility monitoring as an ongoing part of surveillance has also been carried out in 7 sentinel sites. A surveillance system to assist in detecting epidemics has been established in two epidemic prone districts (Rukungiri and Kabale) as part of the Highland Malaria project.

Operations research

There are very high priorities for operations research with regard to transition of first line treatment to ACTs within the HBMF program, and for delivery of ACTs through the private sector. In addition, as ITNs are rolled out and quickly scaled up over the next several years — using a combination of free distribution and the commercial sector, there may be need for careful monitoring of this roll out and the implications for use of ITNs and the sustainability of the private sector in ITN delivery for the long run. Makerere University in Kampala has demonstrated capacity and experience in carrying out operations research in a range of health areas.

B. Preventive Interventions:

ITNs in Uganda: Key Points

- Segmented Market Approach
 - Free distribution (in North IDP camps, via GFATM)
 - Subsidised sales
 - o Commercial sales: 565,000 nets sold in 2004
- Retreatment campaigns
 - o 20 of 56 districts have conducted successfully
 - o about 74% of nets needing treatment were treated
- Shift to LLINs
 - o□ 59% of nets sold in 2004 were LLINs

ITNs:

Uganda has an well-thought-out and comprehensive ITN program, with a historical focus on commercial sector participation. Trends show increasing awareness of ITNs, increasing volume of nets owned, increasing proportion of nets are provided by commercial sector, and an increasing proportion LLINs relative to ITNs or untreated nets.

Current indicator status:

% of households with at least 1 net of any type (treated and untreated)

o 2000: urban= 35.6%, rural=10.5%

o□ 2004/5: Overall: 25.9% urban=60.1%, rural=20.5%

% of households with an ITN/LLIN (end 2004 estimated range):

- o between 12-22% rural
- o between 24-35% urban
- o (note: the ITN figures are estimates from Albert Kilian based on LLIN sales, net retreatment data and net ownership data, and are thus presented as a range rather than a point estimate)

% of children under-5 sleeping under an ITN:

- 2000: 7.3%
- 2004: 15% (2004 AIDS Indicator Survey)

Net distribution pattern in Uganda:

Uganda uses a segmented market approach to distribution of mosquito nets. Broadly speaking, this includes (1) commercial sector nets sold at market prices to anyone, (2) subsidized sales of nets to specific populations (IDPs in the North, pregnant women, children under 5, People Living With HIV/AIDS), and (3) nets distributed free to specific vulnerable populations (pregnant women, children under 5, People Living With HIV/AIDS).

Commercial Sector: Over the past 5 years, serious effort has been put into stimulating the commercial sector to fill as large a role as possible in net supply. For example, PSI has followed a policy of withdrawing from sales of their branded nets from markets in which the commercial sector is active in supplying a quality product. In this manner, PSI, which typically receives significant donor funding to support operational costs, does not compete on unfair terms with the commercial sector distributors. Hence, PSI no longer competes against commercial net distributors or retailers in Kampala and a couple of other major urban centers in Uganda. PSI now takes a role of a development organization facilitating the growth and expansion of the commercial sector while serving populations with limited or no access to commercial nets. At the current time there are very few, if any, formal net manufacturers in Uganda, with most nets imported from Tanzania or SE Asia. In addition, institutional sales of nets in Uganda are made from domestic distributors; thus nets are no longer sold to NGOs by PSI, for example. Vestergaard-Frandsen has opened a distributor outlet in Uganda for its "PermaNet" brand. This partnership with the commercial sector was dealt a serious blow by the change in the MOH policy regarding the planned distribution of nets funded by the Global Fund. The decision was made to cancel the provisions of the Round 4 proposal for an ITN voucher scheme and replace it with a plan for free distribution of the nets. This change imposed from the top, resulted in a major delay in the procurement of the nets (the tender should be awarded in late August 2005), and has created a lot of uncertainty in the commercial sector regarding further investment in net distribution capacity.

The commercial sector supplied 565,000 nets in 2004, including both market and institutional sales to NGOs. About 61% of these sales were by the commercial sector and 26% through social marketing by PSI, (largely the subsidized sales in the north- 21.5% rather than the cost-recovery sales- 4.5%). The Government's projections for future coverage assume that the commercial sector will continue to supply this volume of nets.

Subsidized Sales: PSI sells Permanets at a 50% discount in conflict areas of northern Uganda with funding from USAID (price 5,000 Ugs). The volume of sales is about 150,000 nets per year. PSI has a sophisticated tracking system to ensure no leakage of these nets into the markets. USAID/Uganda has just awarded a new social marketing contract which will also include ITNs/LLINs.

Free Distribution: Currently there are a number of NGOs distributing long lasting nets in IDP camps in the north, but our informants assert that coverage is still far from complete. Free distribution of ITNs has been supported by USAID and others in IDP camps in the North, in conjunction with food relief. Malaria Consortium data suggests high use and popularity of double-size ITNs in the IDP camps.

Global Fund Nets: GFATM Round 2 funds are purchasing 1.8 million ITNs (untreated nets bundled with insecticide kits) which are earmarked for free distribution. The tenders are closing in late August 2005, and delivery is anticipated to be in December 2005. Local women's councils have been identified to draw up the lists of eligible households to receive the free ITNs. It is not clear to what extent, or whether any support or training for the women's councils has been planned to assist this process. Support to ensure comprehensive and equitable lists may be needed, as well as assistance in the logistics to ensure effective and equitable distribution.

Re-treatment campaigns

Very successful retreatment campaigns have been conducted, first round coverage estimated at 74% of nets in the area needing retreatment (estimated at 70% of existing nets). Following these campaigns, another 20 of the 56 districts have conducted retreatment campaigns, and all districts have plans to do so.

Shift to LLINs:

The national programme is now focusing on shifting from bundled nets (untreated nets packaged with an insecticide kit for treatment of the net) to LLINs. Uganda has an increasing proportion of LLINs in its net crop, but problems in availability from manufacturers is constraining the movement to LLINs. For example, the 1.8 million nets from Round 2 were originally intended to be LLINs, but due to procurement shortages from the factories, have had to be tendered as bundled nets in order to have the nets arrive more quickly. (Note: this procurement may also have been affected by the GFATM suspension- at the moment the status of the tendering process is not yet clear).

Progress is being made, however: LLINs were 59% of nets sold in 2004, as compared to 51% in 2003. Vestergaard-Frandsen is expanding a distribution channel for its branded LLINs in Uganda, which it first opened 2-3 years ago. Olyset nets are now being produced by A-Z in Arusha, although production lags far behind demand.

Monitoring & Evaluation issues for ITNs:

The planning process for the 2006 DHS is now underway, with USAID/Uganda playing a major role in gathering partner input into the questionnaire design. The Malaria Module questionnaire will be included in the DHS, as well as questions on the type of net, to allow better quantification of the proportion of the "net crop" in Uganda which is currently LLIN. The London School of Hygiene and Tropical Medicine recently designed and tested such a tool which will be used to gather this data.

Gaps in ITN program:

- 1. There is an urgent need to implement the Roll Back Malaria ITN strategy for a comprehensive approach to ITN distribution- using social marketing and developing the commercial market in conjunction with the MOH planned distribution of free nets. The free nets could be used to prime the market, but will be insufficient numbers for maintenance for the long run. Effective market segmentation is necessary to keep free nets available to those who need them, and a graded subsidization for those who can afford to pay. Uganda will need nets to be available through other means for the long run for replacement nets (in 3-4 years time) and to meet the needs of new babies and pregnant women. Also urgently need to monitor impact of free distribution of nets on market leakage and use of nets.
- 2. A credit facility has been proposed to assist small CBOs and FBOs to access highly-subsidized or free ITNs for distribution. This would provide an ongoing mechanism for continued availability of subsidized nets in rural areas. This issue should be followed up during the Planning Visit in October to get more specifics.
- 3. Distribution systems and mechanisms for getting from the district level to end users are weak. Need to quickly develop routine and sustainable approaches to moving nets to the communities. Suggestions include using community drug distributors, providing support to facilitate effective distribution of the Round 2 nets to target population by the parish women's councils. This will require training and collaborative planning to ensure a smooth distribution process and minimum leakage of nets to non-target populations.

- 4. Given the policy of local procurement of ITNs, USAID needs to explore the options for large-scale importation of LLINs prior to making procurement arrangements via UNICEF. In addition, a buffer stock of ITNs is needed—there is not a buffer stock of LLINs built into the GF round 5.
- 5. Prevention of infection in the IDP camps needs more attention. This includes both ITN provision to households living in the camps and in nearby villages, as well as IRS or ITNs in the shelters used by the night commuters.

IRS in Uganda

- Targeted spraying in epidemic-prone districts
- Potential for use in Northern districts for IDP "night commuter" shelters and IDP camps
- Phased approach to build capacity
 - o 3 districts in first year
 - synthetic pyrethroid insecticides in first vear
 - Operational assistance from USAID for program management, training and logistics
 - o□ Review of insecticide choices before 2nd vear
 - Capacity to prevent leakage of DDT into export agriculture
 - Insecticide resistance levels
 - House wall types in target areas
 - Risk mapping for selective

IRS:

National Strategy:

Large-scale-IRS has not been done since the 1960's. While there is a national strategy which incorporates IRS, a more detailed planning process is needed to organize any new IRS initiative. The plan could discuss: implementation, M & E, criteria such as transmission situations that would benefit from IRS (versus ITN s), technical and operational issues, eg. safety, that attend large scale use of insecticides, environmental issues etc. There has been some recent IRS activity, on a limited/local scale, in Uganda: (1) MSF - in certain IDP camps; (2)GOAL (an Irish NGO) - in IDP camps; (3) MOH - in response to malaria epidemics - carried out by a central team that mobilizes, trains, supervises and manages the activity.

The MOH is planning IRS for populations in 'epidemic-prone areas', where vector biting rates are lower and compliance with nightly use of ITNs less likely. The same strategy, based on epidemiological characteristics, is supported by WHO / Uganda. The GFATM Round 2 proposal provides funds for IRS activities in the highlands of SW and E Uganda (due to the presence of low, and partially unstable malaria transmission). Additionally, areas in districts surrounding the highlands with low-moderate malaria transmission and low perceived vector

biting levels will also be targeted. Projected eventual coverage is 20% of the total Ugandan population by expanding from 3 districts, sprayed as a result of GFATM Round 2 to a total of 15 districts. This plan anticipates the spraying of some 1,000,000 to 1,500,000 households/ spray round. Another area targeted for IRS is in the north of the country, an area where malaria is endemic, due to the presence of approximately 200 displacement camps (IDPs) with a population of 1.3 million people. In particular, the large, often open, structures used by the "night commuters" to sleep in were discussed as a likely spray target. A third target for IRS is boarding schools, hospitals and other institutions. A discussion of all these options in one plan would provide a better picture of the role of IRS in malaria control, the logistical needs of the program etc. - allowing planners to program sufficient resources

The GF program management unit has begun procurement of IRS – related commodities with Round 2 funding: 800 sprayers with spare parts (not Hudson due to cost and GOU restrictions against sole source procurement); insecticides (deltamethrin, alpha-cypermethrin, lambda-cyhalothrin) in sachet form for use with sprayers. The cost is approximately \$100,000, the status of this procurement given the suspension of the Project Management Unit operation by the GFATM is uncertain at this time. The stated objective is to target 3 districts (80% coverage) as described previously. Delivery was scheduled for Nov-Dec 05. Training of spray teams to do IRS was not funded or discussed in the GF proposal. WHO is scheduling a training of trainers course for IRS. IRS is labor intensive and requires well trained and well supported teams.

<u>IRS Operations Support</u>: IRS requires routine spraying Safe, effective, motivated, well-trained spraying services (generally presented as managed from the District level) are central to the sustainability of this program. At present, the limited capacity to mount and manage an effective IRS program was one of the key gaps identified by the NMCP and the assessment team. In addition to trained and equipped 'spraying brigades', the NMCP will need technical units to support IRS; monitoring and evaluation teams to verify correct insecticide dosage on walls, verify duration of insecticidal effect (for timing of subsequent spray cycles), and monitor vector insecticide susceptibility. NMCP will need support to develop and maintain such expertise.

Training and communication programs are also needed. Several NGOs have experience with community communications issues such as public awareness. However IRS programs, unlike ITN programs, are generally not community-based and require direct involvement of teams that are trained and supported from the center, or a combination of center and district. These do not exist in the Uganda. That said, the MOH has conducted IRS for epidemics, suggesting that they have some capacity. Contracting with existing African IRS programs (eg.the MRC in South Africa, or possibly private pest control companies) to conduct IRS operations and to provide training to MOH spray teams could be an area for PMI support. The WHO vector specialist also raised the issue of vector control based on integrated vector management. IVM will be based on ITNs, IRS and larval control depending on local eco-epidemiological evidence.

IRS regulatory Issues: IRS regulatory and oversight issues are also being discussed within the MOH. Among these, (1) Quality control - the National Drug Quality Control Laboratory (NDQCL) of the National Drug Authority (NDA), has been charged with the responsibility of conducting quality assurance of all "public health chemicals", including insecticide to be used for spraying that are imported or produced within the country. NDQCL does not have the equipment or capacity to carry out this responsibility at present. (2) vigilance programs - to insure that insecticide stocks are stored and handled correctly, the NDQCL has the responsibility, but lacks resources and capacity. (3) environmental clearance- discussed below. (4)

procurement-associated issues – arising from the high cost of insecticide for large scale IRS, and the way that the Ministry of Finance treats this commodity under the 'ceiling concept' for the MTEF.

IRS and Technical Issues Related to Insecticide Use:

Environmental impact assessment: There is interest at the political level of the MOH in the use of DDT for IRS. Some environmental assessment studies have been commissioned. However, incomplete data is currently available to address some concerns associated with DDT use in Uganda, as well as for other insecticides. Baseline studies need to be implemented and considered as part of the national plan for IRS which takes into consideration epidemiological, operational and environmental points of view. Some work has been contracted by the MOH. While the results are not yet available, it seems likely that that a supplementary environmental impact review will be necessary for USAID procurement of insecticide should that be necessary in the future (assuming GFATM resources can purchase insecticides for the near term). Such a review is planned for late 2005, under an existing USAID contract with Research Triangle Institute (RTI). The review will cover a range of potential IRS insecticides, including DDT. Strong safeguards against leakage into the agricultural sector will be needed (since contamination of export crops could cause devastating economic consequences for Uganda's exports to the EC). That said, in the north, where IDP camps are located the threat of pesticide contamination would be lower due to lack of export agricultural activity.

Vector insecticide susceptibility surveillance. Large scale use of insecticides (ITNs and IRS) raises the possibility of selection for vector insecticide resistance and control failure. The MOH has conducted vector insecticide susceptibility tests using the WHO bioassay (the tube test) on geographic populations of An. gambiae s.l. Tests for susceptibility to deltamethrin, permethrin and DDT were carried out. Only a verbal summary of the results has been obtained, but this indicates that based on the criteria of mortality at 24 hour post exposure in the WHO test, test mosquitoes were susceptible to the three insecticides (100% mortality). Based on the criteria of time to knock down of 50% (KD₅₀) of the mosquitoes, the data show evidence of some reduction in the DDT susceptibility of some populations. In a second line of testing, based on biomolecular testing to detect genes associated with knock down resistance – a mechanism for DDT and pyrethroid resistance- presence of kdr/sodium channel genes in Uganda An. gambiae s.l. was confirmed. This mechanism has been reported elsewhere in East Africa as well. Implications for IRS efficacy are not clear, but suggest that DDT resistance might develop quite quickly in this mosquito population. At the technical level in the Ministry, where the results were discussed, the thinking was that the data argued for IRS based on synethetic pyrethroids, with any consideration alternative insecticides being postponed until later, pending the experience with IRS and pyrethroids. The current GFATM tender for IRS insecticides has been done for synthetic pyrethroids on this basis, with a tentative delivery date of December 2005.

Gaps & Opportunities in IRS:

1.IRS Operational Support: The capacity to oversee and mount an IRS program is very limited at the MOH. Some support for operational issues and training has been included in the Global Fund grant (Round 2) but is likely insufficient. One of the major gaps identified by the NMCP and the assessment team was for the USG to assist the MOH develop the capacity to effectively plan and manage spray operations. This will require access to people with expertise and experience in spray operations. This could either be done by bringing in experienced staff to organize and implement spray operations, if some of the long term staffing constraints within the MOH can be resolved, or by subcontracting the organization and implementation of IRS out, while

developing a small oversight management capacity within MOH. The former option would require a large scale staff operation within the MOH.

2. Malaria Control in IDP camps: ITNs and IRS for IDP camps may be a 'jump start' option to consider. Currently, there is partial coverage in some camps with long lasting nets (LLINs). Complimenting these with additional ITNs (most likely bulk nets treated on site and retreated every six months - the waiting list for LLINs exceeds 6 months) could be an option to achieve the high coverage goals of the PMI in a setting which has positive interest for the US Congress and the American public. Malaria mortality rates in the IDP camps are high (according to WHO study of health and mortality among internally displaced persons, July 2005). Malaria accounted for approximated 25% of all recorded deaths and nearly half of all deaths in the <5 yr age group. ITN coverage was low, 60% of household interviewed had no net. ITN coverage for the <5 age group ranged from 26-31%. The Malaria Consortium (MC) has data showing high use of ITNs in the camps, and indicated that houses were large enough to accommodate double-size ITNs.

MC also recommended IRS for the IDP night shelters which are used by displaced people on a temporary basis. IRS is also favored by the MOH and programmed for use under GFATM (Round 2) activities; IRS may be a more cost efficient system given the densely populated nature of the IDP camps and their remote location. IRS also removes the need for compliance – nightly use of an ITN is required for efficacy; no individual action is required in houses treated by IRS. IRS may also preclude the concern raised by a study (Albert Kilian data) suggesting that 20% of the nets which are given away are not unfolded (as opposed to purchased nets which have higher use compliance).

Malaria Treatment in Uganda

- New policy is artemether-lumefantrine
- Procurement via GFATM in progress (current status uncertain as of Sep05)
- Private sector has major role in treatment
 - o 70-80% of fever treatment
 - o Other ACTs are allowed in policy
 - Subsidy plan to increase access needed
- Home-based Management of Fever
 - Highly successful "Homapak" program
 - High priority for continuation with ACT included

C. Malaria Treatment

<u>Background:</u> Uganda changed its first line drug from Chloroquine (CQ) to CQ + Sulfadoxine Pyrimethamine (SP) in 2000. However, further efficacy studies carried out done in 2002 – 2004 showed increasing average

resistance to CQ + SP combination of 21.4%, whiles the resistance to Amodiaquine + SP and Amodiaquine + Artesunate to be 5.4% and 1.8% respectively. However, efficacy study of Artemether-Lumifantrine (Coartem) showed no clinical failure in 28 days. With the above results, Uganda has changed policy and adopted Coartem as its first line drug to manage uncomplicated malaria and Quinine for complicated malaria treatment.

<u>ACT Implementation:</u> Uganda is in the process of changing its first line treatment for malaria from a combination of CQ+SP to Artemether – Lumefantrine (AL) combination. Planning for this policy change has been ongoing since 2004 and implementation was originally planned for 2005. To support the implementation of the policy, Uganda successfully applied for a round 4 grant from the GFATM. Official implementation of the policy is dependent on the disbursement of funds from this grant. The five year grant was for US \$158 million (US \$66.4 million for the first two years). Approximately 87% of the funds from the grant will be used for the purchase of AL. The grant also provides some funding to support the strengthening of the procurement and supply management system and the training of 5200 staff in pharmaceutical management for ACTs in Year 1 of the grant with 3900 supervision over the next four years.

The current implementation plan for the new policy assumes a nationwide rollout. In preparation for the implementation, several task forces focusing on key intervention areas were established by the Inter-agency Coordination Committee on Malaria (ICCM). This included a drug procurement and supply management task force which included members from the NMCP, the Chief Pharmacist in the MOH, the NDA, the NMS, the JMS and the WHO. This task force was charged with quantifying the AL requirements and developing a procurement and distribution plan for the AL, developing a plan for phasing out of CQ, developing training materials on AL supply management, and proposing a long-term financing plan for ACTs.

The task force used malaria morbidity and population data based on the 2002 census to estimate the AL requirements for use in public and NGO health facilities (the assumptions used the same as those used for the GFATM Round 4 grant). The estimated requirements are listed in Table 1 below.

Table 1: Estimated number of doses required for Coartem for 2005 - 2007⁶

| Age (years) | Cost | # of Doses needed: 2005 | # of Doses: 2006 | # of Doses: 2007 |
|-------------|---------|-------------------------|------------------|------------------|
| 0 - 3 | \$ 0.90 | 11,721,099 | 7,694,994 | 6,962,046 |
| 4 - 10 | \$ 1.40 | 5,417,315 | 4,201,127 | 4,022,191 |
| 11 - 14 | \$ 1.90 | 1,477,449 | 1,955,434 | 1,572,603 |
| 15+ | \$ 2.40 | 6,032,919 | 7,984,688 | 6,421,464 |
| | | | | |
| Total | | 24,648,782 | 21,836,243 | 18,978,304 |

These estimated requirements are higher than the estimates in the GFATM Round 4 grant due to the expected year delay in the implementation of the new policy and raise the possibility of a shortfall in the ACT requirements when nationwide implementation begins. The GFATM grant in year one provides for the procurement of approximately 16 million treatment doses for all age-groups, while the revised quantification by the task force estimates a requirement of approximately 25 million doses, resulting in a potential shortfall of 8 million doses in Year 1.

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⁶ Task Force on Drug Procurement

Procurement of ACTs using GFATM funds will be done through WHO and the MMSS. WHO has an agreement with Norvatis Pharmaceutical Company (which manufactures AL under the brand name Coartem®), to provide Coartem at cost. WHO charges a 3% handling fee for managing the procurement, consistent with the Executive Board Resolution of EB33.R44 of the World Health Assembly. Uganda had put in an order with WHO for 15 million doses of Coartem in February 2005, and put in a disbursement request to the GFATM on August 2005 to pay for this order. The disbursement request has not been authorized and given the recent suspension of the Uganda GFATM grants, it is not clear at this time when this disbursement request will be honored. Given the shortfall in ACT availability worldwide, and the high demand from other countries, many of whom have also adopted AL as first-line treatment and are also procuring their AL from Novartis through WHO, it is not clear at this time when Uganda will receive the AL required and what quantities of AL will be available. Once received in country, the NMS will responsible for distributing the medicines to the public health facilities and the JMS will be responsible for distributing them to the NGO health facilities.

The Task Force has estimated that an additional 45 million doses of AL treatment will be required to meet the needs of the private sector in year one of implementation of the new policy. This reflects a cost of USD 382 million. At present, Coartem is available in the private sector US\$ $9-12^7$ which is more than most of the population can afford. Strategies to improve access to the ACTs in the private sector have not yet been determined and this has been identified as a major gap in ensuring access to treatment for a large segment of the population.

Pharmaceutical Management:

National Drug Authority: All pharmaceuticals marketed in Uganda must be registered with the National Drug Authority (NDA). The National Drug Quality Control Laboratory (NDQCL) department in the NDA is responsible for the quality assurance activities of the NDA have been operational since 1994. The Drug Registration System has been operational since 1997. As part of the drug registration process, the NDA is required to inspect each site that manufactures a final pharmaceutical product before the product is registered and every three years thereafter to maintain the registration. Separate registration required for co-packaged, coformulated and Fixed Dose Combinations (FDC) even if the mono-therapy products from the same company are already registered. Several artemisinin-based mono-therapy and combination products, including Coartem, have already been registered with the NDA and are currently available for sale in the country. The registered ACTs, as of August 2005 are listed in Table 2.

The NDA is also required by law to inspect all pharmaceutical products imported into the country. The NDA conducts a physical inspection of all medicines imported at their port of entry. Samples selected from each batch and tested if a problem is identified during the physical inspection. However, the law requires that each batch of antimalarials, anti-tuberculosis medicines and anti-retrovirals manufactured in the country or imported into country be tested before distribution. These three groups of pharmaceuticals have been singled out as they are considered to be of vital of public health importance. For imported products, it is estimated that the inspection and testing required prior to the issuance of a proforma verification certificate, takes a minimum of one week for each batch included in the shipment. In 2004, 57.3% of the 1064 medicines tested by the NDQCL were antimalarial medicines. The NDA is also responsible for post-marketing surveillance and pharmacovigilance of pharmaceuticals already in the market. Forms for this have been developed and circulated and NDA teams are currently in the field to sensitize practitioners on how to fill in the forms.

⁷ Task Force on Drug Procurement

Table 2: ACTs currently registered in Uganda

| Generic Name | Tablet Strength | Brand Name | Manufacturer |
|---------------------------|-----------------|----------------------------|--------------|
| Artemether + Lumefantrine | 20mg + 120mg | Coartem® | Norvatis |
| Artesunate + Amodiaquine | 50mg + 150mg | Amquanate® | Cosmos |
| Artesunate + Amodiaquine | 50mg + 150mg | Falcimon® kit ⁸ | Cipla |
| Artesunate + Mefloquine | 300mg + 375mg | Artequin® | Mepha |
| | | 300/375 | |
| Artesunate + Mefloquine | 200mg + 250mg | Artequin® | Mepha |
| | | 600/1500 | |
| Artesunate + Mefloquine | 200mg + 250mg | Artequin® | Mepha |
| | | 600/750 Lactab | |
| Artesunate + | 200mg + | Co-arinate® | Dafra Pharma |
| Sulfamethoxypyrazine / | 500mg/25mg | | |
| Pyrimethamine | | | |
| Artesunate + | 100mg + | Co-arinate® | Dafra Pharma |
| Sulfamethoxypyrazine / | 205mg/12.5mg | junior | |
| Pyrimethamine | | | |

Challenges: The main challenge facing the NDA is a lack of financial resources. Though there is a provision in the law for funding of this department from Ministry of Finance, in reality this has not been happening therefore the NDA is dependent on the fees generated from the registration and testing of products for its operating costs. The fee for inspection and testing of imported products is 0.5% of the value of the products. The NDA provides free testing for the first three batches of a product included in shipment, and charges for the testing of additional batches. To get around this requirement, importers limit their shipments to not more than three batches per shipment therefore incurring no fees for testing.

The NDQCL currently has three HPLC machines, and seven staff members who are trained to use these machines. The HPLC machines are in use seven days a week but the department requires at least one more machine to help reduce the backlog of testing required. It is anticipated that the large quantities of antimalarials that will be imported as part of the GFATM will further strain the system and this may become one of the main bottlenecks in the supply chain.

The NDA is also required to ensure the appropriate disposal of any expired pharmaceutical products. This presents a challenge as there is no government incinerator and the NDA has therefore contracted with a private firm to use their facility for a fee of Ushs 1525 / kg that is born by the institution that wants to dispose of the products. This is a less than optimal solution. The use of the private incinerator has been approved by Uganda national environmental agency for now.

Recent changes in the law will extend the responsibility of the NDA to cover what will be considered Public Health Chemicals. This will include chemicals used for ITNs and IRS. Until these chemicals were recently regulated by the Agriculture and Chemicals Board. An internal committee within the NDA has been established to develop guidelines for regulating these pesticides and this committee has already developed draft guideline forms. There is an immediate need to assess what is currently in the market and a stakeholders meeting is scheduled before beginning import control measures. The NDQCL does not have the capacity at present to test

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⁸ Available in two packages – one for Adults and one for Children

the quality of these products. Testing of the pesticides requires the use of gas chromatography equipment which the department lacks. There is some urgency in the need to strengthen the capacity of the NDA to regulate these public health pesticides as the tenders for the procurement of pesticides for IRS has been published as part of the procurements supported by the GFATM round 2 grant. These tenders require that potential suppliers be registered with the NDA which has since been bombarded by suppliers seeking registration of their products.

The National Medical Store: The NMS is a parastatal which is managed by both the MoF and the MoH. The mandate of the NMS is to procure, store and distribute pharmaceutical products. Procurement is regulated by the Public Procurement and Disposal of Assets (PPDA) Act, 2003. The normal procurement cycle is approximately 52 weeks. After selection of suppliers, framework contracts are signed are valid for two years. Procurement of CQ, SP and Quinine for public health facilities is currently the responsibility of the NMS. The current CQ+SP pipeline at the NMS is sufficient to meet the requirements for the next year. An additional supply for one more year is possible as part of the framework contract with the current supplier. The NMS is also managing supplies of Homapak, on behalf of GFATM and other projects. The last procurement for Homapak has already been done and no additional procurement planned at this time.

NMS also procures additional products for use as trading stock for cash sales to public sectors facilities and to the private sector. In additional to purchasing the antimalarials on the EML, the NMS recently purchased a limited stock, 2000 doses, of Artemether injection for sale to the private sector. They have not placed any additional orders as they anticipate a large influx of ACT from GFATM procurements though these supplies would not be available to the private sector.

The NMS is also responsible for the distribution of the pharmaceuticals to the districts. Delivery occurs every 8 weeks to each district for each district. For HIV treatment centers, delivery occurs every 4 weeks however this is only possible because there are only 100 HIV treatment centers compared to the 2000 public health facilities. As the procurement of most of the AL for use in the public sector is from the GFATM, the NMS will not be responsible for the procurement but will be responsible for the storage and distribution of the medicines.

The pharmaceutical supply system in the country operates on a pull system therefore each health facility is responsible for estimating and placing orders for its required quantities of medicines and other pharmaceuticals. This presents a challenge as the personnel within these districts lack the capacity to adequately quantify their requirements and manage their inventory appropriately. For the AL procured through the GFATM, the plan is to initially push out to all the health facilities a predetermined quantity of the AL, then revert to the pull system for additional supplies⁹.

A credit line of Ushs 4.2 billion provided by the GoU every four months is held at the NMS to support the provision of free pharmaceuticals on the EML to the public health facilities. This credit meets only 52% of the essential medicines requirements of these facilities. Each facility has a predetermined value limit that they can draw down as they place their orders for essential medicines and this limit determined by the MoH. When a facility exceeds its limit it must pay for any additional requirements it orders.

The NMS offers three alternative services for third parties for which they charge a minimum 10% handling fee. The third party can buy directly from the trading stock at the NMS; the NMS can become the procurement agent for the third party i.e. the NMS will procure, store and distribute the product on behalf of the third party;

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⁹ Report from the Task Force on Drug Procurement

or the third party handles its own procurement and NMS is only responsible for the storage and distribution of the products.

Challenges

The NMS is currently operating at near full capacity. It is anticipating the arrival of the AL procured through the GFATM grant but uncertainty surrounding the delivery schedule for these products is causing some anxiety as they can absorb no more than 3 containers of additional supplies at this time. They can contract with some pre-identified private facilities to provide additional storage space should this be needed but will require at least 8 weeks notice to prepare these additional warehouses and have them inspected by the NDA before they can be used to store pharmaceutical products.

Joint Medical Stores: This is a private non-profit organization that works closely with the MoH to supply essential medicines to the NGO sector. They rely on negotiated procurement, negotiating their purchases with pre-selected suppliers. Supplies are purchased every 3 – 4 months using the previous consumption to estimate the quantities required. CQ, SP and QU are purchased primarily from local suppliers though injectable quinine is obtained from local distributors (international manufacturer). The JMS has been having problems obtaining supplies of CQ as local importers and manufactures have started limiting their supplies of this product in anticipation of the policy change.

The JMS has been procuring artemisinin products since 1999. It currently has supplies of Artesunate tablets and Artemether injectables in stock. The Artesunate tablets are procured from DAFRA through a local distributor. These products are sold to the NGO sector and private commercial vendors. The pipeline of artemisinin products on 8/17/2005 is in Table 3. In anticipation of the GFATM procurements of ACTs, the JMS has no pending procurements for additional supplies of these products.

Table 3: Pipeline of Artemisinin products at the JMS

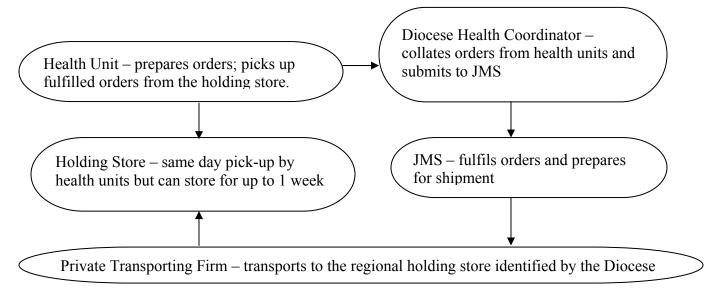
| to the brine of the termismin products at the gives | | | | | | | | |
|---|-----|-----------|---------------|------------|--|--|--|--|
| Item | | Current | Pending sales | Unit Price | | | | |
| | | Inventory | | (Ushs) | | | | |
| Artesunate 100mg tablet | 6 | 5457 | 1203 | 7,000 | | | | |
| Artesunate 100 mg tablet | 120 | 123 | 0 | 109,100 | | | | |
| Artemether 80mg/ml 1ml ampoule | 5 | 3353 | 330 | 8,800 | | | | |
| Artemether 80mg/ml 1ml ampoule | | 1107 | 142 | 9,900 | | | | |

The JMS currently follows a cash and carry policy. Catholic Medical Bureau and Protestant Medical Mission buy at a 5% discount, all other buyers qualify for the discount if they purchase medicines and supplies of at least US \$ 167,000 in a calendar year.

The JMS maintains a credit line on behalf of the MoH for the purchase of essential medicines (14 medicines on list) by predetermined NGO facilities. US\$ 556,000 provided for all the NGO health units every 4 months, and each facility receives \$100 every 4 months for some HC II facilities, up to \$17,000 every 4 months for the NGO hospitals.

The JMS will be responsible for the distribution of the AL procured by the GFATM to the NGO sector and normally charge a 10% handling fee for providing this service, though there has been no formal agreement on how this distribution will occur.

The JMS has just started testing a pilot distribution system this month in partnership with the Diocese Health Coordinators. They have divided the country into 4 zones – West, East, South, North, and have contracted a private transportation firm to transport the shipments to each of the 4 zones. The fee for the transportation is based on the volume of products transported. A standard transport box has been agreed on which costs Ushs 3000 to transport irrespective of the contents. 40% of the transport cost will be covered by JMS and the rest by the purchasing facility. Coordination of orders, and the payments at the district level is provided by the diocese health coordinators. The proposed distribution system is illustrated diagrammatically in the figure below.



The JMS also stock ITNs including LLINs (sold for Ushs 11,000), untreated nets and treatment kits. The pipeline for nets on 8/17/2005 was 1026 ITN Large (160cmx180cmx150cm) and 4 non-impregnated large nets. The nets are sold to the NGO health facilities and private retailers.

Home Management of Fever: The country has community-based malaria treatment program through which community volunteers are given pre-packed boxes containing antimalarial medication made up of CQ + SP (Homapak). There are three boxes, color-coded for the age of the child. The volunteers give these packages to mothers/caregivers in the community free to treat their children when they develop fever as a presumptive treatment for malaria. Homapak is now being implemented in 47 of the 56 districts in Uganda. It is the intention of the Uganda government to continue this program and improve its coverage but will change the present medication to ACT. The change to ACTs will require investments to ensure proper storage of the medicines and improve supervision of the volunteers. There is a plan to set up a pharmacovigilance system in the country to monitor safety and toxicity of ACTs including at the community level, and a major gap is to develop an effective approach to distributing ACTs within the HBMF program. WHO/Uganda reports that it has been proposed to start a pilot using ACTs at community level in about 3 districts next year, and the lessons learnt used for the roll-out of the interventions in the whole country.

As said earlier, the clinic attendance due to malaria has increased in the government health facilities making up to 39% of all cause attendance to out-patient unit. It was reported to us that in areas of the country with increased use of Homapak, there is noted reduced malaria mortality in the less than 5 years old even though malaria incidence continues same. We are looking for documentation to support that statement. The NMCP reports (April 2005) large reductions in severe anemia in communities using Homapak, as well as large increases (to 55%) in the proportion of children receiving antimalarial treatment within 24 hours.

Case Management and Severe Malaria: Guidelines for management of severe malaria have been revised, but there are gaps in the implementation of improved case management procedures which need to be addressed during the PMI Planning Visit in October 2005..

Monitoring & Evaluation of Treatment: Uganda is a member of the East Africa network on malaria drug efficacy monitoring (EANMAT) and has 8 sentinel sites in the country which are used for data collection. ACT efficacy monitoring in Uganda will continue as part of the existing regional network.

Malaria Diagnosis

Current Policy: The MoH has decided that the diagnosis of malaria will largely be made based on the clinical history and physical examination of patients especially in children less than 5 years of age. The MoH, however, recommends laboratory diagnosis with microscopy as the main means for malaria diagnosis in the adult population and encourages confirmed diagnosis before treatment with the introduction of Artemisin Combination Therapy (ACT).

Current operations: There are four specialized laboratories at the national level that provide special services, these are the Nakasero Blood Bank (NBB), the Uganda Virus Research Institute (UVRI), the Joint Clinical Research Centre (JCRC) and the Central Public Health Laboratory (CPHL). Below the national level are 2 regional referral laboratories, 108 district hospital laboratories and 214 HC IV laboratories. Presently only about a third of the HC IV laboratories are manned by a technician. There are 346 HC III facilities with laboratory services out of the 901 available. Laboratory service at HC III is the lowest in the health delivery system and is supposed to be manned by laboratory assistant offering basic laboratory services. Presently, the CPHL is mandated to coordinate, monitor and supervise all the HC III and IV level laboratories but the CPHL is grossly understaffed having only 3 persons and not well resourced to carry out this mandate over the peripheral laboratories. It is believed that many of these peripheral laboratories are run by personnel without any formal laboratory education, but only on-the-job training. All qualified laboratory personnel are expected to be registered by the Allied Health Professions Council before they can practice. Unfortunately, the council is overwhelmed and unable to perform this regulatory task of ensuring that only registered personnel are employed in the health laboratories and there are no functional mechanisms in place to check the qualifications of persons employed in the laboratories. There are 7 schools which train laboratory technicians with a total output of about 150 persons per year. Two of the schools are owned by the government while the rest belong mostly to faith-based organizations.

A number of health facilities have been upgraded without the structural upgrade of the laboratories and hence poor working conditions in especially many of the HC III laboratories. Many laboratories lack basic equipment and adequate reagents and coupled with inadequate supervision from CPHL, standard operating procedures are not observed. This often results in poor quality laboratory services and in some cases inability to perform basic

tests. A recent inventory of laboratory service showed that 75% of the laboratories do not have adequate number of personnel and 90% lacked reagents to perform basic tests.

Through the PEPFAR, funds have been given by CDC for the purchase of microscopes and this represents 35% of the national requirements. Through the GFATM round 2, one hundred and fifty microscopes which represent 25% of the national need have been ordered but there is still a 40% deficit to be catered for. The laboratory services did not have input into the global fund proposal. The laboratory service does not have good data on laboratory consumption making it difficult to know the adequate needs for reagents. AMREF, a non-governmental organization, has been contracted by CDC and it is conducting quality assessment in the various facilities and it will also as from September start training laboratory personnel on how to request for laboratory reagents and data management. Refresher training will also be conducted for all facilities to improve integration of programs like TB and STIs.

Rapid Diagnostic Tests: Presently Rapid Diagnostic Tests (RDTs) are not used in health facilities for diagnosis but it is expected that RDTs will be used from HC III level and above and also in special situations of suspected malaria epidemics. RDTs may also be recommended by the MOH for use in the internally displaced camps, which have weak health delivery systems and very scarce laboratory services. Malaria Consortium is planning an OR activity with RDTs in October 2005, with funding from DfID.

IPT in Uganda

- Policy in place for 2 doses
- Low coverage of 2 dose currently
 - Many women visit ANC once
 - Visits tend to be late in pregnancy
- Poor compliance with policy in HFs
 - Stock-outs of IPT for ANC
 - Little directly-observed treatment
 - Many staff untrained in IPT

Intermittent Preventive Treatment (IPT)

Current policy: The MoH has a national policy for the prevention and control of malaria during pregnancy with SP as the selected drug. This policy is in accordance with the WHO recommendation of giving SP first dose after quickening and a second dose at least one month apart. This policy has been implemented for some years now through antenatal clinics which are found in HC III and above; however, not all HC III's run antenatal care. It is only in the district where IPT was piloted that has achieved 80% coverage for combined IPT 1 and 2.

Current Status: The national average of IPT 1 and 2 is 33% which is far below the Abuja target. Moreover, it is important for the program to record IPT 1 and 2 separately, as the target is to have IPT 2 over 60%. The national average presently will be lower for IPT 2 (estimated by the program manager to be around 20%). The

delivery of IPT at the antenatal clinic is run as a vertical program instead of integrating it into other programs to offer quality antenatal care. The antenatal service is not guaranteed SP supply, as hence whenever there is a shortage in the health facility for SP, the SP for the antenatal is withdrawn into the general pool which leaves antenatal without SP for IPT. Also, unavailability of basic supplies such as water, often prevents implementation of the IPT strategy as a directly observed treatment, as recommended by the NMCP. SP is purchased by the MoH through the credit line established at the medical stores. However, this credit line normally caters for only 52% of the essential drug needs of the health facilities.

Gaps and Opportunities for IPT:

The training of health staff on IPT needs strengthening; the quality of the training materials and procedures needs to be examined and supported as part of scaling up focused antenatal care.

Monitoring & Evaluation:

<u>Surveillance/Health information systems:</u> Through a routine HMIS system, districts report on a weekly basis health information, including cases and deaths due to malaria (which are also published in the newspapers) At the same time, there are monthly summaries from health units on the in and out patients for all diseases including malaria. There are separate forms too that capture specific interventions like IPT included within the HMIS. The Central Public Health Laboratories also feed information into MOH surveillance systems. In addition, in 2 epidemic-prone districts, Kabale and Rukungiri, the Highland Malaria (HIMAL) surveillance project has been introduced and is functioning in those two districts. The purpose is for early detection of malaria outbreaks, based on weekly reports using sentinel sites and regular reporting. The District Health Management Team is the focus for action; there are plans to integrate it with the routine surveillance system.

<u>Evaluation surveys:</u> A Demographic and Health Survey is planned for 2005/2006 which will include a malaria module. In addition, WHO does facility surveys every two years, and another survey is planned for 2007. In addition, various other partners and NGOs collect data from project districts and areas. UPHOLD collects program progress data from its 20 districts, including malaria information on ITN coverage and access to antimalarials. UPHOLD is working with UNICEF in 13 districts to use the same data gathering instrument (lot quality assurance sampling).

Malaria in other settings

1. Epidemic malaria occurs in 15 districts but is limited to the highlands and thus not all of the district. There is a threshold established for each epidemic-prone area but the sensitivity of this surveillance is unknown. There is no detailed plan on epidemic response and containment and this needs to be addressed.

2. Malaria in refugees

There are IDPs in the northern part of the country and malaria mortality is very high especially among children less than 5 years. The health delivery system in this IDP camps are run by both government and non-governmental organizations but the quality of services is unknown. A study conducted by WHO, MoH and Partners in July 2005 surveyed 3 districts and one municipality and showed malaria mortality ranging between 42.9% and 52.5% making malaria the single most important cause of childhood mortality in the IDP camps. There is no documented strategy for malaria control in these camps but there are opportunities for intervention to improve the health of the camps in general and malaria control in particular.

Gaps and Opportunities:

- 1. <u>IRS Operational Management:</u> The Ministry of Health is committed to implementing an IRS program, beginning in 3 districts in the next year. Equipment and insecticides are currently being purchased with Global Fund grant monies. Implementation of an effective spray operation will require considerable management and oversight. The capacity to do this is very limited at the MOH. Some support for operational issues and training has been included in the Global Fund grant (Round 2) but likely insufficient. The USG could assist the MOH develop the capacity to effectively plan and manage spray operations. This will require access to people with expertise and experience in spray operations. Options:
 - a. If long term staffing solutions at the MOH can be resolved, bring in experienced staff to organize and implement spray operations. This would require a large staff devoted to this operation.
 - b. Subcontracting the organization and implementation of IRS out, while developing an oversight management capacity within MOH;
- 2. <u>ITNs</u>: If the Global Fund round 5 grant is approved, there will be sufficient nets procured to provide the bare minimum required (1 per household with child under 5). The needs for ITNs include:
 - a. Urgently to implement the Roll Back Malaria ITN strategy for using social marketing and developing the commercial market in conjunction with the MOH planned distribution of free nets. The free nets could be used to prime the market, but will be insufficient numbers for maintenance for the long run. Need to develop effective market segmentation to keep free nets available to those who need them, and a graded subsidization for those who can afford to pay. Will need nets to be available through other means for the long run for replacement nets (in 3-4 years time) and to meet the needs of new babies and pregnant women. Also urgently need to monitor impact of free distribution of nets on market leakage and use of nets.
 - b. National Malaria control program estimates that after GF round 5 nets distributed, will need 2 million ITNs each year 500,000 of which would come through the commercial sector (and 500,000 through NGOs)
 - c. Buffer stock of ITNs there is not a buffer stock of LLINs built into the GF round 5.
 - d. Weak distribution systems and mechanisms for getting from the district level to end users. Need to quickly develop routine and sustainable approaches to moving nets to the communities. Suggestions include using community drug distributors, etc.
- 3. <u>Drugs</u>: With Global Fund Round 4 grant, there will most likely be sufficient ACTs for facilities (according to current plans).
 - a. Issue with inventory management; and likely drug planning/management gap at the central and particularly the district level, including of SP for IPT at the health facility level
 - b. Issues with storage capacity central stores at full capacity (can increase with 2 months notice) and very limited at district level
 - c. Drug information system very weak
 - d. Requirement for small buffer stock, although management of the buffer stock because of short shelf life will require careful management
 - e. Districts are not given sufficient resources to purchase all the drugs they need

- f. There is a need to explore delivering subsidized ACTs through the private sector pilot different options including looking at SEAM experience.
- g. Need for supervision/oversight structure to monitor introduction of new antimalarias identifying any adverse reactions, etc.
- h. Unclear whether sufficient ACT drugs will be in country and available at all health facilities as required. Clear and specific delivery dates and information on quantities from the Global Fund grant are not available.
- i. It was not clear to the team that there is a comprehensive transition plan for introducing the new ACT drugs.
 - i. Will likely be a drug stock out in the summer for Home Based Management of Fever (HBMF) may need to consider placing another order for chloroquine/SP to manage transition to ACTs. Last procurement order for CQ/SP just placed, will take the country through June/July 2006.
 - ii. ACTs cannot be used by children under 5 kgs (up to 3 months). Need an alternative.
 - iii. Uganda has not yet worked out how to transition very effective Home Based Management of Fever/Homapak to new ACT front line treatment policy. After June/July, no more CQ/SP will be available for the Homapak.
- j. Currently there are artemisinin monotherapies in the private sector. There is a need to have a strategy for handling monotherapies so as not to increase resistance.
- 4. Malaria in Pregnancy: Key issues:
 - a. very low coverage of IPT, especially two doses of IPT.
 - b. Currently private midwives are not delivering IPT could be an effective approach for expanding access
 - c. There is a need for a comprehensive approach to antenatal services, integrating reproductive health, IPT, and HIV programs in order to improve quality of services
- 5. <u>Laboratories</u>: Currently laboratory system is weak. With <u>WHO</u> recommending a policy to test all suspected malaria cases in children above 5 years and adults prior to treatment, the burden o the lab system will be even greater. Key needs:
 - a. Insufficient equipment/microscopes: Central labs say they need 600 microscopes; 150 included in GF grant. Gap of 450 more.
 - b. Reagents and other consumable supplies: 90% of labs not able to do tests because they do not have the reagents.
 - c. Limited quality assurance and quality control system
 - d. Need space and storage space insufficient physical space for the established labs; many do not have required storage space.
 - e. Staff insufficient numbers, not enough money at the district level to pay staff
 - f. Information management is a gap no data base at central public health labs
 - g. Issue of how to maintain rapid diagnostic tests one they are widely used esp. regarding inventory and procurement.
- 6. <u>National Drug Authority</u>: Within the NDA, the National Drug Quality Control Laboratory is the Quality Control and Assurance department of the NDA. In addition to having responsibility for regulating all drugs and testing all drugs manufactured locally and imported, the NDQCL was recently given

responsibility for regulating public health chemicals. The NDQCL is severely under-resourced. If they cannot test drugs coming in fast enough, will create a bottleneck and slow access to the meds. With the expected increase in ACTs, capacity will need to be build up ASAP. Needs (which could be filled for about \$500,000) identified by the NDQCL include:

- a. Consumable supplies for testing, including chemical reference substances for testing antimalarials; reagents
- b. Need for an extra semi-automatic dissolution testing apparatus
- c. New automated HPLC is required to test antimalarials in the ACT group to keep up with expected increase in volume(currently only have 3)
- d. NDQCL does not have a microbiology lab to carry out sterility testing for antimalarials and other products
- e. To do quality control and testing of public health chemicals, will need gas chromatography equipment which is currently lacking.
- f. Need assistance in training of analysts
- g. Need help in disposal of expired drugs
- 7. <u>Communication/behavior change</u>: There is a communication plan for roll out of the new ACT drugs; however there may be a need for comprehensive behavior change and communication messages and updated information on a regular basis for providers and communities on the new drugs as well as ITNs, IRS and encouraging women to come to antenatal clinics early in pregnancy to ensure 2 doses of IPT. (Need to confirm)

Issues for Planning Visit:

- 1. Global Fund implementation status post-suspension.
- 2. MTEF Ceiling will President's malaria initiative be on top of ceiling
- 3. Purchase of consumables much of need is for purchase of consumables. What is the plan for sustaining supply of consumables in the long run?
- 4. Need to protect home based management of fever program. With shift to ACTs and elimination in the future of use of CQ/SP, Homapak will soon have no drug in the short run. How best to maintain this program until issues regarding delivery of ACTs at the community level are sorted out?
- 5. One of the gaps identified by National Malaria Control Program is for services for school age children ITNs and treatment. However, the target of President's initiative is explicitly children under 5 who are largely covered with Global Fund grants.
- 6. MOH has indicated that President Museveni would like to build a malaria research facility to help Uganda stay on top of malaria for the long run. How can the Initiative effectively contribute to this?
- 7. There are a number of health systems issues some of which could be addressed through improvements in drug management/procurement, laboratory services etc., but many are broader and will likely effect the implementation of the malaria program. What is the latitude for addressing these broader issues within the President's Initiative?
- 8. Improved malaria case management in health facilities is needed information on successful approaches or testing of different approaches is needed to quickly bring effective case management to scale.

Option)s for Jump Starts

- 1. Distribution of ITNs in IDP camps in the north, where malaria mortality is very high, supplemented by IRS for the "night commuter" shelters for the IDPs. This could be a prelude to introduction of a comprehensive package for malaria. There is a question of whether it will be possible to use LLINs given the LLIN supply issues. There is a 6 month lead time for LLINs to be available. Alternatively, if no supply can be found, conventionally treated nets could be used, which are available now. However, some LLINs have already been distributed in camps, making use of conventionally treated nets more complicated. Existing platforms exist through NGOs, UNICEF, or Malaria Consortium which could ramp up coverage to 85% of households in camps.
- 2. Distribute ITNs through HIV care/treatment and/or through OVC programs (Note PSI is already including 2 ITNs in home care packages via CDC funding.)
- 3. Scaling up ITNs for general communities in conjunction with PEPFAR ITN distribution. Platform currently exists through PEPFAR programs and could be done quickly.