The East African Drug Seller Initiative

Getting Medicines to People—Creating Sustainable Private-sector Drug Seller Programs

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Situational Analysis for the Pharmaceutical Sector and Access to Medicines in Uganda

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CONTENTS

ACRONYMS

ACT	artemisinin-based combination therapy
DADI	District Assistant Drug Inspector
EADSI	East African Drug Seller Initiative
HBMF	home-based management of fevers (initiative)
HSSP	Health Sector Strategic Plan
IMCI	Integrated Management of Childhood Illness (initiative)
ITN	insecticide-treated nets
JMS	Joint Medical Stores
MMV	Medicines for Malaria Venture
MOH	Ministry of Health
MSH	Management Sciences for Health
NDA	National Drug Authority
NGO	nongovernmental organization
NMS	National Medical Stores
TB	tuberculosis
UAC	Uganda AIDS Commission
UGX	Ugandan shillings
UNIDO	United Nations Industrial Development Organization
USD	U.S. dollar
WHO	World Health Organization

UGANDA COUNTRY OVERVIEW

Demographics and Health Indicators

Uganda's health indicators are similar or better than other sub-Saharan countries with similar economic profiles, including early decreases in the number of people with HIV/AIDS; however, the country has many challenges in delivering health services. Life expectancy at birth is nearly 52 years (CIA 2007), which is up from 43 years in 2000 (UNDP 2005), and geographical access to health services have also improved from 49 percent in the 1990s; estimates suggest that at least 53 percent of the population lives less than 5 kilometers from a health facility, ranging from 9 percent in parts of Kitgum district to 100 percent in Kampala (UN Millennium Project 2005). A major challenge comes with the large percentage of people who live in rural areas—about 87 percent (UNICEF 2007). In addition, about 1.2–1.7 million people in the northern part of the country are internally displaced—many living in camps—mainly due to conflict between the Lord's Resistance Army and the Government of Uganda (CIA 2007).

Uganda Demographics (2008 Estimates)

31,367,972 population

48.1 births/1,000 population

12.3 deaths/1,000 population

6.81 children born/woman

52.3 years life expectancy

Source: CIA Factbook

As might be expected by the large proportion of the population residing in rural areas, agriculture has traditionally played an important role in the country's economy; however, agriculture's impact has been decreasing, while industry and services have been increasing (UNDP 2005). Thanks to government reform programs, the country's rate of gross domestic product growth varied between 4.7 percent and 6.6 percent a year between 2001 and 2006 (UBOS 2007). This strong economic growth has resulted in a reduction in the proportion of Ugandans living in absolute poverty—from 56 percent in 1992 to 38 percent in 2004 (UNDP 2005). But those gains have not been distributed equally; for example, 63 percent of the population in Northern Uganda lives below the poverty line. However, the United Nations Development Programme predicts that Uganda can achieve the Millennium Development goal on poverty, which is to have only 28 percent of the population below the poverty line by 2015 (UNDP 2005).

Epidemiology of Major Health Concerns

HIV/AIDS

Uganda was the first country in sub-Saharan Africa to report a decrease in HIV prevalence in the 1990s; however, the Joint United Nations Programme on HIV/AIDS (UNAIDS) still estimated the prevalence of HIV infection among adults to be about 6.7 percent in 2005 (UNAIDS 2006), with a higher prevalence in urban areas (10 percent) compared with rural areas (5.7 percent) (UNAIDS 2007). As of 2005, 190,000 adults and 39,000 children were estimated to be in need of treatment, while approximately 75,000 patients were receiving antiretroviral therapy from 175 sites (WHO/UNICEF/UNAIDS 2006).

Tuberculosis

Although the tuberculosis (TB) rate in Uganda has decreased somewhat, probably due to the decrease in HIV/AIDS, Uganda had an annual TB incidence rate of 355 cases per 100,000 in

2006—the fifteenth highest burden in the world (WHO 2008). The relationship between HIV infection and TB is still strong; Stop TB Partnership data from 2005 estimated that 30 percent of TB patients diagnosed in Uganda in 2005 were HIV-positive. Uganda, like most other countries in the high-burden category, is still working towards meeting the World Health Organization (WHO) TB global targets of a 70 percent case detection rate and an 85 percent treatment success rate. The most recent detection rate of sputum smear-positive cases was 44 percent (2006) with a treatment success rate (treatment completion and cure) of 73 percent (2005) (WHO 2008a).

Malaria

Malaria is a major cause of illness and death in Uganda. In most parts of the country, climate results in a highly endemic malaria transmission with relatively little seasonal variability. In the high altitude areas of the southwest and east, malaria transmission is seasonal and epidemic, however, far more deaths result from endemic rather than epidemic malaria. According to Roll Back Malaria, in 2006, Uganda reported over 8 million cases of malaria and over 110,000 deaths in 2004, and malaria was the is the cause of 40 percent of outpatient visits, 25 percent of hospital admissions, and 14 percent of hospital deaths (Roll Back Malaria 2005; 2008). Children under five years of age and pregnant women are most affected by malaria.

Although the country's malaria control strategy includes bed nets, the use of bed nets in general and insecticide-treated nets (ITNs) in particular is low, although rising. According to the Demographic and Health Survey of 2006 (UBOS 2007), only 34 percent of households had bed nets with 16 percent owning ITNs. In addition, only 22 percent of children under age five and 24 percent of pregnant women slept under a mosquito net, while only 10 percent of both groups slept under an ITN.

Child Health

Although Uganda has made progress in some major health indicators, the country's high child mortality rate of 134 per 1,000 live births, which is 23rd in the world (UNICEF 2007), leaves it far from its 2015 millennium development goal of 74 per 1,000 (World Bank 2005). Deaths of children one to four years account for about 42 percent of the total child mortality rate, the rest coming in the neonatal and postnatal (one month to one year) periods. As in other developing countries, after neonatal causes, acute respiratory infection, diarrhea, and malaria are the primary killers of Ugandan children under age five, with malaria the most common.

THE HEALTH SECTOR

Public Sector Health Structure

In the past decade, Uganda has decentralized its government to the 80 districts (up from 69 districts in 2005). Before government decentralization, the Ministry of Health (MOH) controlled health management functions, but now, service delivery activities are centered at the district level. The national government is still responsible for establishing national policies and standards and monitoring compliance with those policies and standards. Central ministries, such as the MOH, carry out technical supervision, provide technical advice, monitor local government activities, and liaise with international agencies. Specifically, the MOH retains responsibility for setting standards and quality assurance, mobilizing resources, developing capacity, providing technical support and services such as epidemic control and health research, and monitoring and evaluating sector performance (UNDP 2005).

In the local government system (meaning below the national level), the district has local government councils and administrative unit councils. Local government councils have the power to make and enforce bylaws, establish policies based on local priorities, and regulate service delivery. They control their own budgets. The administrative unit councils serve as political units that advise on planning and service implementation.

The district health system is self-contained, with the District Health Officer in charge of overall service coordination, and assistance from a multidisciplinary district health team that carries out planning, budgeting, and monitoring of health services, including providing disease prevention, health promotion, and curative and rehabilitative services; communicable disease control; vector control and ensuring safe water and sanitation; managing health system data, and overseeing health facility operations in the district, including private for-profit and nonprofit (mainly faith-based) facilities. District health teams also have the power to address local priorities, such as sleeping sickness and schistosomiasis, which are not included as part of the national minimum package of care. The 1999 National Health Policy shifted the delivery of the minimum package of care to a new subdistrict level, which created service zones that are closer to the community. Subcounty councils and health committees serve similar roles to district-level teams, but for smaller populations (table 1).

The decentralization of health services varies in terms of how well it functions. Although the strategy of decentralization was to make public medical care more accessible, the same pot of money (which is based on population) is now split among more districts (AGHA 2007). Many districts, especially new districts and those in the north, are limited by severe human resource and infrastructure constraints and sometimes security concerns (BASICS 2006); for example, the Katakwi district has fewer than 20 health care providers per 100,000 population compared with over 200 in Kampala (World Bank 2005). Newly established districts have yet to establish functional infrastructure or management systems, and it appears that districts have too few resources to supervise or accredit health facilities (MOH 2007; World Bank 2005).

Table 1 shows the breakdown of the health and administrative structure after decentralization. The lowest level of health care services, health center I, does not necessarily exist as an actual facility, but comprises volunteer community members who are often organized as a village

health team focusing on health education (PMI 2007). Level II health centers provide outpatient care, prenatal care, immunization services, and outreach. They are supposed to be run by a nurse and a midwife, but based on data that MSH collected in Mpigi and Kibale districts, nurse assistants are often in charge of health center II facilities.[1] Nurse assistants were dispensing medicines at almost two-thirds of the 22 health center IIs where data was collected.

The list of essential medicines approved for health center I and health center II is in Annex 1.

Table 1. Health sector structure

Administrative structure	Local council level	Health structure level (population served)	Number of facilities (2006)
Village	I	Health center I (1,000)	—
Parish	II	Health center II (5,000)	1,887
Subcounty	III	Health center III (20,000)	905
Subdistrict or county	IV	Health center IV (100,000)	165
District	V	District general hospital (500,000)	101*

*Including referral hospitals
Source: World Bank 2005; MOH 2007

Government data from 2003 analyzed by Xu and colleagues (2005) indicate that when ill, 53 percent of people turn to the private sector for treatment, 24 percent to the public sector, 4 percent to "other," and 19 percent do not seek care. These figures show an increase in both public and private sector usage since 1997 because a larger proportion of people sought health care in 2003 compared with 1997.

Public Health Sector in Kibale and Mpigi

The two target districts for the EADSI program are Kibale (intervention) and Mpigi (control). In Mpigi, the district health team is comprised of the district health officer, a health educator, health inspector, and a councilor/secretary for health. The district health team supervises the health levels on a quarterly basis, trains health workers, and plans the health programs for the district. Villages also have village health teams. The health subdistrict level (health center IV) supervises the lower-level health units (health centers II and III) and provides the link to the district level.

In Kibale, the district health team and village health teams are in place; however, the village health teams have not been active because they have not received training yet. Currently, the health subdistrict and the district assistant drug inspector (DADI) supervise and monitor lower-level health activities, reporting up to the district health officer.

In its 2006–2007 health sector assessment, the MOH outlined the following challenges to the public sector's pharmaceutical system.

- Scale-up of HIV/AIDS, malaria, and tuberculosis treatment and diagnostic programs

[1] Data collected June 2008.

- Deferrals of improvements in pharmaceutical management capacity; a large number of positions in the pharmaceutical sector are unfilled
- Underfunding, particularly to the health center IV level
- Poor stock availability at the National Medical Stores (NMS) and public facilities
- Poor adherence to standards and regulations and a lack of enforcement
- Inconsistent and unclear pharmaceutical laws and regulations
- Low level of pharmacovigilance practice
- Insufficient capacity to manage pharmaceuticals in health facilities

Private Sector Health Services

One of the goals of the 1999 National Health Policy was to strengthen collaboration between the public and private health sectors to increase access to health care coverage. The private sector, comprising nongovernmental organizations (NGOs), private providers, and traditional medicine practitioners, plays a very significant role in health care in Uganda—especially in rural areas.

Most NGO facilities are affiliated with religious organizations—Catholic, Protestant, or Muslim. Although they receive government subsidy, they are autonomous and decide which services to offer and how much to charge patients. The Ugandan Catholic Medical Bureau supposedly put into place an accreditation process for its lower-level health facilities to assure they are meeting certain standards (World Bank 2005).

Ssewanyana and colleagues (2004) noted that although public health facilities still predominate, the number of private facilities has increased rapidly, and that the proportion of public facilities overall has decreased from 72 percent in 1996 to 52 percent in 2002. A 2005 study estimated that Uganda had 4,639 health facilities, of which 2,154 (46 percent) were in the private sector (nonprofit and for-profit); however, 45 percent of those were in the Kampala District (PHR*plus* 2005). The estimate does not include pharmacies or drug shops. In its recent survey of six districts, Medicines for Malaria Venture (MMV) found that most health facilities (up to 84 percent) were private (MMV 2008). Although for-profit facilities including drug shops are supposed to register with the government, enforcement is limited, and unregistered providers operate without any regulation or oversight.

For example, in a study of the Luwero district, 50 kilometers (km) north of Kampala, an inventory of formal and informal private practitioners showed that most providers had not registered with the district health authorities as required, including 44 percent of traditional healers, 46 percent of private clinics, and 61 percent of drug shops (Tawfik et al. 2006). Private practitioners complain that the registration procedures are complex and expensive (MOH/IMCI 2001)—license fees cost from 50 to 70 U.S. dollars (USD) and dispensers must be qualified health workers, such as a nurse or pharmacy technician, which is a difficult requirement to fulfill in rural areas (MMV 2007).

Some informal outlets that sell medicines, such as general retail shops or mobile vendors, are not licensed to sell medicines at all (MMV 2008). In addition, many facilities in the Luwero survey

were offering unauthorized services; for example, many drug shops were providing clinical case management services and selling unauthorized medicines (Tawfik et al. 2006). Even when registered, drug shops and private clinics were often operated by unqualified staff, and the attendants were usually not the business owners. Not surprisingly, service quality is poor, and private providers often do not follow standard treatment guidelines for common illnesses (MOH/IMCI 2001). Despite this poor quality, however, the public perceives services in the private sector favorably, because providers are often more accessible and courteous than their public sector counterparts and they generally have better medicine availability and will allow customers to buy medicine on credit (MOH/IMCI 2001). A World Bank paper (2005) indicated that for-profit community drug vendors provide about 75 percent of drugs in rural communities—an activity that is largely unregulated.

Health Sector Policy

Health sector policies are influenced by a range of different government policies including those related to poverty reduction, financing, and development. In the late 1990s, the government of Uganda intensified its health reform efforts to strengthen service delivery within a government health policy framework, starting with the white paper on health in 1993 and the three-year plan frame (1993–1995). With its development partners and other stakeholders, the government then developed a 10-year National Health Policy (published in 1999) and the first National Health Sector Strategic Plan (HSSP 2000/01–2004/05). Together with the Poverty Eradication Action Plan, those policies initially guided health sector reform in Uganda. Because a sector- wide approach (SWAp) is the framework for implementing the HSSP, multiple stakeholders have a say in health policy issues; however, the MOH retains overall responsibility.

The policies' goals have been to reduce mortality, morbidity, and fertility, and provide Ugandans with an essential health care package of interventions that address common conditions in the country. The Ugandan National Minimum Health Care Package is structured into four clusters—

- Cluster 1: crosscutting health promotion issues, such as community health initiatives, environmental health, school health, and gender and health
- Cluster 2: maternal and child health
- Cluster 3: prevention and control of communicable diseases
- Cluster 4: noncommunicable diseases with emphasis on healthy lifestyles and control of poverty-producing conditions such as mental health and disability

Reform initiatives have included the further decentralization of public health services delivery to the subdistrict level, an increased focus on collaboration with the private sector to deliver health services, and most important, the abolition of user fees for medicines and services in public facilities in March 2001. The MOH's mid-term review of the HSSP in 2003 noted that the policy changes and initiatives, and especially the abolition of user charges in the public sector, had resulted in a significant increase in the population's use of primary health care services, particularly among the poor. However, that growth highlighted the shortage of trained health care workers, inadequate health infrastructure, and lack of available drugs in public health facilities. In addition, geographic access to public health facilities was still a problem.

The HSSP II, which covers 2005–2010, focuses on prevention and control of communicable diseases. The HSSP II concentrates effort and resources on a limited set of evidence-based, cost-

effective interventions under each cluster in the minimum health care package with the goal of scaling up the interventions nationwide. One of the main objectives under HSSP II is to reduce communicable disease in order to achieve the millennium development goals and the Poverty Eradication Action Plan (MOH 2005).

Policies to Prevent and Control HIV/AIDS

The government of Uganda received kudos for its early government response to the HIV/AIDS epidemic, starting in 1986 when it created the AIDS Control Program within the MOH. Initially, the response was confined to the health sector, but in 1992, recognizing that HIV/AIDS affected every sector, the government established the Uganda AIDS Commission (UAC) to oversee, plan, and coordinate the country's HIV/AIDS prevention and control activities. To assure multisectoral representation, the UAC created a national partnership committee that provides a formal mechanism to involve stakeholders in the HIV/AIDS response. Members of the partnership include representatives from government ministries, Parliament, AIDS development partners, the private sector, international and national NGOs, research and academia, and organizations representing people living with HIV/AIDS, youth, media, culture, and arts.

The Uganda AIDS Commission developed the first HIV/AIDS national policy guidelines in 1993, which have been revised in 1996 and 2005 as the existing national AIDS policy. In addition, the UAC also drafted a National Strategic Framework for HIV/AIDS Activities in Uganda covering 2000–2006. The UAC conducted a mid-term review of this framework in 2003 and then revised the framework accordingly, taking into account shifts in epidemiology, increased funding, and changes in the availability of prevention, care, and treatment, including the introduction of universal free access to antiretroviral therapy in 2004. Before the framework expired in 2006, the UAC started the process of developing a new five-year planning framework (2007–2012), which was finished in November 2007. The goal of the strategic plan is to reduce the incidence of HIV and AIDS by 40 percent and to assure that care and treatment are accessible to 80 percent of those who need it by 2012 (UAC 2007a).

The UAC also recently published a road map to achieving universal HIV prevention (UAC 2007b). Through the road map, the UAC's goal is to mobilize activities to achieve 80 percent access to a package of HIV/AIDS prevention interventions that will reduce the rate of new HIV infections by 40 percent by 2012. One of the objectives is to use all social, religious, health, and economic facilities and services to deliver HIV/AIDS prevention information and services.

In addition, government ministries, such as the MOH, are responsible for developing sector-specific policies and guidelines related to HIV/AIDS. These policy and implementation documents relate to—

- Voluntary counseling and testing
- Prevention of mother-to-child transmission (PMTCT)
- Antiretroviral therapy
- Orphans and vulnerable children
- HIV/AIDS in the world of work
- HIV/AIDS in the education sector
- Fisheries and AIDS

- Co-trimoxazole prophylaxis
- Home-based care
- TB/HIV collaboration

Although district-level HIV/AIDS coordination guidelines were developed in 2002 and were ratified in 29 districts, other districts had difficulty carrying out the mandates because of inadequate funding for the national and district coordination mechanisms (UAC 2006).

Policies to Prevent and Control Malaria

The MOH's national malaria control program works as part of a broad Roll Back Malaria partnership that includes stakeholders from multiple sectors. The partnership follows one strategic plan, one coordination mechanism, and one monitoring and evaluation plan to measure progress (PMI 2007). The coordinating body of the partnership is the Interagency Coordination Committee and its four technical working groups. The National Malaria Control Program leads the committee.

In 2002 the country adopted a new strategy for home-based management of fevers (HBMF) using prepackaged chloroquine and sulfadoxine/pyrimethamine ("Homapak"), which are distributed by community medicine dispensers who were recruited and trained specifically for the HBMF program. The primary components of the HBMF strategy are sensitizing the community; building community capacity by training volunteers and providing them antimalarial medicines to distribute; providing information, education, and communication materials; and monitoring and supervision. At least two interventions have involved training drug vendors to provide medicines as a part of the HBMF strategy in Uganda (CORE Group and Minnesota International Health Volunteers 2004; Greer et al. 2004) (See Annex 4 for more information). The community medicine dispensers have been inactive since the change of treatment policy to artemisinin-based combination therapy (ACT); however, a pilot study in Kiboga district will investigate the feasibility of using the volunteers to dispense artemether-lumefantrine.

Standard Treatment Guidelines for Uncomplicated Malaria in Uganda

- **First-line**: artemether/lumefantrine
- **Alternative first-line**: artesunate + amodiaquine
- **Second-line**: quinine

In 2004, the Interagency Coordination Committee's Case Management Working Group recommended that the government adopt ACTs for first-line treatment, and in April 2007, the government changed its treatment policy for HBMF to ACTs (artemether-lumefantrine). WHO initially piloted the use of artemether/lumefantrine in HBMF in three districts. The malaria control program had planned to roll out ACTs in the HBMF program nationwide starting June 2007, but delays have shifted the estimated rollout until late 2007 or early 2008. The National Drug Authority has also been asked to reclassify ACTs from prescription-only to over-the-counter to help improve access through community distribution.

The National Malaria Control Strategy (2005–2010) has a goal of providing universal access to malaria prevention and treatment and eliminating malaria as the primary cause of illness and death in Uganda. The main components of the strategy are case management, vector control,

epidemic preparedness and response, and intermittent preventive treatment during pregnancy. The core interventions supporting the strategy include—

- Increasing the use of ITNs with special emphasis on long-lasting nets in highly endemic areas
- Using indoor residual spraying and environmental management, with a focus on low transmission and epidemic-prone areas
- Providing universal access to ACT and improved diagnosis as well as severe malaria management
- Increasing treatment and prevention of malaria in pregnancy including intermittent preventive treatment
- Improving people's knowledge about preventing and treating malaria through public information, education, and communication efforts and social mobilization

In addition to the national control strategy, Uganda has several other policies and guidelines related to malaria control, such as the—

- *National Policy on Malaria Treatment* (2005)
- *Malaria in Pregnancy Control* (2000)
- *Home Based Management of Fever* (2005)
- *Policy and Strategy for Insecticide Treated Nets* (2006)
- *Implementation Guidelines for the HBMF Strategy, Second Edition* (2006)
- *Management of Uncomplicated Malaria, a Practical Guide for Health Workers, Third Edition* (2005)
- *Policy and Strategy for Indoor Residual Spraying* (2006)

Policies to Prevent and Control Tuberculosis

Uganda's combined National Tuberculosis and Leprosy Program was initiated in 1990, and the Uganda Stop TB Partnership was launched in 2004; its current membership includes 27 technical and financial partners and three working groups (WHO 2007). The national TB program oversees TB services.

During HSSP I, the national TB control strategy adopted sputum-smear microscopy for diagnosis and integrated it into the national laboratory network. In addition, the TB program standardized short-course therapy using four fixed-dose combination medicines, and in 2001, adopted community-based TB care, which relies on experienced community volunteers recruited and trained specifically to implement TB services. Also, recognizing the close relationship between HIV and TB infection, the MOH established a national TB/HIV coordination committee in 2005. However, neither sputum-smear microscopy nor direct observation of treatment are routine services in all health units, and collaborative TB/HIV activities were under way in only 28 districts in 2006 (WHO 2007; RPM Plus 2007).

The public-private mix initiative, which is part of the Stop TB global plan, seeks to broaden the provision of TB services, including within the public sector. Private sector providers might include NGO health facilities, private physicians, private pharmacies, and the informal private health care sector (Stop TB Partnership 2006). Some private health care providers in Uganda have received DOTS training and the national TB program has provided them with generic TB treatment guidelines; the goal is to increase the involvement of the private sector in TB control and treatment (WHO 2008a).

Policies to Improve Child Health

In 1995, Uganda launched the Integrated Management of Childhood Illnesses (IMCI) initiative as its major strategy to address childhood mortality and morbidity. IMCI is now part of the country's essential health care package in the public sector, and training has also been extended to the private sector (Nsungwa-Sabiiti et al. 2004). In addition, Uganda had been one of the lead countries to implement the household and community component of IMCI, known as C-IMCI, which the MOH introduced in 1998. C-IMCI promotes household and community behaviors that are likely to have the greatest impact on child care, survival, growth, and development.

According to Greer et al. (2004) in their report of an intervention to train retail drug dispensers in malaria treatment, the government produced the following documents related to using the private sector to advance child health practices in Uganda—

- *Utilizing the Potential of Formal and Informal Private Practitioners in Child Survival in Uganda–Situational Analysis and Outline for Developing a National Strategy* (MOH/IMCI Unit 2001)
- *National Strategy for Utilizing the Potential of Private Practitioners in Child Survival* (Tawfik et al. 2002)
- *Inventory of Private Health Practitioners in Luwero, Ntungamo and Rakai Districts* (2002)

As part of its expansion phase into C-IMCI, IMCI helped create a steering committee of principal NGOs involved in child health. This group is linked with the U.S. Agency for International Development (USAID)-funded Child Survival Collaborations and Resources (CORE) Group, which functions across many countries.

Policies for Noncommunicable Diseases and Disabilities

The government's minimum health care package includes noncommunicable diseases, and specifically strengthening mental health services and providing care and rehabilitation for people with disabilities, however, the government of Uganda began recognizing that health care strategies focused primarily on communicable diseases. In 1998, the Ministry of Health published Guidelines for Non Communicable Diseases at District Level, which provided information on the epidemiology, diagnosis, and treatment of five common chronic diseases in Uganda: diabetes mellitus, hypertension and cardiovascular diseases, epilepsy, asthma, and sickle cell anemia (MOH 1998). In addition, the Ministry of Health published a five-year strategic plan addressing deafness, which it estimated as the largest proportion (5 percent) of

disability (MOH 2000) and published an update of a 1992 plan to improve prevention of blindness in 2000 (NPBC/MOH 2000).

National Policy on Public Private Partnership in Health

The MOH launched the Public Private Partnership in Health project in 1997, which supports the National Health Policy goal of strengthening the collaboration between the public and private sectors in health as well as HSSP I and II priorities. The Public Private Partnership in Health Working Group, appointed by the Health Policy Advisory Committee, is divided into three sub-groups: (1) Private Not-For-Profit, which includes facility and non-facility based providers; (2) Private Health Practitioners, which includes health professionals who provide services outside of the public or private not-for-profit sectors; and (3) Traditional and Complementary Medicine Practitioners, which include traditional healers and herbalists.

The Public Private Partnership in Health Working Group drafted a National Policy on Public Private Partnership in Health in 2000 (MOH 2003a), which identifies specific structures at the local government level that can promote the private sector's active participation in the health services delivery. Although the policy was not officially adopted, the government has accepted the tenets into its strategy. The HSSP II also addresses the goal of taking the partnership strategy to the local level, starting with the districts. The District Health Management Team has the lead at the district level while the MOH Directorate of Planning and Development has the lead at the central level.

Financing of the Health Sector

Uganda's health system is financed by the central government budget (including donor budget support and project funding); local government and parastatal contributions; the private sector, including nonprofit agencies and for-profit entities, and out-of-pocket expenditures (MOH 2005). The government adopted SWAp in 2000, with several donors now providing direct budget support. Among donors, some provide only health budget support, some only support projects, and a few offer both kinds of support. The government has also developed a fiscal decentralization strategy as part of its overall decentralization, with plans to increase the proportion of resources allocated to district health services. In addition, the government subsidizes the private nonprofit sector. These government subsidies, in the form of primary health care grants, comprise about 11 percent of the total recurrent government health budget (World Bank 2005). The purpose of the subsidy is to help NGO facilities, which often are the only health care facilities in rural areas, maintain their services and keep user fees low.

The proportion of spending on health as a percentage of the total government of Uganda budget increased from 7.5 percent in fiscal year 2000–01 to 9.6 percent in 2006–07; however, the Abuja target[2] is 15 percent (MOH 2007). The combination of donor project and government funds results in a per capita expenditure of USD 7.84 (MOH 2007), which is well below the USD 30–40 estimated as needed to implement the Uganda Minimum Health Care Package. (PMI 2007). This per capita figure, however, is only a small part of the estimated figure spent on health—the rest coming from the private sector and about half coming from out-of-pocket spending (MOH 2005a; WHO 2008). For example, in 2002–03, the total per capita estimate was USD 17.1, which

[2] African heads of state signed the Abuja Declaration in 2000 to commit to malaria control and prevention in support of the Millennium Development Goals.

comprised USD 3.9 from the government, USD 2.2 from donors, and USD 9.9 from out-of-pocket (World Bank 2005). WHO figures from 2005 indicate that the total per capita expenditure had increased to USD 22 (nearly a 30 percent increase), with about USD 6 coming from the government and a little over half coming from out-of-pocket (WHO 2008b).

Pharmaceutical and Health Supply Financing

Three main sources fund the purchase of public pharmaceutical and supplies: the MOH budget, primary health care conditional grants, and donors. The World Bank (2005), however, notes that records on government pharmaceutical expenditures are not adequate and that analysis of spending is difficult.

The MOH budget comprises credit line funds from the Ministry of Finance and the Danish International Development Agency, but like the rest of the health care sector, pharmaceutical budgets have been decentralized. Therefore, primary health care grants are issued to the districts and must be used within the fiscal year or be forfeited.

According to the government's Committee on Social Services, grants to the district are based on population size alone, without considering factors such as disease morbidity or border migration (Republic of Uganda 2006). In addition, 50 percent of the primary health care funds are earmarked for drug procurement, and yet the Committee noted that the districts do not always follow this guideline. The combination of factors results in problematic pharmaceutical shortages and stock-outs in the public sector facilities (Republic of Uganda 2006). And after the abolition of user fees in 2001, demand for essential medicines has far exceeded supply (Xu et al. 2005). As a result, although medicines are free in the public sector, people often must buy medicines out-of-pocket in the private sector when they are not readily available in public facilities. A WHO/HAI study showed that less than half the household respondents actually got their medicines in the public sector (WHO/HAI 2004); however, World Bank data indicate that some medicines are not actually free in the public sector; only 65 percent of survey respondents had not paid for the medicines they received in public facilities, possibly as a result of informal payments (World Bank 2005).

As mentioned, the government also subsidizes mission sector facilities through a credit line to procure medicines and primary health care grants for medicines and operational expenses. The government provides funds to the mission sector based on the number of people the facilities serve, the number of facilities in the region, and the level of service provided by the facility.

Data indicate that funding for medicines and health supplies has decreased from USD 1.20 per capita in 2002–03 to USD 0.72 per capita in 2006–07, which is far less than the HSSP II projections of USD 5.30 per capita needed for essential medicines and health supplies (MOH 2007). Predictably, a larger and larger percentage of pharmaceutical funding is coming from donor or global initiative mechanisms, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria. Such mechanisms can result in planning problems due to their unpredictability. In 2007, the government made a special budget allocation of 5.59 billion Ugandan shillings (UGX) to procure medicines in Health Center III and regional referral facilities; however, in July 2007, the Minister of Health apparently underscored a 156 billion shilling shortfall in drug procurement funds (AGHA 2007).

Table 2 below illustrates the country's available health and medicines expenditure data and extrapolates the figures to estimate per capita and total government and out-of-pocket expenditures on medicines and related health supplies.

Table 2. Estimated expenditures on medicines in Uganda based on identified sources

Out-of-pocket health expenditure per capita (USD)[a]	11.40
Out-of-pocket expenditure on medicines[b]	45%
Estimated per capita out-of pocket expenditure on medicines (USD)	5.13
Population (2007 estimate)	30,262,610
Estimated total out-of-pocket medicines expenditures (USD)	155,247,189
Government per capita expenditure on medicines and supplies (2006/2007)[c] (USD)	0.72
Estimated government expenditure on medicines (USD)	21,789,079
Donor per capita expenditure on medicines and supplies (2006/2007)[c] (USD)	3.34
Estimated donor expenditure on medicines (USD)	101,077,117
Estimated total expenditure on medicines and supplies (USD)	**278,113,385**
Total per capita expenditure on medicines and supplies (USD)	**9.19**
Out-of-pocket (%)	**56%**
Public (including donor) (%)	**44%**

[a]WHO 2008b Health Statistics
[b]2003 household data cited in World Bank, 2005
[c]MOH 2007

Community-Based Health Financing and Microfinancing

The MOH began supporting community health financing (i.e., community-based health prepayment schemes) as an option to ensure equity for the poor. Currently, there are around 13 schemes in the central and southern parts of the country—mostly owned and managed by hospitals, although Save for Health is owned and run by local communities in Luwero. The MOH's Department of Planning provides financial support to the schemes through an NGO, Uganda Community Based Health Financing Association. This organization provides both technical and financial assistance—about 400,000 Ugandan shillings per quarter (PHR*plus* 2006).

Despite the government's promotion of community health insurance, a recent evaluation noted that although almost all of the schemes have been operating for over 10 years, only about 30,000 people have enrolled, which equals about two percent of the catchment population (Basaza et al. 2007). Not surprisingly, the funds have not contributed much to budgets—only about two percent in the member hospitals (Basaza et al. 2007). The study authors noted that many factors contributed to the low interest level, including little understanding of the concept among the public and health care professionals, inadequate community involvement in scheme management, and the lack of a public policy framework to promote community health insurance. The two public hospital schemes highlighted in the article did cover the cost of medicines for members.

Another source of financing for private sector facilities is through microfinancing schemes. A recent article described an initiative to offer private sector providers with small businesses the opportunity to improve their services with microloans (Seiber and Robinson 2007). The initiative

started with midwives, then expanded in 2002 to include doctors, nurses, clinical officers, pharmacists, and other clinic owners. Loan recipients were identified through professional organizations and through direct marketing by the Uganda Microfinance Union, which also administered the loans. Exit interviews showed that clients perceived the businesses that had received loans as having more medicines available, being cleaner, charging fair prices, and offering more confidentiality. The majority of the providers reported using their loans to buy more medicines—an important factor contributing to client patronage and satisfaction. In addition, the providers attended five days of training conducted by the National Smallholder Business Center.

Human Resources

Like in other sub-Saharan countries, Uganda's health system suffers from severe and chronic human resource constraints. The MOH's 2007 health sector assessment indicates that the number of health workers in the public sector was about 25,000 in 2007, which was up about 28 percent from 2004, and the number of health workers in the private, nonprofit sector was about 11,000, which was about a 10 percent increase.

However, a 2004 assessment of the human resource capacity in the health sector showed that staffing norms were not being met overall, and certain cadres had critical gaps, including the pharmacy cadre, which had only 36 percent (201) of the estimated needed staff (561) (MSH 2004). WHO data indicate that in 2004, Uganda had 215 pharmacists and 473 pharmacy technicians/assistants in the country, which was about 30 pharmacy staff per million persons (WHO 2008c). In comparison, neighboring Kenya had 100 staff per million, while Tunisia and South Africa had 290 and 280 staff per million, respectively. Factors contributing to the low level of pharmacy staffing include the low capacity and output of Uganda's training institutions, which graduated 55 students with pharmacy training in 2004 (MSH 2004).

As the Uganda HIV/AIDS Partnership Committee points out, better trained workers tend to be located in urban areas, such as Kampala, Jinja, and Mbarara, at the expense of the rural communities, where less qualified workers are called on to provide services in the absence of appropriately skilled professionals; an estimated 10 percent of the districts are severely underserved (MSH 2004; UAC 2007). Also, new districts have a hard time enticing workers to transfer because of worker fears that they will lose their pensions (AGHA 2007). For example, an assessment of three new districts in the southwest showed that all of the districts suffered serious human resource shortages in the public health sector—from only 8 to 32 percent of the WHO-recommended 2.5 providers per 1,000 people (AGHA 2007).

In addition, public sector health workers often participate in outside activities, such as concurrent work in the private sector and owning or managing private clinics or drug shops, where public sector drugs are sometimes leaked (World Bank 2005). One estimate had 54 percent of physicians working in the private sector also working in the public sector (Mandelli et al. 2005). The MOH recognizes the country's human resource crisis and is trying to address long-term issues while assuring that enough trained health workers are available to deliver the National Minimum Health Care Package (MOH 2007).

Official statistics on human resources in health in Uganda do not include the cadres of private sector drug sellers, which generally include those that work in licensed shops (Class C shops), unlicensed shops, and unlicensed mobile drug sellers (selling in markets or out of vehicles).

Qualifications of Health Facility Staff

In MSH's recent study in Kibale and Mpigi districts, we interviewed staff at public health facilities (health center II level), private clinics, and drug shops (see Appendix 4 for study methodology). Over 30 percent of the public health center II facilities were run solely by nursing assistants in the two districts (Figure 1). Further analysis revealed that majority of the dispensing is done by nursing assistants (Figure 2). Although not officially recognized by the MOH, the nursing assistant cadre plays a significant role in providing care in the public sector.

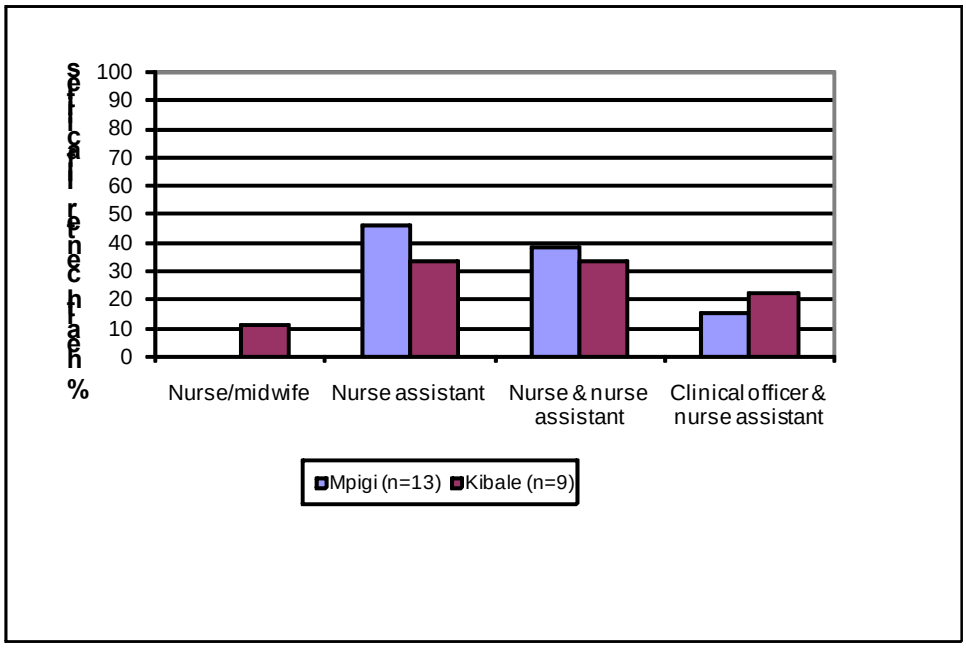


Figure 1. Qualification of personnel working in health center II facilities

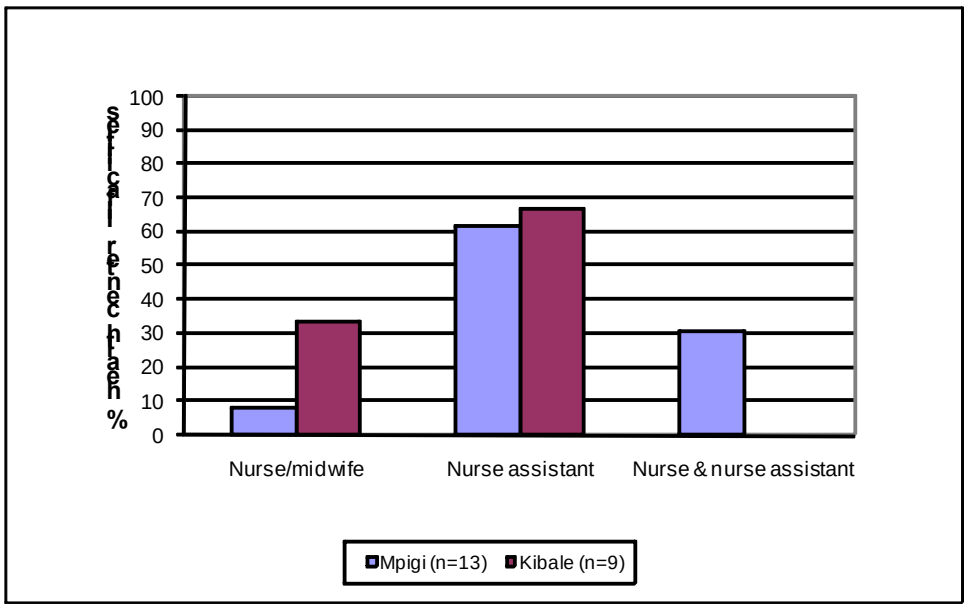


Figure 2. Qualification of personnel dispensing medicines in health center II facilities

The qualifications of the personnel operating private clinics ranged from medical officers to nursing assistants. Some clinics had only one cadre of staff represented, while others had more than one cadre operating the clinic. Across the two districts, nurses and nursing assistants also played a significant role in clinic operations (figure 3); however, nursing assistants did the majority of medicine dispensing (figure 4).

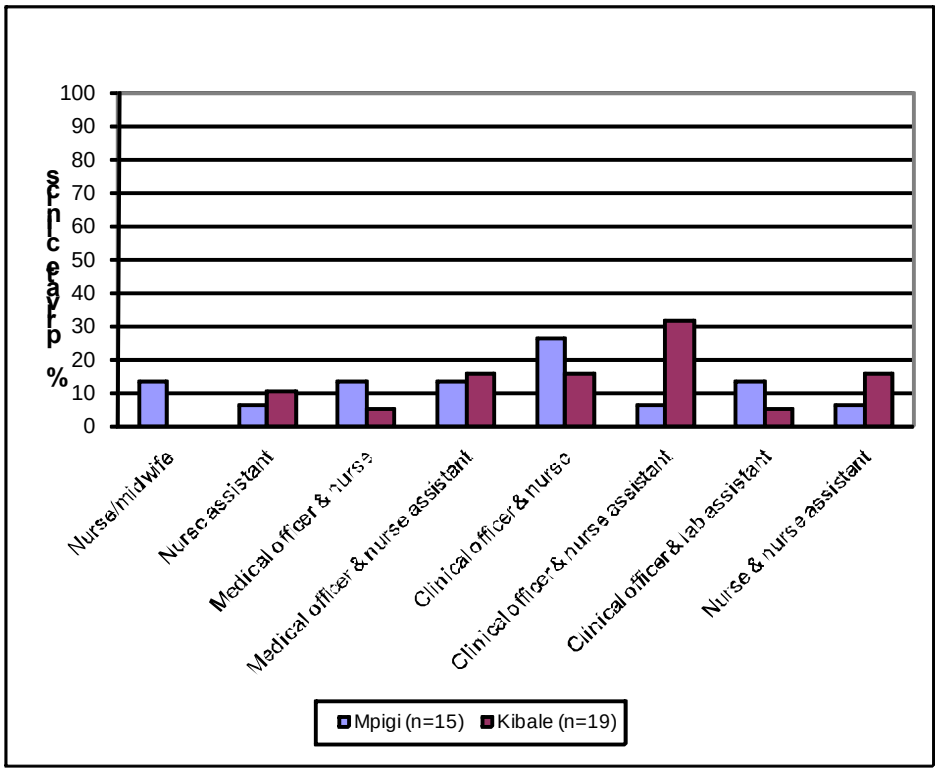


Figure 3. Qualification of personnel working in private clinics

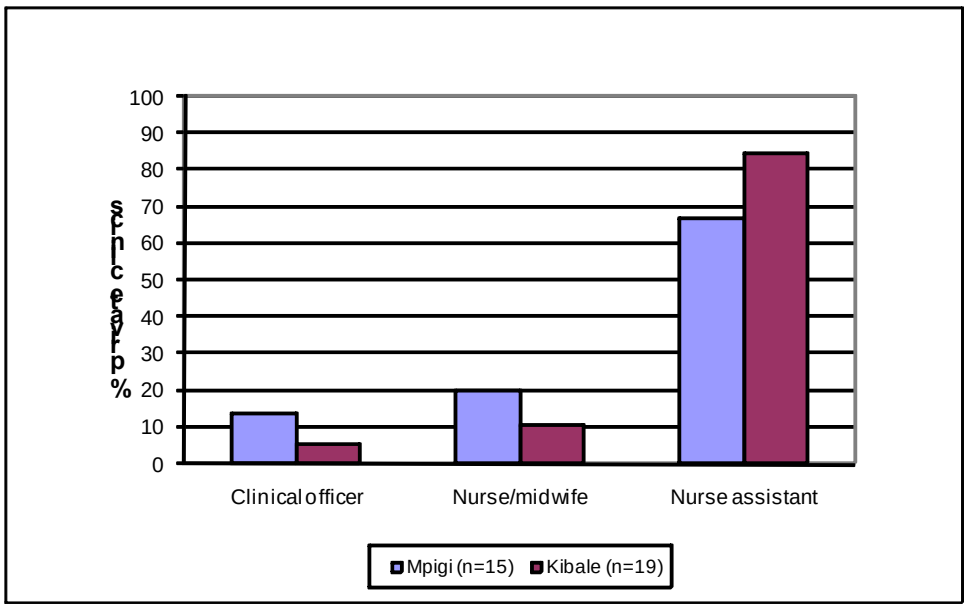


Figure 4. Qualification of personnel dispensing medicines in private clinics

The distribution of the qualifications of personnel who owned or operated Class C drug shops was not markedly different across Kibale and Mpigi. Over 60 percent of the drug shops were operated by nursing assistants, despite statutory regulations requiring a minimum qualification of a nurse (figure 5). The majority of the owners had some medical background—primarily as nurses. Mpigi district had the highest number of nurses owning drug shops; 35 percent compared to 21 percent in Kibale (figure 6).

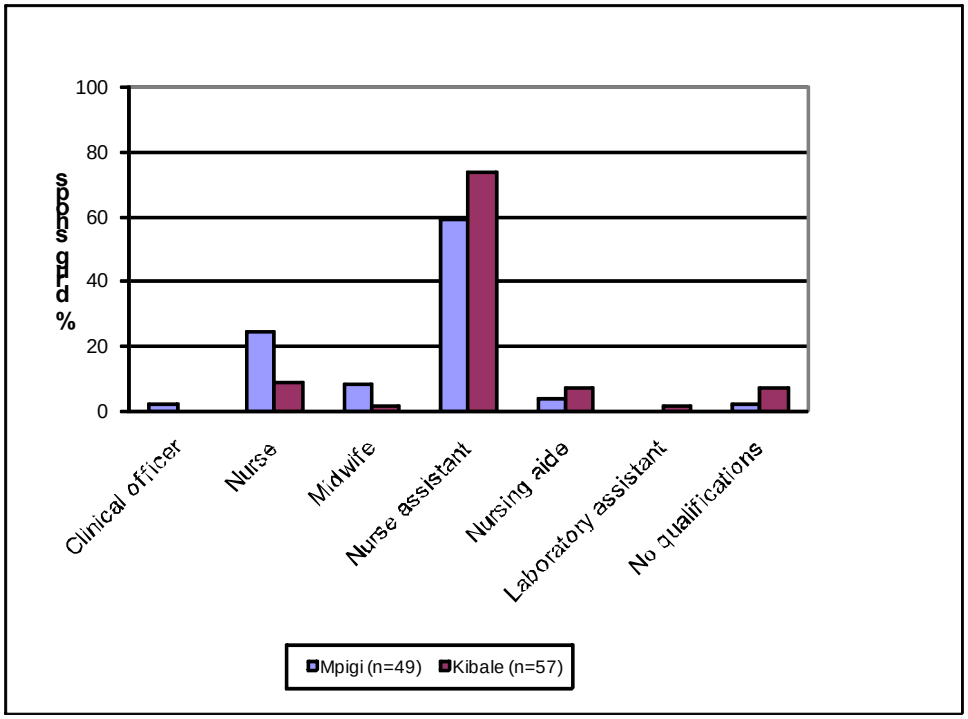


Figure 5. Qualification of personnel working in Class C drug shops

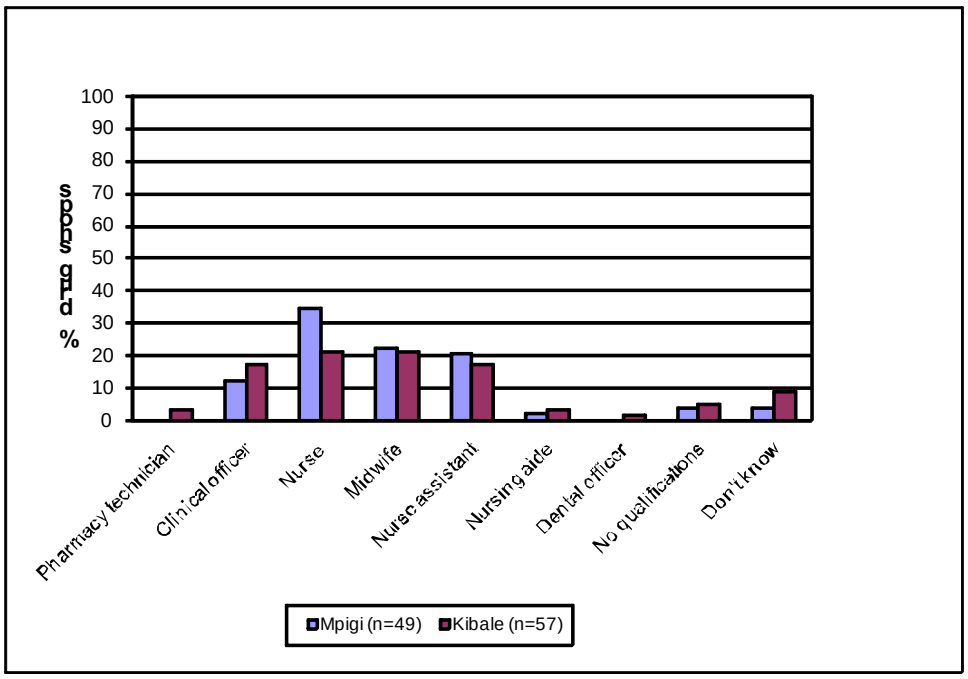


Figure 6. Qualification of Class C drug shop owners

Training

As in other countries with shortages of pharmacists and other pharmacy professionals, dispensing medicines in both the public and private sectors often falls to nurses and nurse assistants. Although nurses' training includes basic pharmacology, they do not receive specific training in dispensing practices. However, nurses who work in pharmacies as auxiliary staff undergo additional training sponsored by the Pharmaceutical Society of Uganda and the Pharmacy Department, Faculty of Medicine at Makerere University. The training covers standards of pharmacy practice, drug regulation, ethics, patient management, handling prescriptions, rational use of medicines, drug interactions, drug storage, infection control, pharmaceutical record keeping, and antiretroviral therapy. Nurses who complete the training receive a certificate.

In our study of Class C drug shops, less than 40 percent of the drug sellers interviewed had attended an organized training within the last two years (figure 7), which had mostly lasted for one day. Despite changes in the antimalarial policy, less than 20 percent of the drug sellers had attended a training course on malaria within the last two years (figure 8). Overall, drug seller training was poor for all the common illnesses.

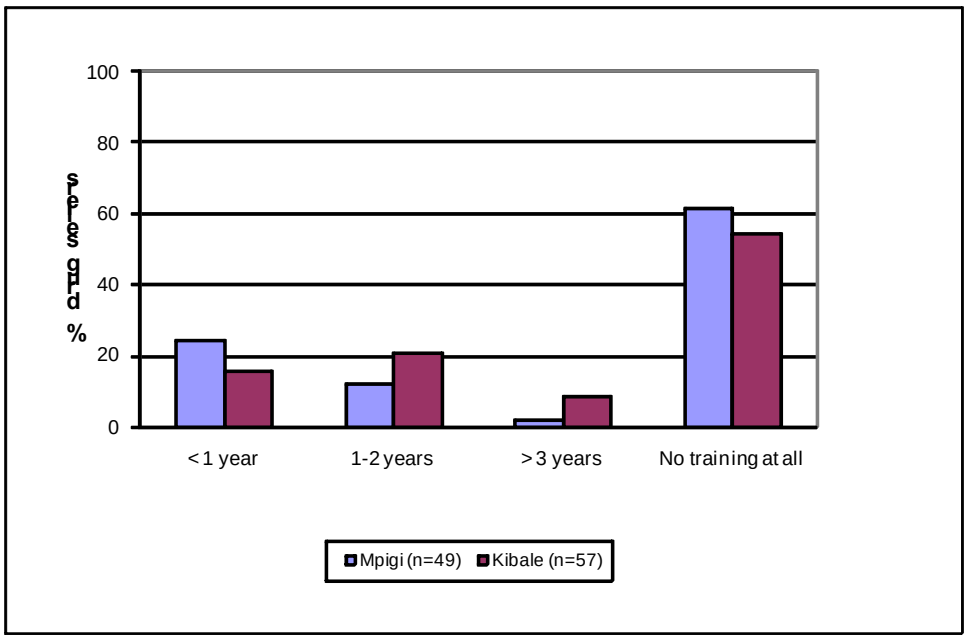


Figure 7. Last time drug seller received formal training

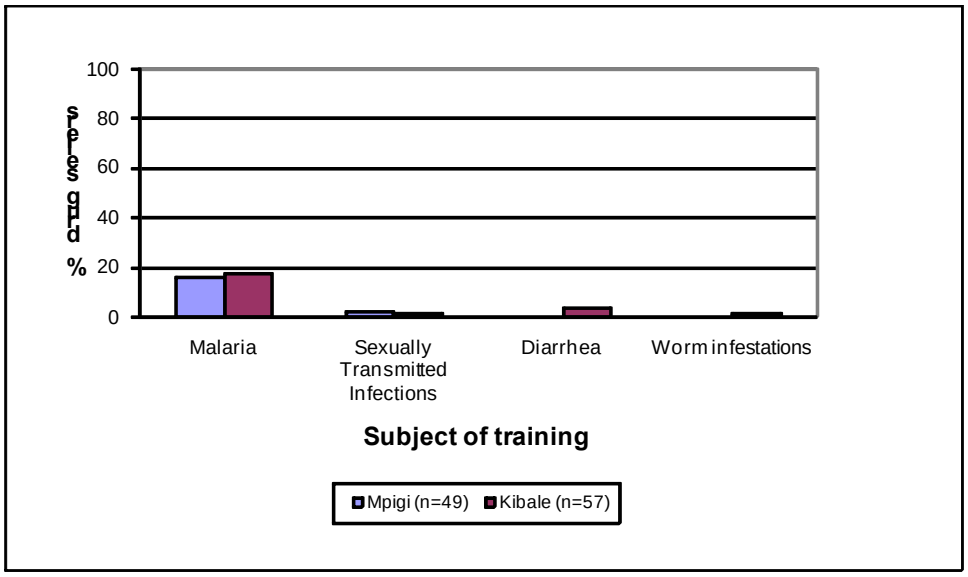


Figure 8. Training courses attended within previous two years

As mentioned, the MOH does not recognize the cadre of nurse assistants; therefore, there is no defined training curriculum for this class of health worker. Nurse assistants are usually supervised by a nurse or a midwife. Table 3 lists the countries health care provider training institutions.

Table 3. Health care training institutions

Institutions	Number in Uganda
Accredited nurse training institutions	36
Accredited allied health training institutions	9
Private training schools	14
Accredited physician training institutions	4
Accredited pharmacist training institutions	3[3]

[3] Makerere University in Kampala, the Mbarara University of Science and Technology, and the Kampala International University, western campus

PHARMACEUTICAL POLICY, LAWS, AND REGULATIONS

Uganda passed its first drug regulation law, *Eddagala Luwangula*, in 1952, followed by a poisons guide in 1960, a dispensary tariff imposed in 1962, and a trade guide in 1963. In 1970, the government enacted the Pharmacy and Drugs Act to regulate the pharmacy profession. The National Drug Policy and Authority Act and the National Medical Stores Statute of 1993 are the most recently enacted pieces of major drug legislation (WHO 2002). The Local Government Act of 1997 gave districts responsibility for providing their own health care and procuring pharmaceuticals (MCDI/SEREFACO 2006).

National Drug Policy

Uganda developed a National Drug Policy in 2002—the work of a drug management task force that was established based on recommendations from a joint mission of government and development partners in 1999. The National Drug Policy's goal is "to contribute to the attainment of a good standard of health by the population of Uganda through ensuring the availability, accessibility and affordability at all times of essential drugs of appropriate quality, safety and efficacy, and by promoting their rational use."

The National Drug Policy addresses the regulation of the importation, production, distribution, marketing, exportation, and use of pharmaceuticals in the public and private sectors.

The policy's main objectives include—

- Making essential drugs accessible to all those who need them by ensuring that they are affordable and always available in all parts of the country
- Ensuring that all drugs available to the public are of appropriate quality, safety, and efficacy
- Continuously and actively promoting the rational use of drugs, and providing objective, relevant, and practical information to health workers, patients, and the general public
- Instituting and sustaining suitable drug financing mechanisms that will ensure the continuous availability of adequate quantities of the required essential drugs
- Ensuring the availability of sufficient suitably trained pharmaceutical and other relevant staff to enable effective implementation of the National Drug Policy

National Pharmaceutical Sector Strategic Plan

The most recent National Pharmaceutical Sector Strategic Plan covered 2002–2007. It states that "the overall aim is to stimulate and improve local production of required essential medicines so that they form a much more substantial proportion of national requirements thus reducing dependence on imports, supporting local industrial enterprise and providing employment opportunities" (cited in UNIDO 2007). A performance review related to the strategic plan was due in July 2008 from WHO; the results of the review will inform the revised plan for 2008.

Essential Medicines List

The MOH's health sector review for 2006–2007 indicated that the National Medicines List of Uganda was revised in 2006 and published in 2007. Although the National Drug Policy indicates that the National Drug Authority (NDA) should revise the essential medicines list at least every three years, the NDA last published the list in 2001. Therefore, changes in standard treatment guidelines for malaria in 2003 and ART should be reflected in the newest list.

Health Professional Councils

The country adopted three bills in 1996 that established a supervisory council for the three main categories of professional health workers: the Uganda Medical and Dental Practitioners' bill, the Uganda Nurses' and Midwives' bill, and the Allied Health Professionals' bill. The Pharmacy Council, whose responsibilities are defined in the Pharmacy Profession and Pharmacy Practice Bill of 2006, makes the fourth supervisory council under the Ministry of Health. The councils set, regulate, monitor, and supervise professional standards of practice and exercise disciplinary control over their respective professionals, including those in the private sector; however, the capacity of the regulatory councils to enforce their standards is limited (MOH/IMCI 2001).

A pharmacy bill that is pending in parliament aims to shift some responsibility from the NDA to the Pharmacy Council. Currently, the Pharmacy Council registers pharmacists in Uganda, but the future goal of the Pharmacy Council would be to regulate pharmacy profession and practice in both the public and the private sectors and control the conduct of registered pharmacists. In addition, the Council would approve the registration of pharmacy and drug shop premises. Specifically, the Council would be responsible for (MOH 2007)—

- Setting and enforcing pharmacy practice standards through visits[4]
- Registering new pharmacists and maintaining a pharmacist register
- Ensuring that pharmacy training institutions conform to standards
- Approving all pharmacy practice outlets both public and private[5]
- Conducting continuing pharmacy education
- Empowering the community to seek quality pharmaceutical services

In addition to the MOH's regulatory councils, parallel professional associations exist, including the Pharmaceutical Society of Uganda,[6] which receives oversight from the Pharmacy Council. The Pharmacy and Drugs Act of 1970 governs pharmacy practice in the country and established the Pharmaceutical Society of Uganda. To practice in the public or private sector, a pharmacist must be a member of the Society, and all manufacturers must have a registered pharmacist on staff. To renew annual licenses, pharmacists must present evidence of credit for continuing education. Most recent figures indicate that the Society has 262 pharmacists registered—mainly Ugandan with a few from other countries (UNIDO 2007). The Society's activities include coordinating pharmaceutical internships, workshops, exhibitions, publication of the

[4] According to an MOH official, due to restricted funding, supportive supervisory visits to pharmacies are limited.
[5] The NDA has current responsibility for this function, although the pharmacy bill pending in parliament will transfer the activity to the Pharmacy Council.
[6] Other associations are the Uganda Private Medical Practitioners Association, the Uganda Private Midwives Association, the Uganda Medical Association, the Uganda Dental Association, and the Uganda Association of Allied Health Professionals.

Pharmaceutical Bulletin, and pre-registration examination for pharmacists. The WHO assessment of national drug authorities indicated that the Pharmaceutical Society of Uganda is involved in self-regulation, but further details were unavailable (WHO 2002).

Uganda National Drug Authority

The National Drug Policy and Authority Statute of 1993 established the National Drug Authority to oversee compliance with and implementation of the country's drug policies, and to ensure the availability of essential, efficacious, and cost-effective medicines. The NDA controls and regulates importation, manufacture, export, quality, storage, and wholesale and retail sales of pharmaceutical products. A parastatal pharmaceutical supplies organization, the National Medical Stores, was created to work with the NDA to ensure efficient procurement, safe storage, distribution, and quality assurance of medicines and other medical supplies.

The NDA is charged with the implementing the National Drug Policy, which includes—

- Regulating import, export, and sale of pharmaceuticals
- Promoting and controlling local production of essential medicines
- Controlling the quality of medicines and medical supplies
- Regulating pharmacies in the country
- Revising the national essential drugs list
- Estimating medicine needs and ensuring that needs are met as economically as possible
- Promoting rational use of medicines through appropriate professional training
- Establishing and revising professional guidelines and disseminating information to health professionals and the general public
- Encouraging research and development of herbal medicines

In addition, the East African Community and the Common Market for Eastern and Southern Africa, of which Uganda is a member, are harmonizing rules and regulations, including those of the pharmaceutical sector. NDA staff is involved in harmonizing pharmaceutical regulations related to quality assurance, safety and efficacy, and Good Manufacturing Practices.

The NDA operates with executive committees and some specialized advisory committees. Although the Minister of Health appoints board members, their independence is established by statute. In a 2002 assessment of 10 drug regulatory authorities, Uganda had the smallest number of drug regulatory staff at about 3 per one million population, compared with, for example, 9 for Tunisia, and 23 for Estonia (WHO 2002). WHO also noted that the Ugandan NDA was financed primarily by donor funds (60 percent), followed by government budget allocation (20 percent), and fees collected for drug registration, (20 percent).

According to a more recent assessment from United Nations Industrial Development Organization (UNIDO 2007), the NDA is constrained by a lack of financial resources and local expertise. Specifically, the organization needs more regulatory staff with administrative and technical expertise in quality control and inspections. In addition, NDA does not have an

adequate information management system that allows users to monitor key data such as medicine prices and availability and import/export data. Physical space is also a problem, especially in the National Quality Control Laboratory.

Departments under the NDA include Drug Assessment and Registration, the Drug Quality Control and Quality Assurance, Drug Information, and Inspectorate.

Drug Assessment and Registration

Uganda started its medicines registration program in 1996. The NDA's Drug Assessment and Registration Department assesses pharmaceutical products by evaluating evidence to assure that pharmaceutical products meet their intended purpose, and then puts them on the National Drug Register, which authorizes them for use in Uganda. Uganda uses the WHO-recommended Certificate of Pharmaceutical Products to assess the safety, efficacy, and quality of medicines (WHO 2002). Uganda does not require the registration of traditional/herbal medicines.

According to the MOH (2007), during fiscal year 2006–2007—

- 539 new human and veterinary medicine applications were received; 460 out of 517 human medicines were approved and registered
- 60 dietary supplement applications were received and 50 were evaluated
- 520 applications to amend products on the register were evaluated

National Drug Quality Control and Assurance

Previously constrained by the lack of specialized equipment and materials, the National Drug Quality Control and Quality Assurance Department's capacity to test drugs entering the country has improved in recent years. Uganda reported that from 1994 to 1997, the NDA tested over half of the pharmaceuticals sampled, and that almost one quarter of them failed (WHO 2002). However, by 2006–2007, the National Drug Quality Laboratory tested 1,806 samples, of which 18 failed (MOH 2007). The laboratory also tests devices, such as condoms, and long-lasting insecticide-treated nets.

As part of its support from the President's Malaria Initiative, the National Drug Quality Laboratory received support from the U.S. Pharmacopeia's Drug Quality and Information program in 2006 including staff training on Good Laboratory Practices and major testing methods, such as high performance liquid chromatography, dissolution, ultraviolet spectrophotometry, and gas chromatography. The laboratory also received equipment such as a gas chromatographer and a high-performance liquid chromatographer.

Drug Information

The Drug Information Department carries out pharmacovigilance activities and provides information on pharmaceuticals to health professionals and the public. The department's Pharmacovigilance Centre (established 2005) is responsible for developing a nationwide system for monitoring and reporting adverse drug events. However, insufficient staff and funding have limited its activities to mainly adverse drug reaction reporting. To ensure that the public and health professionals have access to unbiased medicine information, the Drug Information

Department provides guidelines for advertisements and pharmaceutical marketing representatives. The department is also responsible for promoting the public's awareness of the rational use of medicines.

As part of its responsibilities, the Drug Information Department "sensitized" 1,307 health workers on rational medicines use, pharmacovigilance, and drug regulations in 2006–2007 (MOH 2007).

Inspections

The Inspectorate Department is responsible for inspecting national and international pharmaceutical manufacturers (including conducting Good Manufacturing Practice audits) and distributors, such as pharmacies, drug shops, and health clinics and dispensaries. The goal of inspection is to assure compliance with statutory and quality requirements. There are seven regional NDA offices with a one NDA inspector stationed at each office: Southeastern, Central, Eastern, Northern (2), Western, and Southwestern. According to the MOH, in 2006–2007, the Inspectorate Department inspected 360 pharmacies to ensure that authorized people were supervising operations. In addition, they inspected 3,720 drug shops to ensure that premises and practices complied with the licensing provisions (MOH 2007).

The MOH noted in 2007 that inadequate coordination with other regulatory and professional councils had resulted in multiple private clinics and dispensaries being licensed or authorized by other councils without adequate NDA inspection and supervision. When those private facilities mishandle medicines, the NDA can receive public criticism.

As a result of government decentralization efforts, the MOH created the District Assistant Drug Inspector (DADI) position to operate in each district. Although DADIs have been employees of the district and reported to the District Health Officers, they received some financial support and training from the NDA (MCDI/SEREFACO 2006). Their responsibilities included regulating the use, storage, and handling of pharmaceutical products, and they also had inspection responsibilities; for example, they helped the NDA carry out premises inspections of drug shops that are required before licensing and assist in postmarketing surveillance of drug quality. And although they report their findings to the NDA regional drug inspectors, they otherwise are not part of the NDA organizational structure. However, according to sources at the Ministry of Health, recent MOH restructuring has resulted in the elimination of the DADI position. Their responsibilities will be taken up by NDA zonal inspectors, who are required to have a Diploma in Pharmacy. The current DADIs will begin working as senior dispensers at the subdistrict level as soon as NDA can recruit more zonal inspectors. The zonal drug inspectors will report to the regional drug inspector; each zone will comprise three districts.

Currently, there are seven regional offices with regional inspectors directly responsible for inspecting pharmacies—

Region	Duty station/Office
South Western	Mbarara
Western	Hoima
Eastern	Tororo

Northern	Lira
Northern	Arua
Central	Nakawa
South Eastern	Jinja

Regulations Related to Pharmacies and Drug Shops

Besides the Pharmacy and Drugs Act of 1970, which regulates pharmacy practices, the National Drug Policy and Authority Statute regulates the operation of pharmacies and Class C drug shops, which are only allowed to sell Class C medicines as defined by the National Drug Policy and Authority Regulations of 1995.[7] (See Annex 2 for a list of the Class C drugs.) Any change to the list of Class C medicine list requires a change in the law. The National Drug Policy and Authority (Certificate of Suitability of Premises) Regulations of 1995 describe the standards that pharmacies and drug shops must meet to be registered/licensed.

Drug shop/clinic in Nkooko Kitegura parish, Kibale district

The NDA is responsible for licensing pharmacies, drug shops, wholesalers, and manufacturers. The NDA's licensing requirements and guidelines for 2007 (see Annex 3 for a copy of the guidelines) indicate that Class C drug sellers have to renew their licenses every year and pay the accompanying fees, which vary based on the location of the shop (licenses in rural areas are cheaper). Shops must also pay an annual fee to the Pharmaceutical Society of Uganda and additional fees to amend the license, such as to note a change of ownership or management. Retail pharmacies can apply for a license to sell wholesale as well as retail; they must meet some additional requirements to get dual licenses. Class C drug shops are not allowed to sell drugs on a wholesale basis.

To register a drug shop with the NDA, the Local Council Chairman 3 must first endorse the application, which is followed by inspection of the premises by the DADI, and then the final approval by the district health officer. Once the shop has a license from the NDA, the DADI inspects and provides supportive supervision of drug shops, reporting both to the NDA and the district health officer.

In our study, we found that more drug shops in Kibale and Mpigi had a business license for 2008 than had an NDA license (63.8 percent compared to 46.7 percent). Within the last year, 65.7

[7] The government defines three drug classes in the National Drug Policy and Authority (Certificate of suitability of Premises) Regulations of 1995.

percent of the drug shops had been inspected, mainly by NDA; 3 percent of the shops that had been inspected in Kibale had received inspection from the local government authority. Almost a quarter of the drug shops that were surveyed in the two districts had never been inspected by either NDA or the district local government (table 4).

Table 4. Last time the shop was inspected

	Percentage of drug shops	
	Mpigi (*n* = 49)	Kibale (*n* = 56)
Within the last year	67.3	64.2
Within the last 2 years	2.0	0
Don't know	8.2	9.0
Never	22.5	26.8

A Class C shop must be at least 500 meters from a pharmacy or other drug shop; in addition, certain areas, such as Kampala district are closed to new shop openings. These restrictions are an attempt to increase services in underserved (rural) areas. Any drug selling outlet, either a pharmacy or a drug shop, can have its license cancelled if found to allow unqualified staff to handle medicines or be the person in charge, or by stocking/selling medicines it is either not authorized to sell or that are unregistered or counterfeit. Although over 40 percent of the drug sellers in Mpigi and Kibale refused to answer the question, 16 percent said they were unaware of the medicines that they were not allowed to stock (*n* = 106).

The drug shop owner must assure that the employee in charge of the shop is qualified and present his or her professional certification to the Pharmaceutical Society of Uganda at the time of application. The employee in charge must be a clinical officer or pharmacy technician or at minimum, a nurse, and he or she must be registered by their respective professional councils (e.g., the Nurses Council or Allied Health Council). However, as we reported above, in the rural districts of Kibale and Mpigi, nurse assistants are dispensing medicines in drug shops.

PHARMACEUTICAL DISTRIBUTION SYSTEM

The NMS and the Joint Medical Stores (JMS) are the two primary pharmaceutical distributors. They distribute over 90 percent of imported medicines within the public and private nonprofit sectors. Registered imported medicines must have a local technical agent who is responsible for the drug in the Ugandan market (MMV 2008). The local technical agents either wholesale the medicines they receive or they sell them to other local wholesalers, who then sell to retailers, although the NMS can also buy from wholesalers if necessary (MCDI/SEREFACO 2006). The reach of these private wholesalers is geographically limited and serve mainly the district health facilities and private pharmacies where they are located. Pharmacies can legally operate retail/wholesale operations with the appropriate licenses, and drug shops often source their products from these retail/wholesale establishments. In districts without pharmacies, small drug shops may buy from large drug shops that in turn have bought from pharmacies in neighboring districts, although drug shops are not legally allowed to sell products as wholesalers (MMV 2008).

The local manufacturers either manage their own distribution through private transporters or use subsidiaries as wholesalers. Some local manufacturers also operate as local technical agents for imported products (MMV 2008). The NMS is the only supplier in Uganda that distributes to all districts—districts have to arrange for their own transport if they use any other supplier. Some NGOs manage their own distribution for vertical programs (MCDI/SEREFACO 2006).

National Medical Stores

The NMS is an autonomous government agency overseen by the MOH and the Ministry of Finance. It is responsible for procuring and distributing essential medicines and supplies to public sector health facilities. NMS also procures additional products for use as trading stock for cash sales to public sector facilities and to the private sector. NMS delivers orders every 8 weeks to each district (to the District Health Officer or agreed upon premises) and every month to the 100 or so antiretroviral therapy sites nationwide.

The MOH has converted the pharmaceutical supply system from a kit-based push system to an order-based pull system, making each health facility responsible for quantifying how many medicines they need and placing orders directly with the district authorities, who consolidate them and send them to NMS. In addition, the government established a central essential medicines account to integrate all funds to procure public sector medicines and health supplies. The Health Sector Strategic Plan II and the MOH's Annual Health Sector Performance Report for 2006–2007 note that pharmaceutical management and procurement have been complicated by initiatives such as the Global Fund and the President's Emergency Plan for AIDS Relief, for example, by increasing the amount of pharmaceuticals in the distribution system and increasing the complexity of planning, managing, and reporting.

A 2005 President's Malaria Initiative assessment noted that the NMS was operating at near full capacity at that time, and the MOH's 2006–2007 review indicated that the distribution system was laboring. Only 35 percent of health units surveyed did not report any stock-outs of indicator medicines in six months, significantly missing the 55 percent target (MOH 2007). Contributing factors to poor availability include inadequate human resources at all levels; facility personnel

who lack the capacity to quantify their medicine requirements or manage inventory; crowding at the NMS, which resulted in slower order processing; and NMS's failure to adhere to published delivery schedules. In addition, cash flow problems at NMS caused delays in procurement, which led to central level out-of-stocks.

Joint Medical Stores

The JMS is a major nonprofit organization that supplies pharmaceuticals and medical supplies to mission facilities, other nonprofit providers, private pharmacies, and to government facilities. It is the second largest distributor in Uganda after NMS and also has customers in neighboring countries (Wehrens 2007). When the NMS is out-of-stock, public health facilities can send orders to JMS; it distributes about 20 percent of the public sector's medicines and supplies (UNIDOS 2007). JMS receives some government support and works closely with the MOH. JMS has no distribution system outside of the Kampala area and generally operates on a cash-and-carry basis with some contracted transport to certain districts; however, in 2005, JMS was piloting a system in partnership with the Diocese Health Coordinators to use a private transportation firm to deliver shipments to four country zones (PMI 2005).

Private Retail Sector Supply Chain

As mentioned, although the NMS and the JMS are the primary supply source for the public and private nonprofit sectors, retail outlets located outside of Kampala, such as pharmacies and drug shops, rely on wholesalers and larger retail pharmacies that also function as wholesalers as their source of pharmaceuticals. However, this wholesale/retail pharmacy supply network does not cover all districts (e.g., Mpigi), so outlets in underserved districts must travel to neighboring districts to buy medicines. This situation results in a complex supply chain web of trading among the various wholesalers and retailers in multiple districts.

In almost all of the drug shops that we surveyed in two districts, shops placed their orders with suppliers in person and picked them up themselves the same day (tables 5 and 6 and figure 9). The frequency of order placement varied; 13 percent of the drug shops had no regular schedule for ordering medicines—basing orders on need (table 7).

Table 5. Number of days between placing order and receiving supplies

	Percentage of drug shops	
	Mpigi (*n* = 49)	Kibale (*n* = 57)
Less than a day	98.0	73.7
1–7 days	2.0	22.8
7 –15 days	0	3.5

Table 6. Method of receiving supplies

	Percentage of drug shops	
	Mpigi (*n* = 49)	Kibale (*n* = 57)
Commercial transportation paid by buyer (e.g., bus)	0	15.8
Drug shop picks up	95.9	84.2
Supplier transportation	4.1	0

Table 7. Frequency of ordering

	Percentage of drug shops	
	Mpigi (*n* = 49)	Kibale (*n* = 57)
Daily	4.1	1.8
Weekly	30.6	22.8
Bi-weekly	22.4	7.0
Monthly	24.5	36.8
Bi-monthly	0	8.8
When needed	8.2	17.5
Other	10.2	5.3

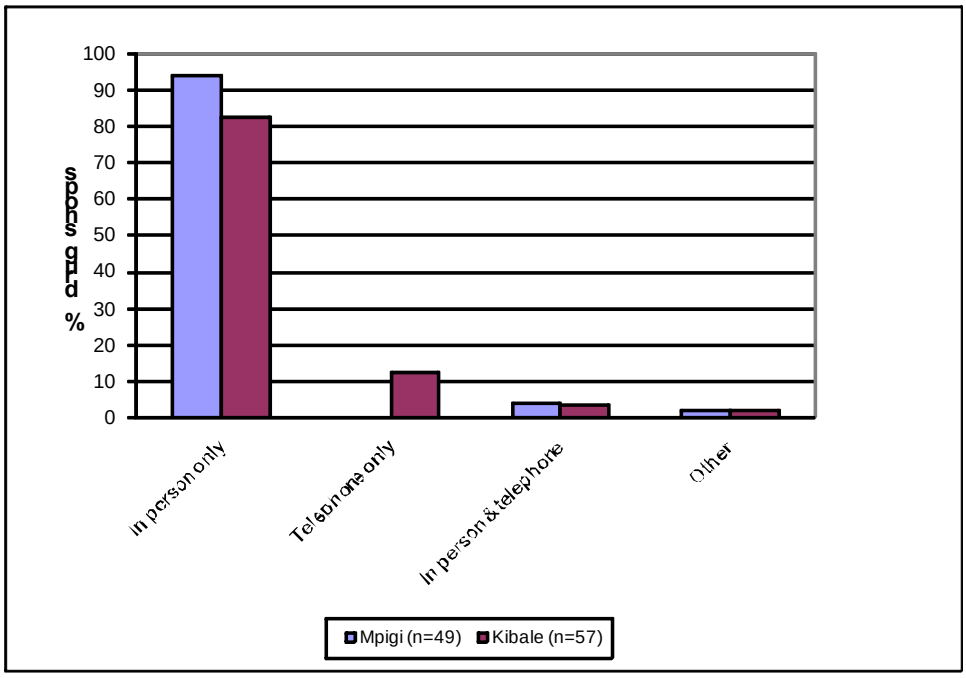


Figure 9. Method of placing orders to pharmaceutical suppliers

As a result of the complex and less competitive procurement scenario outside of Kampala, pharmaceutical and commodity prices tend to be higher. According to MMV (2008), wholesale mark-ups are generally not high (5–10 percent), except in the case of limited source products, which tend to have a higher mark-up. On the other hand, products with low demand, short shelf life, and higher prices to begin with tend to have smaller mark-ups, although shortages drive increases.

By far, the greatest proportion of a medicine's price is the retail mark-up. MMV (2008) reported that pharmacy mark-ups average about 110 percent; private clinic mark-ups average 300 percent; and drug shop mark-ups average 100 percent, but those mark-ups vary dramatically by product—up to 900 percent in some clinics. The different retail mark-ups provide the most variability in the prices that clients pay.

Public and Private Sector Dispensing Facilities

According to recently cited government data on the numbers of public and private health facilities that dispense medicines indicate that there are 2,100 public health facilities; 485 private nonprofit facilities (MMV 2008); about 290 private retail pharmacies, of which two thirds are located in the Central region (NDA 2008); 2,700 private for-profit health facilities (MMV 2008); and almost 4,000 drug shops (NDA 2008). According to data provided to MSH by NDA, Uganda had 362 registered/licensed pharmacies (wholesalers and retailers) in 2007. Table 8 shows the regional break down.

Table 8. Number of registered/licensed pharmaceutical outlets by region: 2007*

Type	Southeast	Southwest	Northern	Eastern	Western	Central	Total
Wholesale pharmacies	4	3	6	4	4	50	**71**
Retail pharmacies	11	0	2	1	0	131	**145**
Wholesale/retail pharmacies	12	28	15	10	20	61	**146**
Drug shops	598	655	517	517	646	1,010	**3,943**

*Not including distributors of veterinary products only
Source: Personal communication, NDA, April 2008

The number of nonregistered/nonlicensed pharmaceutical outlets overall is unknown; however, it is estimated that the sale of medicines through informal outlets is large (UNIDOS 2007). Figures 10 and 11 show the results of a mapping exercise in EADSI's demonstration districts of Kibale and Mpigi, which designate both registered and unregistered drug shops; the Mpigi and Kibale maps show 17 and 44 unregistered outlets, respectively. Other informal sources of medicine include traditional healers and mobile drug sellers. Published information on mobile drug sellers was not found.

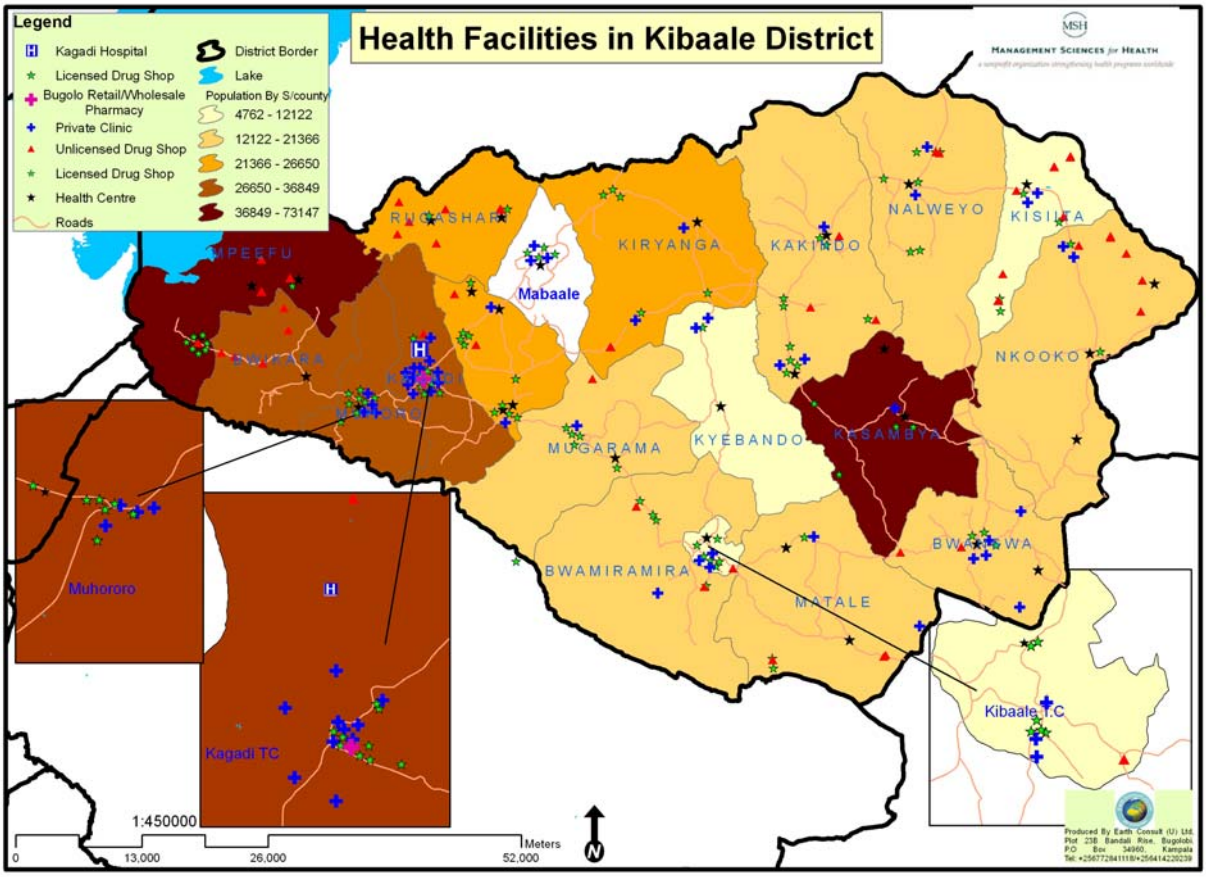


Figure 10. Map of licensed and unlicensed drug shops and public and private clinics in Kibale

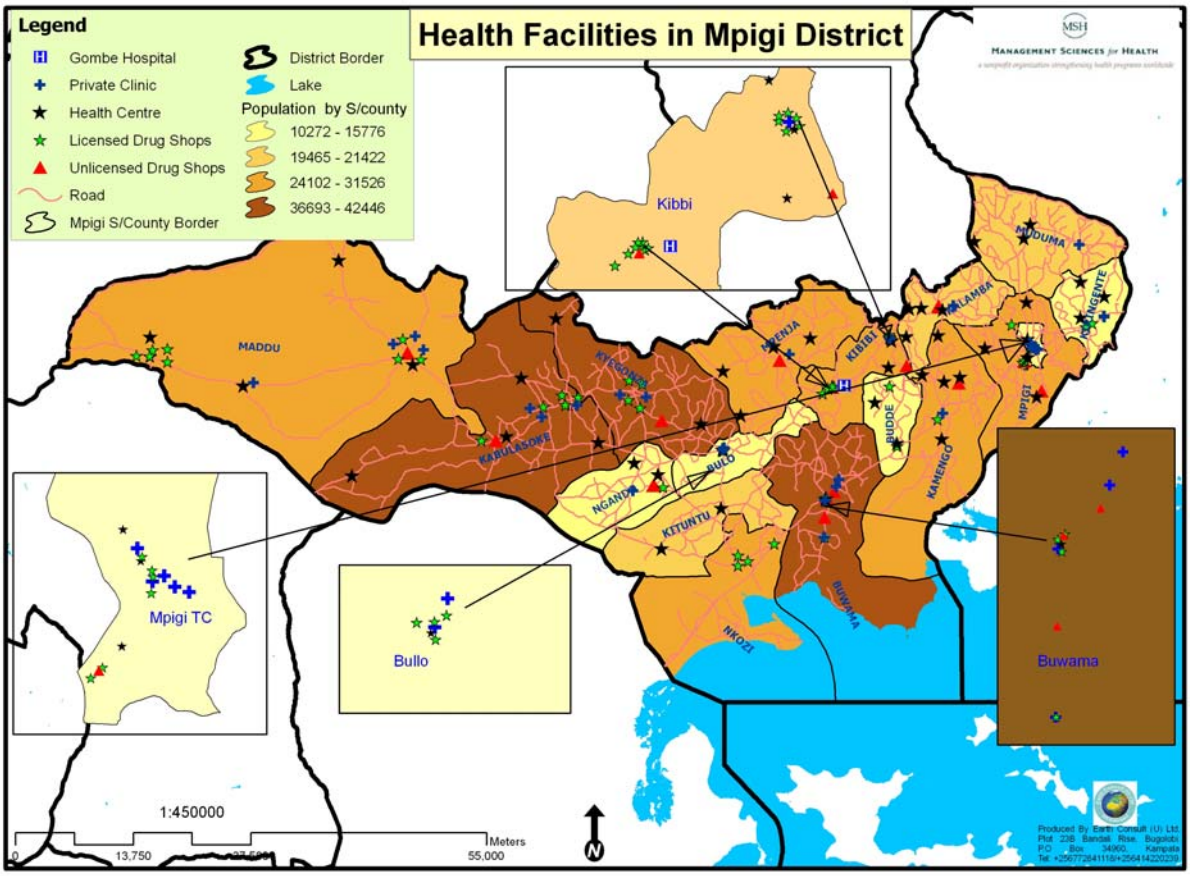


Figure 11. Map of licensed and unlicensed drug shops and public and private clinics in Mpigi

MSH's survey of health center II facilities, private clinics, and drug shops in Mpigi and Kibale found accessibility differences between public and private facilities. For example, 88 percent of the private clinics and 87 percent of the drug shops were open seven days a week, while only 36 percent of the public health facilities were open seven days a week. The private facilities were also open longer—the clinics averaged 4.5 hours per day and the drug shops about 12 hours per day, while the public facilities only averaged about nine hours per day.

A relatively recent accounting of registered private, for-profit health providers in the country showed that these providers offer a wide range of primarily curative health services (table 9), with most located in the Central region (Mandelli et al. 2005). This survey did not include unregistered providers, pharmacies, or drug shops.

Table 9. Health Services Offered by Private For-Profit Health Providers by Region

Services offered	Central (*n* = 241)	Eastern (*n* = 35)	Northern (*n* = 29)	Western (*n* = 54)
Tuberculosis	17%	26%	3%	7%
Community-based services	20%	17%	10%	6%
Immunization	28%	14%	10%	7%
Dental services	28%	29%	3%	9%
Adolescent reproductive health services	41%	40%	59%	24%
Post-abortion care	37%	49%	62%	39%
Maternity services	43%	54%	17%	35%
Prenatal care	56%	60%	24%	59%
Childhood illnesses	62%	74%	55%	46%
Family planning counseling	76%	69%	72%	76%
Family planning products	85%	74%	79%	76%
Sexually transmitted infection treatment	90%	94%	90%	96%
Malaria treatment	96%	94%	93%	96%

Source: Mandelli et al. 2005

MSH found that drug shops offered additional services contrary to what they are legally allowed; for example, 66 percent of the facilities offered injections to patients, mostly in Kibale district. Very few drug shops (less than 10 percent) carried out clinical diagnosis/laboratory services or immunization. However, over 70 percent of the drug shops treated wounds/burns with no marked differences across the two districts (Figure 12). In addition, premises labeled as clinics often dispense medicine.

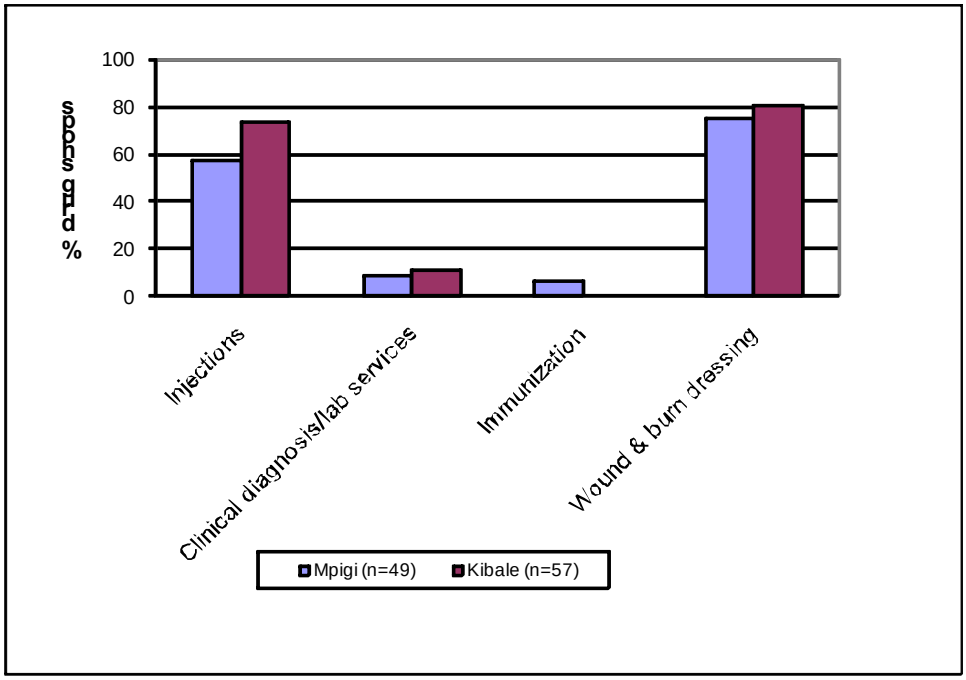


Figure 12. Services offered by Class C drug shops

Medicine Prices and Medicine Expenditure in Uganda

Public sector facilities provide medicines free of charge, while NGO/mission sector facilities and private sector facilities charge fees. However, data from Uganda's 2003 household expenditure study show that more than 45 percent of people's health spending is on medicines (World Bank 2005). Only 65 percent of people who sought care in public health centers were able to obtain their prescribed medicines—the others paid for all or part of their prescriptions indicating that some drugs were not available and some drugs were not actually free of charge (World Bank 2005).

Medicine Prices in the Private Sector

The most recent nationwide information available on pricing comes from the 2004 WHO/Health Action International medicine pricing survey of 45 medicines in the nongovernmental facilities (primarily rural) and retail pharmacies (primarily urban) (WHO/HAI 2004).
The assessment compares medicine prices to international reference prices and creates a median price ratio, which is the ratio of the local price divided by an international reference price converted into the same currency. A median price ratio of 2.0 means that the price is twice the international reference price. The 2004 pricing survey revealed that market prices can be two to three times the manufacturers' and/or importers' selling price (international reference prices). For example, at private retail pharmacies, the median price ratio that patients paid for the lowest priced generics was 2.6 compared to the international reference price (range 0.28–16.1) and for innovator brands, the price was to 13.6 times the international reference price (range 1.68–118.0). In the NGO sector, the median price ratio for the lowest prices generics was 2.7 compared with international reference price, with a range of 0.53 to 12.34. Assessors did not find any innovator brands in the NGO facilities. In both the retail pharmacies and the NGO facilities, the prices that patients paid for medicines varied widely from place to place; patients were paying significantly more for some medicines depending on which pharmacy or health center they attended. In general, however, the patient prices in the private sector were the same as those in the NGO sector.

The WHO/HAI report noted that NGO facilities, which are generally located in rural areas, are charging the same as urban-centered private pharmacies, despite being subsidized by the government through primary health care grants and a credit line as mentioned previously. In addition, the report noted that drug shops are also important medicine dispensers in rural areas, and that an evaluation of their actual and potential role in the supply of medicines was an information gap (WHO/HAI 2004).

An update from late 2006 noted that in a review of 73 public, private, and mission facilities, there were still no differences in medicine prices between private urban and private rural facilities, nor were there significant differences in prices in the mission sector compared with the private sector. Mission sector prices were about 11 percent higher overall in urban areas compared with rural areas (HAI 2006).

In our study in June 2008, we checked the availability and prices of a list of tracer commodities in Kibale and Mpigi. Table 10 lists the median prices of available drugs on the tracer list in 106 drug shops and 35 private clinics. Prices were generally higher in Mpigi than in Kibale overall, but the differences in prices in drug shops compared with private clinics were minor.

Table 10. Median Prices of 30 Essential Medicines and Supplies in Drug Shops and Private Clinics

Disease	Key Medicines	Median prices of lowest priced medicine			
		Mpigi		Kibale	
		Drug shops (*n* = 49)	Private clinics (*n* = 14)	Drug shops (*n* = 57)	Private clinics (*n* = 11)
Malaria	Artemether/lumefantrine tablet	N/A	N/A	N/A	N/A
	Chloroquine 300 mg (150 mg base) tablet	50	25	20	20
	Sulfadoxine + pyrimethamine 500 mg+ 25 mg tablet	333	333	167	200
	Sulfamethoxypyrazine + pyrimethamine 500 mg + 25 mg tablet	1,750	1,500	1,250	N/A
	Quinine injection 300 mg/ml, 2 ml amp	1,000	1,000	800	1000
Acute respiratory tract infections	Co-trimoxazole tablet 480 mg	50	50	30	30
	Co-trimoxazole syrup 240 mg/5ml, 60 ml	1,500	1,500	1,000	1000
	Amoxicillin tablet/capsule 250 mg	100	100	100	50
	Amoxicillin syrup 125 mg/5 ml, 100 ml	2,000	2,000	1,650	1750
Skin infections	Benzoic/salicylic acid ointment, 30 g	1,500	N/A	1,500	N/A
Protozoal infestations	Metronidazole tablet 200 mg	50	50	25	25
Urinary tract infections	Erythromycin tablet 250 mg	100	100	100	100
	Doxycycline tablet 100 mg	100	100	100	100
Fungal infections	Ketoconazole 200 mg tablet	500	N/A	N/A	N/A
	Nystatin oral susp 100,000 IU/ml, 30 ml	2,500	N/A	2,500	N/A
	Nystatin pessary 100,000 IU	200	232	200	200
Pain	Ibuprofen tablet 200 mg	50	50	25	25
	Paracetamol tablet 500 mg	20	20	13	13
	Acetylsalicylic acid tablet 300 mg (aspirin)	17	10	10	10
Conjunctivitis	Tetracycline eye ointment 1%, 3.5 gm	600	600	500	500
Worm infestations	Albendazole tablet 200 mg	500	500	400	400
	Mebendazole tablet 100 mg	50	40	20	25
Diarrhea	Oral rehydration solution	300	300	300	300
	Zinc tablet 30 mg	200	N/A	N/A	N/A
Others	Benzylpenicillin inj (PFR) 1MU	500	500	500	500
	Procaine penicillin fortified (PPF 4MU)	1,000	1,000	1,000	900
	Glucose infusion 5%	2,000	2,250	1,500	2,000
	Sodium chloride infusion 0.9%	2,000	2,500	1,500	2,000
	Condoms	300	300	300	300
	Combined contraceptive pills	300	300	300	300

N/A = information or drug not available

Cost of Malaria Treatment

In a recent study of malaria treatment practices in Nakasongola district, researchers asked 420 caretakers of children the cost of medicines, consultation, and other associated fees (excluding transportation) to treat a child with suspected malaria (Batega et al. 2006). Respondents reported the range of costs as 100 Ugandan shillings (UGX)[8] to UGX 120,000 for the first treatment episode with an average cost of UGX 5,781. About 28 percent of respondents reported spending

[8] USD 1 = UGX 1,640

between UGX 100–1,000, 39 percent spent between UGX 1,001–5,000, and 33 percent spent more than UGX 5,000.

MMV's survey of health facilities in six districts illustrated a wide range of prices for antimalarials, including ACTs, which were 5–60 times more expensive than ineffective medicines, such as chloroquine (MMV 2008). Prices also varied by type of outlet (private clinic, pharmacy, or drug shop) and by district. The typical cost for a course of ACTs for adults ranged from UGX 9,000–20,000, while the ACT course for children ranged from UGX 5,000–15,000. The prices of other antimalarials also varied. The researchers noted that the average out-of-pocket cost for an average family's malaria treatment using ACTs for a year would range from UGX 85,000–148,750—or the equivalent of 91 days of income for the average household.

AVAILABILITY OF MEDICINES

In a survey of the Ugandan pharmaceutical sector conducted by WHO/HAI (MOH 2002), representatives from 300 households reported that the main reason that they did not receive all of the medicines they were prescribed was because the public facility did not have all of the medicines (44 percent); the next most commonly reported reason was that they did not have enough money to pay (27 percent), indicating that they had sought to buy drugs in the private sector. The public facility was still the most popular source of medicines (46 percent) because medicines are free. Twenty-one percent got their medicines from a private health center, 10 percent from a private pharmacy, and 11 percent from a shop or market.

One of the main reasons cited for less than expected uptake in the public sector after 2001 is the lack of availability of medicines in facilities (Anokbonggo et al. 2004; Xu et al., 2006). Table 11 compares availability percentages among public-sector facilities, private pharmacies, and private nonprofit facilities; private pharmacies were far more likely to have the indicator medicine on hand. The pharmaceutical sector survey also noted that in the public health facilities assessed, 75 percent of the key medicines were available, but stock-out durations lasted three months (MOH 2002). In the government's most recent health sector performance report (MOH 2007), out of 36 facilities, 65 percent had stock-outs of at least one of six indicator medicines over six months—and at the health center II level, where the majority of people seek care, 88 percent had stock-outs.

Table 11. Availability of selected medicines by drug dispensing facility type, 2004

Tracer Medicine	Public sector facilities (*n* = 20)	Private retail pharmacies (*n* = 20)	NGO sector (*n* = 20)
Amitriptyline	15%	75%	60%
Atenolol	10%	60%	40%
Betamethasone cream	10%	85%	15%
Captopril	20%	75%	50%
Carbamazepine	40%	80%	45%
Cephalexin	0%	50%	20%
Co-trimoxazole suspension	15%	80%	40%
Fluconazole 200 mg	15%	45%	0%
Glibenclamide	25%	85%	60%
Metformin	25%	85%	50%
Omeprazole	0%	95%	45%
Ranitidine	5%	80%	30%
Salbutamol inhaler	0%	95%	10%

Source: WHO/HAI 2004

A follow-up monitoring report in 2006 (HAI 2006) showed that the median medicine availability overall in 27 public facilities was only 33 percent. The situation in 14 mission facilities was worse, with only 29 percent medicine availability. The 32 private facilities had better availability overall at 58 percent, but that was skewed toward the urban facilities (70 percent availability) compared to rural facilities (33 percent availability). The list included 45 medicines—29 on the essential drug list.

Our 2008 data collection exercise showed that the 30 tracer medicines were available in 50 percent of the 76 outlets in Mpigi and 46 percent of the drug shops in Kibale. There was a wide variation in availability of individual medicines in each district (Table 12); however, the only about one-third of the public health facilities had artemether/lumefantrine available, while chloroquine was still widely available in the private sector.

Table 12. Percentage availability of 30 essential medicines and supplies in drug shops, private clinics, and health center II-level facilities

Disease	Key Medicines	Mpigi			Kibale		
		Percentage of facilities with medicines available					
		Drug shops (*n* = 49)	Private clinics (*n* = 14)	Health center IIs (*n* = 13)	Drug shops (*n* = 57)	Private clinics (*n* = 19)	Health center IIs (*n* = 9)
Malaria	Artemether/lumefantrine tablet	2.0	0	30.8	5.3	0	33.3
	Chloroquine 300 mg (150 mg base) tablet	75.5	71.4	15.4	80.7	63.6	0
	Sulfadoxine + pyrimethamine 500 mg+ 25 mg	81.6	78.6	61.5	82.5	90.9	44.4
	Sulfamethoxypyrazine + pyrimethamine 500 mg +25 mg	18.4	50.0	0	12.3	27.3	0
	Quinine inj 300 mg/ml	26.5	92.9	23.1	50.9	90.9	11.1
Acute respiratory tract infections	Co-trimoxazole tablet 480 mg	79.6	92.9	53.8	70.2	100	33.3
	Co-trimoxazole syrup 240 mg/5 ml	49.0	64.3	0.0	63.2	72.7	0
	Amoxicillin tablet/capsule 250 mg	65.3	92.9	15.4	61.4	90.9	22.2
	Amoxicillin syrup 125 mg/5 ml	57.1	64.3	0.0	45.6	72.7	0
Skin infections	Benzoic/salicylic acid ointment, 30 g	36.7	7.1	0.0	19.3	27.3	0
Protozoal infestations	Metronidazole tablet 200 mg	79.6	92.9	38.5	82.5	100	44.4
Urinary tract infections	Erythromycin tablet 250 mg	49.0	78.6	0.0	42.1	81.8	11.1
	Doxycycline tablet 100 mg	51.0	85.7	46.2	35.1	81.8	33.3
Fungal infections	Ketoconazole 200 mg tab	14.3	21.4	7.7	5.3	18.2	0
	Nystatin oral susp 100,000 IU/ml, 30 ml	20.4	21.4	0.0	21.1	18.2	0
	Nystatin pessary 100,000 IU	38.8	28.6	7.7	29.8	36.4	0
Pain	Ibuprofen tablet 200 mg	77.6	85.7	30.8	71.9	81.8	11.1
	Paracetamol tablet 500 mg	91.8	100	46.2	98.2	100	33.3
	Acetylsalicylic acid tablet 300 mg (aspirin)	67.3	78.6	84.6	50.9	54.5	33.3
Conjunctivitis	Tetracycline eye ointment 1%	63.3	71.4	30.8	35.1	54.5	33.3
Worm infestations	Albendazole tablet 200 mg	46.9	42.9	0.0	21.1	36.4	33.3
	Mebendazole tablet 100 mg	69.4	92.9	15.4	82.5	81.8	11.1
Diarrhea	Oral rehydration solution	71.4	92.9	69.2	43.9	72.7	33.3
	Zinc tablet 30 mg	10.2	14.3	0.0	5.3	0.0	0
Other	Benzylpenicillin injection (PFR) 1MU	20.4	64.3	30.8	52.6	90.9	11.1
	Procaine penicillin fortified (PPF 4MU)	28.6	78.6	30.8	52.6	81.8	22.2
	Glucose infusion 5%	16.3	57.1	15.4	17.5	90.9	11.1
	Sodium chloride infusion 0.9%	20.4	50.0	23.1	14	90.9	11.1
	Condoms	77.6	78.6	69.2	80.7	72.7	33.3
	Combined contraceptive pills	83.7	71.4	61.5	50.9	63.6	22.2

Overall, common antibiotics that are used to treat urinary tract infections, respiratory tract infections, and sexually transmitted infections were available in at least 40 percent of the drug shops surveyed, although they are not legally allowed to dispense antibiotics. Amoxicillin 250

mg capsules, co-trimoxazole 480 mg tablets, and metronidazole 200 mg tablets were the most common antibiotics, available in over half the drug shops (figure 13).

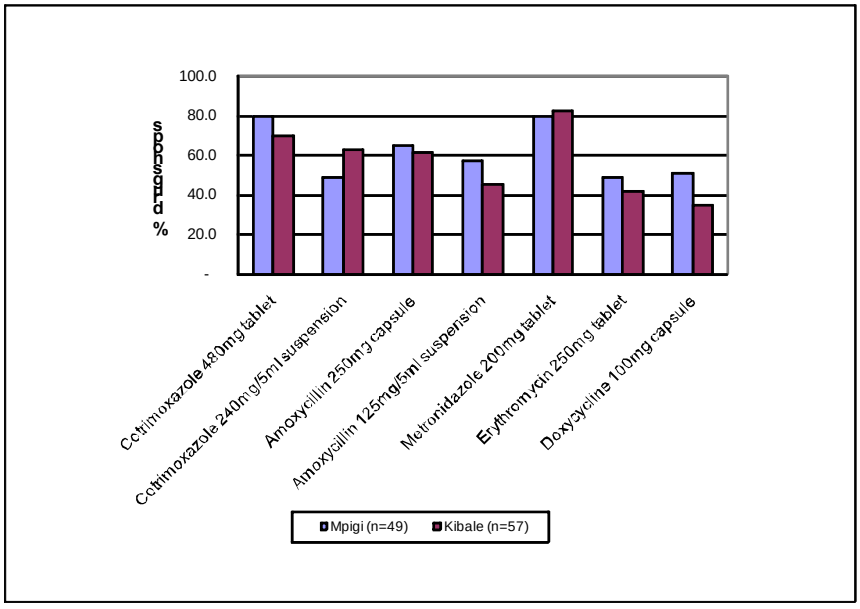


Figure 13. Availability of antibiotics in Class C drug shops

Another recent study looked at the availability of the recommended first-line malaria treatment, artemether-lumefantrine, in 30 facilities (health center II–IV) in three newly established districts (AGHA 2007). Many facilities did not stock ACTs at all, but the old treatments, chloroquine and Fansidar, were still commonly available, although no longer recommended. A study of six districts showed better availability of artemether-lumefantrine in 124 public and 50 NGO facilities (42–95 percent of facilities in each district had artemether-lumefantrine), but many facilities were low in stock (MMV 2008). In addition, the facilities still had abundant stock of chloroquine, and outlets that stocked antimalarials generally stocked six to nine different types; however, the same study surveyed 539 private sector retail outlets and found that only nine percent stocked any type of ACT.

Although private outlets generally are better stocked with essential medicines, about three-quarters of the 100 private sector dispensers interviewed in Nakasongola district (Batega et al. 2006) said they sometimes ran out of stock of antimalarial drugs because of—

- Long distance to replenishment source
- Lack of sufficient capital to restock
- Unreliable suppliers
- High demand during the rainy season

The MOH's pharmaceutical sector survey of 2002 (MOH 2002) concluded that the problem with medicines being out of stock at public health facilities should be a major cause for concern that the MOH should address; however, the latest data from the MOH health sector assessment in 2007 indicate that availability is an ongoing problem, which will keep people returning to the private sector.

QUALITY OF MEDICINES

Most available data on medicine quality in the Ugandan market relates to antimalarials. In 2001, 39 percent of chloroquine tablets sampled from pharmacies and drug shops and tested using high performance liquid chromatography were found to be substandard (Ogwal-Okeng et al., 2003); a more recent study found that over one-third of antimalarial samples sampled from private pharmacies (23/66) failed either the dissolution test or thin-layer chromatography (Bate et al., 2008). In addition, reports of counterfeit drugs in Uganda have been published over the years (as noted in USP-DQI 2008), although the NDA reported that 237 recent antimalarial samples from public and private sector outlets were genuine (Nafula 2008).

A simpler method to gauge the quality of medicines dispensed is to use registration by a country's national drug authority as an indication of the overall appropriateness of medicines available in the marketplace. This is not a true indication of product quality because products are not tested; rather, it represents the legality of available products. The higher the number of unregistered products available, the greater the uncertainty of quality. MSH examined a limited list of tracer drugs in 57 drug shops in Kibale district and 49 facilities in Mpigi; all the stock for these medicines found on their shelves was on the NDA registry list. However, this data cannot be extrapolated to other medicines or to other drug shops or facilities that dispense medicine. In their recent assessment of antimalarials, MMV also looked at registration and found that 10 percent (20/200) of samples from nine districts/district groupings were unregistered[9] (MMV 2008). In addition, a report from INTERPOL indicated that unregistered medicines were recently confiscated from drug shops and pharmacies in a counterfeit crack-down (INTERPOL 2008).

[9] The study did not indicate if the unregistered drugs were found in public and/or private facilities.

QUALITY OF DISPENSING SERVICES IN THE RETAIL SECTOR

A study of drug shop and pharmacy attendants' knowledge and behavior in Kampala District showed that most of the attendants had medical or pharmacy training (most were nurses), but that they had little knowledge of the symptoms or dangers of acute respiratory infection and usually prescribed an antibiotic without other advice or referral (Tumwikirize et al. 2004a). Attendants noted that patients self-treated, so actions were demand-driven. The study respondents suggested that public education, training for the attendants, and more government supervision of shops would improve rational dispensing. Another study indicated that some drug shops in areas of low malaria transmission were dispensing quinine, which is only recommended as a second-line drug for severe malaria (Ndyomugyenyi et al. 2007).

One hundred shop attendants in Nakasongola district were knowledgeable about the general signs of malaria, and that the disease is caused by mosquitoes, although only 32 percent had been trained in some sort of health care, and 35 percent thought pain relievers were the most effective treatment for malaria (Batega et al., 2006). Almost three-quarters of these attendants also noted that most caretakers came into the shop asking for a specific treatment and that many did not want to buy a full dose. For those patients, dispensers either offered credit (45 percent) or gave them the dose they could afford (40 percent). About 41 percent of the shops had information materials available related to malaria and about half had received supportive supervision visits to provide advice about dispensing. A recent report indicated that only about half of clients in the private sector bought full courses of antimalarials of any type, and that outlets price by the tablet, which encourages purchases of less than the full dose (MMV 2008).

In MSH's study in two districts, 65 percent of the drug shops surveyed in Kibale dispensed based on prescriptions provided to the patient at clinics or other health facilities, while 71.4 percent in Mpigi dispensed from prescriptions. A majority of the prescriptions came from HC II-level facilities. The drug shops in both districts received an average number of four prescriptions per day with an average number of three medicines per prescription. The drug sellers reported selling to an average of 20–25 customers per day (range: 3–100).

Our study methodology included a simulated client exercise to assess the quality of services, where a data collector entered the drug shop and requested treatment for fever (uncomplicated malaria) in a six-year-old child.

None of the drug sellers in either district gave or recommended the first-line treatment for malaria, artemether-lumefantrine, which they are not yet licensed to sell. Treatment varied from chloroquine and sulfadoxine-pyrimethamine to quinine; however, those treatments are no longer recommended. Only 71 percent and 56 percent of the drug sellers in Mpigi and Kibale, respectively, sought information on the signs and symptoms of malaria. Up to 67 percent and 75 percent of the drug sellers gave instructions on how to take the medications dispensed. Overall, drug sellers did not have adequate dispensing skills and malaria case management was poor (Table 13).

Table 13. Uncomplicated malaria case management and dispensing skills in drug shop dispensers

Malaria case management indicators	Percentage of drug sellers	
	Mpigi (*n* = 21)	Kibale (*n* =16)
Drug seller sought information on symptoms	71	56
Drug seller sought information about any other medication previously taken	38	31
Drug seller gave instructions on how to take the medicine	67	75
Drug seller gave information on how to look for danger signs	10	13
Drug seller immediately recommended referral	10	13
Drug seller recommended referral in case of danger signs	14	6
Drug seller recommended returning if symptoms did not improve	10	19

QUALITY OF INFRASTRUCTURE AND PHARMACEUTICAL MANAGEMENT IN DRUG SHOPS

Overall in our survey, the majority of the shops surveyed had functioning telephones (mobile or fixed landline). Less than 30 percent of the drug shops in Kibale had electricity, compared to Mpigi, where over 70 percent of the shops had electricity. Less than 20 percent of the shops had a separate storage room for drugs (Figure 14). None of the shops had refrigerators to store medicines that required temperature control.

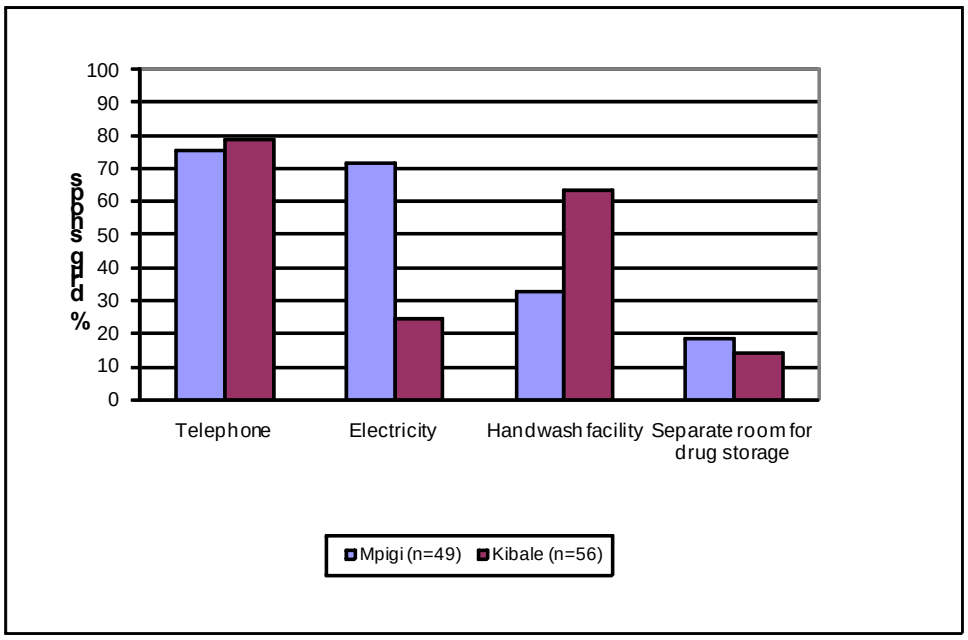


Figure 14. Available infrastructure in Class C drug shops

At least half of the shops were painted and had clean walls and shelving; however, over 70 percent of the shops in Kibale had dirt floors that were untidy and unclean (Figure 15).

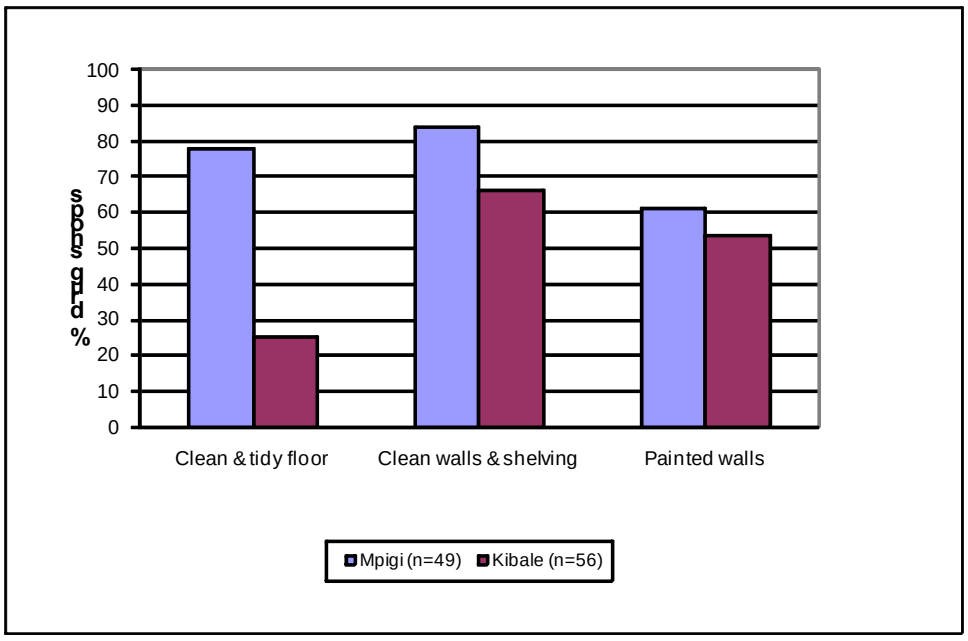


Figure 15. Cleanliness of Class C drug shops

Only eight percent of the drug sellers in Mpigi and 26 percent in Kibale said they had ever received any training on how to store drugs. Most shops did not keep any records of drugs in stock (31 percent in Mpigi and 7 percent in Kibale); the drug shops most commonly kept books of sales, but few other records. Overall, 33 percent of the drug shops never kept any record for drugs that they sold (Figure 16).

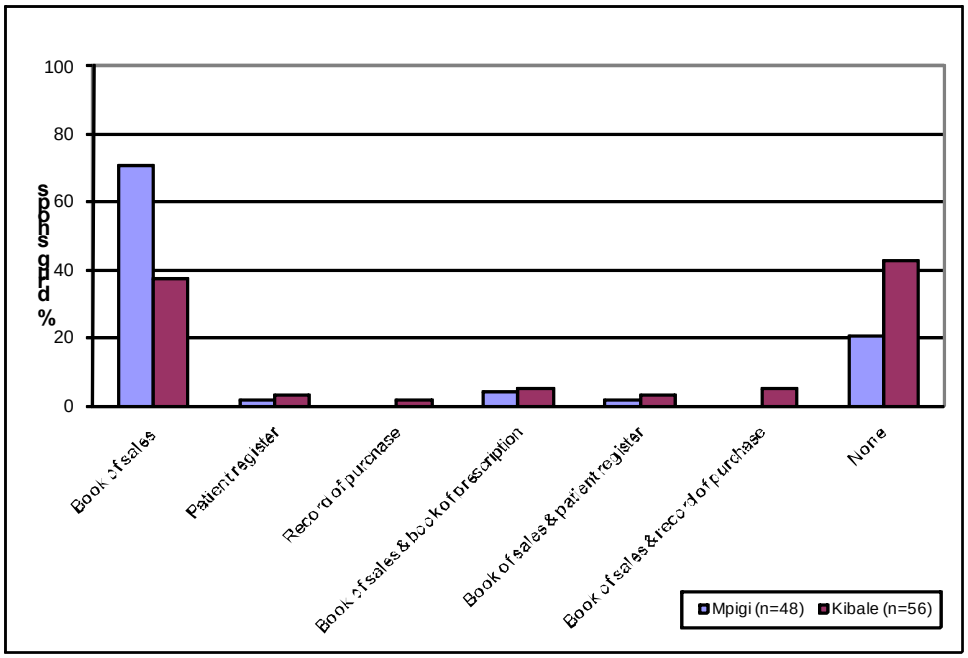


Figure 16. Records kept by Class C drug shops

In terms of expired medicines, shops most often dumped them. No drug shops returned expired products to the NDA or the district assistant drug inspector as per the legal requirements (Figure 17).

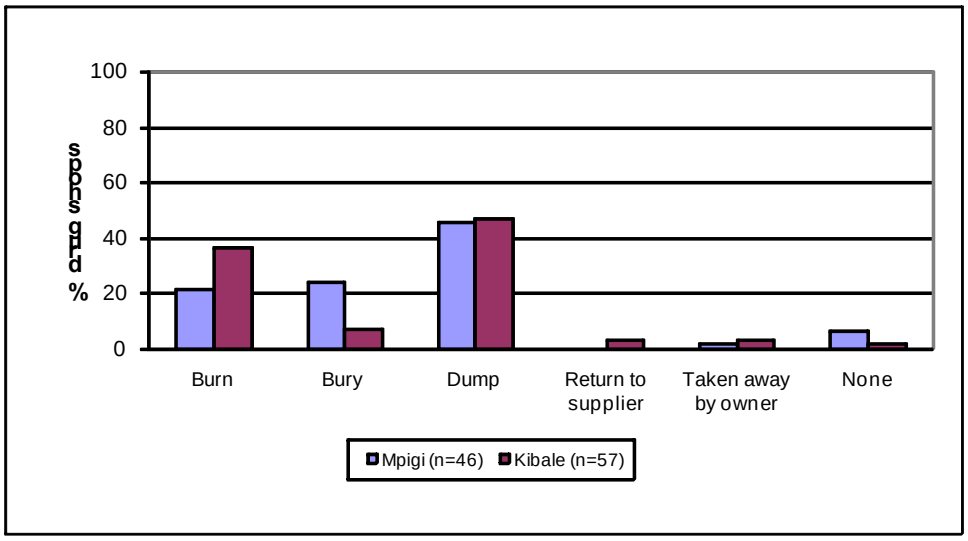


Figure 17. Methods Class C drug shops use to dispose of expired medicines

CARESEEKING PRACTICES

People's careseeking patterns differ according to geography, wealth, and health condition, and on factors such as availability of medicines at facilities and how comfortable they feel with the provider. In Uganda, for example, the higher their level of formal education, the more likely people are to seek health care in general, and private health care in particular; however, overall, the proportion of people seeking formal health care has been on the rise from 55 percent in 1992 to 80 percent in 2002 (Ssewanyana et al. 2004). Although intuitively the increase would be due to the abolition of user fees in public facilities in 2001, in reality, the majority of the increase came in the private sector (World Bank 2005).

> "Despite the fact that few of Ssembabule's 300 drug vendors had been formally trained and few of their shops were registered or regulated, they enjoyed enormous respect. In an environment where access to health services is poor, and clinics frequently experience drug shortages, caregivers go directly to drug vendors, thereby eliminating the need to visit a trained health provider, who is perceived as a 'middle man.'"
>
> *CORE Group and Minnesota International Health Volunteers, 2004, p. 6.*

Before Uganda abolished public-sector user fees in 2001, the country had one of the highest levels of careseeking in the private sector. Data from 2001 indicated that when a child was sick, 78 percent of the poorest people sought care outside the home, and of those, 68 percent used the private sector (Marek et al. 2005).

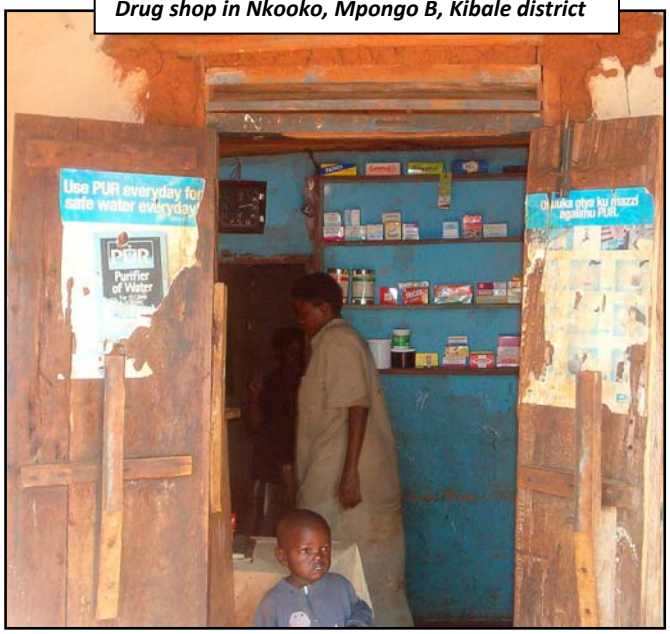
Studies on careseeking often focus on malaria treatment and the behavior of children's caretakers. Although children are more likely than adults to receive formal health care, caretakers often treat children at home for common illnesses, such as malaria and diarrhea, and retail drug sellers may be their only contact regarding the child's health if that is their source of medicine (e.g., as described in Goodman et al. 2007). For example, a review of literature looking at the role of drug sellers in child health in Africa reported that the use of retail drug outlets during child illnesses ranged from 15–82 percent with a median around 50 percent, and that caretakers used retail outlets even when cheaper alternatives existed, such as village health workers (Brieger 2003). A literature review of caretakers in Uganda indicated that almost 80 percent used private sector outlets (general retail shops, drug shops, private clinics) as their first destination outside of the home when a child is sick because the shops are more convenient, offer credit, and have fewer restrictions on drug quantities compared to public health facilities, even though caretakers knew that drug vendors were less knowledgeable (Twebaze 2001). When researchers asked 420 caretakers in a rural district in Uganda about which service provider they preferred to treat their under-age-five children with fever (Batega et al. 2006), respondents cited the following preferences (more than one answer allowed)—

- Public health facility: 69 percent
- Drug shops/chemists 11 percent
- Other private providers: 27 percent
- Community drug dispensers (volunteer): 27 percent
- Traditional healers: 1 percent
- Others: 1 percent

The caretakers who preferred private providers cited reasons such as proximity, availability of credit, and quick service. Some expressed reservations about private providers including sales of expired drugs, lack of record keeping, and untrained dispensers.

Many people who use drug shops and pharmacies are seeking medicines for self-treatment (Tumwikirize et al. 2004a; Anokbonggo et al. 2004), although another study of caretakers for children with malaria in two rural districts indicated that the drug seller prescribed the treatment about 95 percent of the time (Nshakira et al. 2002). The differences in careseeking might be explained by the location of the facilities—rural caretakers may be more likely to seek advice rather than self-medicate. In some areas of the country, people seek treatment first from traditional healers (Twebaze 2001), although other research suggests that traditional healers are seldom consulted first (Batega et al. 2006). Again, careseeking from traditional healers and herbalists probably depend on geography, wealth, and health condition and perhaps also the communities' perception of the traditional care providers' level of care.

Drug shop in Nkooko, Mpongo B, Kibale district



Information on careseeking practices from demographic and health survey interviews in 2002–2003 show that although care in public facilities was free, both poor and non-poor populations preferred private health care providers. This is also true despite the fact that 400 new health centers II (parish level) were constructed and almost 200 centers were upgraded to level III (subcounty level) (Ssewanyana et al. 2004). Clearly, the efforts to improve public health care in Uganda have not influenced people's preferences for private sources of care; although more people are seeking care in general than they were before the user fees were discontinued in the public sector.

Reasons that interviewees cited for not consulting formal health care practitioners include feeling that their illness was too mild (39 percent); treatment was too costly (34 percent); and the facility was too far (19 percent) (Ssewanyana et al. 2004). The 34 percent who cited cost in 2002 was much less than the 50 percent citing cost in 1999, although still more than expected given the free care offered in public facilities at that time. Although that interpretation of cost could be transportation costs to get to the facility, the same study noted that the percentage of communities with a health facility within 3 km had increased from 49 percent in 1992 to 71 percent in 2002. It is possible that some people choose their provider not by proximity, but by some other factor, such as services provided or the perceived quality of care. For example, 5 percent of rural residents reported having a pharmacy in their community, but almost 20 percent sought care from a pharmacy, which indicates that people are willing to travel outside the community for care they want.

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ANNEX 1. ESSENTIAL MEDICINES LIST OF UGANDA FOR HEALTH CENTER LEVELS I AND II

Essential Medicines List of Uganda 2007[10]

1. ANAESTHETICS	
1.1 General anaesthetics and oxygen	
1.2 Local anaesthetics	
Lignocaine injection 2%	HC2
1.3 Preoperative and peri-operative medication	
Diazepam rectal tube 2mg/mL	HC2
2. ANALGESICS, ANTIPYRETICS	
2.1 Non-opioids	
Acetylsalicylic acid tablet 300 mg	HC1
Ibuprofen tablet 200 mg	HC2
Paracetamol tablet 500 mg	HC1
3. ANTI-ALLERGICS & MEDICINES USED IN ANAPHYLAXIS	
Chlorphenamine tablet 4 mg	HC2
Epinephrine (adrenaline) inj 1 mg/mL IV/IM/SCM	HC2
Promethazine tablet 25 mg	HC2
4. ANTIDOTES	
4.1 General	
Charcoal activated tablet 250 mg	HC2
Ipecacuanha syrup 0.14%	HC2
5. ANTIEPILEPTICS AND ANTICONVULSANTS	
Diazepam rectal tube 2mg/mL	HC2
6. ANTI-INFECTIVE MEDICINES	
6.1 Anthelmintics	
6.1.1 Intestinal anthelminthics	
Mebendazole tablet 500 mg	HC1
Albendazole tablets 500 mg	HC 1
6.2 Antibacterials	
6.2.1 Beta Lactam Medicines	
Amoxicillin tablet or capsule 250 mg	HC2
Amoxicillin syrup (PFR) 125 mg/5 mL	HC2
Benzylpenicillin inj (PFR) 1MU (600 mg) IM	HC2
phenoxymethylpenicillin tablet 250 mg (Pen V)	HC2

[10] List includes only those products approved for use in health center 1 (HC1) and health center 2 (HC2) level facilities.

6.2.2 Other antibacterial medicines

Co-trimoxazole tablet 120 mg	HC2
Co-trimoxazole tablet 480 mg	HC2
Co-trimoxazole syrup 240 mg/5mL	HC2
Doxycycline tablet 100 mg	HC2
Erythromycin tablet 250 mg	HC2
Metronidazole tablet 200 mg	HC2
Nitrofurantoin tablet 100 mg	HC2

6.3 Antifungal medicines

Nystatin oral susp 100,000 IU/mL	HC2

6.4 Antiprotozoal medicines

6.4.1 Antiamoebic medicines

Metronidazole tablet 200 mg	HC2

6.4.3 Antimalarial medicines

Artemether /lumefantrine tablet	HC2
Sulfadoxine + pyrimethaminetablet 500 mg + 25 mg (SP)	HC1

7. ANTIMIGRAINE MEDICINES

7.1 Treatment of Acute Attacks

Acetylsalicylic acid tablet 300 mg	HC1
Paracetamol tablet 500 mg	HC1

8. ANTINEOPLASTIC & IMMUNOSUPPRESSIVE MEDICINES[11]

9. ANTI-PARKINSONISM MEDICINES[11]

10. MEDICINES AFFECTING THE BLOOD[11]

10.1 Antianaemia medicines

Ferrous salt tablet 60 mg	HC1
Elemental iron/ferrous sulphate oral solution paediatric BP	HC2
12mg elemental iron/5mL ferrous sulphate + folic acid tab 60 mg	
Elemental iron + 400 µg	HC1
Folic acid tablet 1 mg	HC2
Folic acid tablet 5 mg	HC2

13. DERMATOLOGICAL MEDICINES

13.1 Topical antifungals

Benzoic acid + salicylic acid ointment 6% + 3%	HC2

13.2 Topical antiinfectives

Iodine tincture 2%	HC1
Methylrosanilinium chloride aqueous paint 1% (gentian violet)	HC1

[11] Categories do not include medicines recommended for HC1 or HC2 levels, so not included here.

13.4 Keratoplastics and keratolytics	
Salicylic acid ointment 2%	HC2
Salicylic acid ointment 5%	HC2
13.5 Scabicide	
Benzyl benzoate lotion 25%	HC2
13.6 Pediculicide	
Malathion lotion aqueous 0.5%	HC2
15. DISINFECTANTS and ANTISEPTICS	
15.1 Antiseptics	
Cetrimide + chlorhexidinesolution 0.5% + 0.05%	HC2
Chlorhexidine gluconate solution 20%	HC2
Hydrogen peroxide solution 6%	HC2
15.2 Disinfectants	
Calcium or sodium hypochlorite solution 5%	HC1
17. GASTROINTESTINAL MEDICINES	
17.1 Antacids and other antiulcer medicines	
Magnesium trisilicate co. tablet 370 mg	HC1
17.2 Antiemetics	
Promethazine tablet 25 mg	HC2
17.6.1 For oral rehydration	
Oral rehydration salts powder for 1L Low osmolarity ORS (WHO citrate formula)	HC1
18. HORMONES, OTHER ENDOCRINE MEDICINES & CONTRACEPTIVES	
18.3 Hormonal contraceptives	
Ethinylestradiol + 30 μg + 150 μg levonorgestrel tablet	HC2
Ethinylestradiol + 30 μg + 300 μg levonorgestrel tablet	HC2
Ethinylestradiol + 50 μg + 250 μg levonorgestrel tablet	HC2
Ethinylestradiol + 50 μg + 1 mg norethisterone tablet	HC2
Norgestrel 75 μg tablet	HC2
19. IMMUNOLOGICALS	
19.3.1 Vaccines for routine immunisation	
BCG vaccine dried injection ID 20 dose vial	HC2
Diphtheria-pertussis-tetanus injection IM/deep SC (DPT) (20 dose vial)	HC2
Measles vaccine injection IM/deep SC (10 dose vial)	HC2
Poliomyelitis vaccine oral solution 20 dose (live attenuated)	HC2
Tetanus toxoid vaccine injection IM/deep SC (20 dose vial)	HC2

19.3.2 Vaccines for specific groups of individuals

Hepatitis B vaccine inj IM/deep SC single dose	HC2
Meningococcal vaccine A+C inj IM/deep SC single dose	HC2
Plague vaccine inj IM/deep SC single dose	HC2
Rabies vaccine human diploid inj IM/deep SC single dose	HC2
Typhoid vaccine inj IM/deep SC single dose	HC2

21. OPHTHALMOLOGICAL PREPARATIONS

21.1 Antiinfective medicines

Chloramphenicol eye ointment 1%	HC2
Chloramphenicol eye drops 0.5%	HC2
Tetracycline eye ointment 1%	HC1

22. OXYTOCICS & ANTI-OXYTOCICS

22.1 Oxytocics

Ergometrine + oxytocin injection 500 μg + 5 IU/mL IM	HC2
Methylergometrine inj 200 μg/mL IM/slow IV	HC2

24. PSYCHOTHERAPEUTIC MEDICINES

Chlorpromazine tablet 25 mg	HC2
Chlorpromazine tablet 100 mg	HC2
Chlorpromazine injection 25 mg/mL deep IM	HC2

25. MEDICINES ACTING ON THE RESPIRATORY TRACT

25.3 Cough soothing preparation

Simple linctus syrup (BNF formula)	HC2

26. SOLUTIONS CORRECTING WATER, ELECTROLYTE, & ACID-BASE DISTURBANCES

26.1 For oral rehydration

Oral rehydration salts powder for 1 L (Low osmolality formula)	HC1

26.3 Miscellaneous

Water for injection injection 2mL IV/IM	HC2
Water for injection injection 5mL IV/IM	HC2
Water for injection injection 10mL IV/IM	HC2

27. VITAMINS & MINERALS

Multivitamin tablet (BPC 73)	HC1
Retinol (vitamin A) capsule (drops) 50,000 IU	HC2
Retinol (vitamin A) capsule (drops) 100,000 IU	HC2
Retinol (vitamin A) capsule (drops) 200,000 IU	HC2

ANNEX 2. CLASS C LICENSED DRUG LIST

SCHEDULE 3. CLASS C LICENSED DRUGS

(as per National Drug Policy and Authority Statute No. 13, 1993)

Note—The following drugs, except such as are in a form suitable for administration by injection, are the drugs included in this Schedule. They may be sold by retail only be a person or company operating a licensed pharmacy or a licensed drug seller, but in the case of the latter only in accordance with the terms of his license.

GROUP I

Any proprietary preparation which does not contain any class A or B drugs.

Aconite, alkaloids of, in preparations containing less than 0.02 percent of the alkaloids of aconite.

Antibiotics, when contained in preparations or concentrates for animal feeding stuffs.

Antihistamines as listed in class B, Group II, but only when contained in preparations for external application only, other than for the eye or nose, and in preparations containing not more than 1 percent of an antihistamine substances intended for application only to the eye or nose.

Arsenic in preparations containing less than the equivalent of 0.01 percent of arsenic trioxide, and dentifrices containing less than 0.5 percent of acetarsol.

Barium sulphide when contained in depilatories.

Belladonna, alkaloids of, in preparations containing less than 0.15 percent of the alkaloids of belladonna, calculated as hyscyamine.

Brucine, when contained in surgical spirit containing not more than 0.2 percent of brucine.

Chloroform, in preparations containing not more than 5 percent of chloroform.

Codeine, when contained in preparation in a proportion of less than 1.5 percent; and also when contained in compound tablets of Codeine B.P., or tablets of a similar composition each containing not more than 10 milligrammes of codeine; and being in sealed containers holding not more than twenty-five such tablets.

Coniine in preparations containing less than 0.1 percent of coniine.

Creosote, preparations containing not more than 10 percent of creosote obtained from wood.

Emetine, preparations containing less than 1.0 percent emetine.

Ephedrine salts when contained in preparations containing less than 1 percent of the alkaloids of ephedra; tablets of ephedrine hydrochloride containing not more than 30 milligrammes of ephedrine hydrochloride per tablet, and being in sealed containers holding not more than fifty such tablets.

Ethylmorphine, in preparations containing less than 0.2 percent of ethylmorphine.

Hyoscine, when in preparations in the form of tablets and intended for use in travel sickness.

Hyoscyamine in preparations containing less than 0.15 percent of hyoscyamine.

Lobelia, alkaloids of, in preparations for the relief of asthma or in substances containing less than 0.50 percent of the alkaloids of lobelia.

Mercuric ammonium chloride when contained in an ointment containing not more than 5 percent of mercuric ammonium chloride or when contained in approved cosmetic preparations.

Mercuric oxide when contained in yellow oxide of Mercury ointment.

Morphine in approved preparations containing less than 0.2 percent of anhydrous morphine.

Pholcodine in approved preparations containing not more than 1 percent of pholcodine.

Nux Vomica, alkaloids of; in preparations containing less than 0.2 percent of the alkaloids of Nux Vomica calculated as strychnine.

Phenylene diamines, touene diamines, other alkylated benzene diamines, their salts, when contained in preparations intended for use as hair dyes.

Ohenothiazine, when in approved preparations, specially formulated and labelled for animal treatment.

Solenium; its compounds when contained in hair lotions and similar preparations.

Stramonium, alkaloids of, in preparations for the relief of asthma or substances containing less than 0.15 percent of alkaloids calculated as hyoscyamine.

Strychnine, in preparations containing less than 0.2 percent of strychnine.

Sulphadimidine, when contained in approved preparations formulated and labelled for the treatment of poultry diseases containing not more than 16 percent w v of sulphadimidine.

GROUP II

Aldrin, when contained in preparations for agricultural or horticultural purposes, and sold in the original container as supplied by the manufacturer.

Ammonia.

Barium carbonate, when in preparations intended for the destruction of rats and mice.

Barium silico fluoride.

Chloralose, when contained in preparations for the destruction of rats and mice.

Chlordane, when contained in preparations for agricultural or horticultural purposes.

Dieldrin, when contained in preparations for agricultural or horticultural purposes and sold in the original container as supplied by the manufacturer.

Endothal, when contained in preparations for agricultural or horticultural purposes.

Endosulfan, when contained in preparations for agricultural or horticultural purposes.

Endrin, when contained in preparations for agricultural or horticultural purposes.

Formaldehyde.

Formic acid.

Hydrochloric acid.

Hydrofluoric acid.

Metallic oxalates other than potassium quadroxalate in photographic solutions.

Nicotine, its salts; when contained in preparations intended for agricultural or horticultural purposes.

Nitric acid.

Nitrobenzene; when contained in agricultural or horticultural insecticides; in substances for the treatment of bee disease; and in ointments for animal treatment.

Paraquat; salts of.

Phenols as defined in class B, Group II of Schedule 2 to this Statue in substances containing less than 60 percent weight of phenols; compounds of phenol with a metal in substances containing less than the equivalent of 60 percent weight of phenols.

Phosporic acid.

Phosphorus, yellow, when contained in rat poisons.

Phosphorus compounds as listed in class B, Group II but only when contained in preparations specially formulated, packed and labelled for agricultural or horticultural purposes and sold in the original container as supplied by the manufacturer.

Potassium fluoride.

Potassium hydroxide.

Potassium quadroxalate.

Sodium fluoride.

Sodium hydroxide.

Sodium nitrate.

Sodium solico fluoride.

Sulphuric acid.

Toxaphene, but only in preparations intended for use in agricultural or horticultural purposes, and sold in the original container as supplied by the manufacturer.

Warfarin, its salts, when contained in preparations for the destruction of rats and mice.

Zinc phosphide when in preparations intended for the destruction of rats and mice.

ANNEX 3. UGANDAN NATIONAL DRUG AUTHORITY PHARMACY LICENSING REQUIREMENTS AND FEES

LICENSING REQUIREMENTS AND GUIDELINES FOR 2007

1. General Requirements for all Applicants

1.1 All applicants should **effective 1st October 2006** collect application forms from:

- District Assistant Drug Inspector (DADI) based in the office of the DDHS in every district
- Regional office located at the following locations:
  - **Central Region: -** Premier Complex, Nakawa
  - **South Eastern Region: -** Stanley Street, Jinja
  - **Eastern Region: -** Bukedi Cooperative Union Building, Tororo
  - **Northern Region: -** Erute road, Lira
- NDA Headquarters, Plot No. 46-48, Lumumba Avenue, Kampala

1.2 Renewing applicants should submit the following not later than 31st January 2007:

- The completed application forms,
- Letter of acceptance from the professional in charge plus a copy of his/her relevant Certificate of Practice and/or Registration/Enrollment Certificate,
- The previous year's licenses number filled in the space provided on the form for application for license.

1.3 In case of new applicant or any modifications, a sketch plan of the premises should be attached to the application in addition to those listed in section 1.2 above.

1.4 In line with "***Guidelines for Equitable Distribution of Drug Outlets,***" no persons shall open up or transfer any drug outlet anywhere without the prior approval of the location by National Drug Authority. ***An application for pre-inspection of the location of the proposed premises should be submitted to NDA prior to any financial or legal commitment to the premises and the approval should be obtained in writing following a pre-inspection***. This is to avoid loss in case of rejection of application based on these and any other guidelines. ***NDA shall not be obliged to license premises opened without following these procedures and shall not be liable to any claims of resultant financial loss.*** This approval shall be valid for a period of 3 months and, if not implemented, the location may thereafter be allocated to a new applicant.

1.5 **All new applicants for a pharmacy or manufacturing license or in case of change of pharmacist or ownership** must submit **a certified copy of the Articles and Memorandum of Association or Partnership Deed showing the Supervising Pharmacist as one of the Directors or Partners respectively**.

1.6 A Pharmacist shall be allowed to supervise pharmaceutical operations of two pharmacy premises and must indicate to NDA and PSU at the time of application:

- the time and duration he/she is expected to be physically present in each premises
- the name and qualification of the Professional Auxiliary Staff (PAS) to deputize the pharmacist during the hours of his/her physical absence, attending to the other pharmacy
- Premises applying for ***both Wholesale and Retail Licenses*** may be required to have at least ***two PAS***.

1.7 A drug outlet ***shall be considered unlicensed*** and should close its operations to the public if National Drug Authority has not received the application ***for renewal of licenses*** by 31st Jan 2007. T**he premises shall be subject to closure and all operations shall cease forthwith until when licensed.**

1.8 Fees are payable **within 30 days from the date of the invoice or the letter** notifying the applicant that the license(s) have been approved. **Late application** and/or **late payment of the**

fees shall attract **a surcharge of 50% of all total payable fees**. For administrative convenience, the fees for ***renewing drug shops*** are payable at the time of application.

1.9 Licenses will not be renewable for applicants with unsatisfactory required records of operations or transactions for 2006.

1.10 ***Licenses shall be cancelled*** where it is confirmed that **unqualified staff** have been allowed to **handle drugs** or **have been left in charge of a drug outlet**.

1.11 ***Licenses shall be cancelled*** where it is confirmed that the drug outlet has been involved in ***stocking and/or selling drugs beyond those prescribed by the respective license***, or ***unregistered, unauthorized, smuggled or counterfeit drugs***.

1.12 In case the Pharmacist or in-charge of drug shop ceases to be responsible for the outlet before the expiry of the operating license issued in his/her name, ***it shall be his/her responsibility to return to NDA the said license. Such a pharmacist or in-charge shall not be issued with a new license if he/she has not returned the valid license previously issued in his or her name.***

1.13 ***Any drug outlet that does not renew its license for at least one year without written acceptable and prior approved reasons shall, on reapplication, be treated as a new applicant with respect to location and fees.***

1.14 Applicants must also comply with these and all other statutory and regulatory requirements.

2. Requirements for an Application for a Pharmacy

2.1 In addition to the general requirements, the applicant should submit also the following:

2.1.1 A valid Certificate of Practice of the supervising pharmacist as issued by the Pharmaceutical Society of Uganda.

2.1.2 A letter of commitment from the supervising pharmacist

2.1.3 **In addition**, for Retail/Wholesale pharmacies *(human)*: a copy of the certificate of the dispenser or approved registered or enrolled nurse.

2.1.4 **In addition**, for Retail/Wholesale pharmacies *(veterinary):* a copy of the certificate of the qualified veterinary professional (Veterinary Surgeon, Animal Husbandry Officer, Approved Veterinary Assistant)

3. Requirements for an Application for a Drug Shop

3.1 **In addition to the general requirements, the applicant should submit also the following:**

3.1.1 A copy of the certificate of the qualified medical/pharmaceutical/veterinary profession in-charge. **NB: It is the responsibility of the applicant/owner of the drug shop to ensure that the certificate submitted to NDA is valid and authentic. Submission of an invalid or non-authentic certificate shall lead to denial or revocation of a license and may lead to blacklisting of the owners of the drug shop.**

3.1.2 Two black and white passport photos of the qualified professional in charge.

4. Requirements for an Application for Small Scale Pharmaceutical Manufacturing

4.1 In addition to the general requirements, the applicant should submit also the following:

4.1.1 The Certificate of Practice of the supervising pharmacist as issued by the pharmaceutical Society of Uganda.

4.1.2 A certificate of a qualified person to carry out quality control and quality assurance

4.1.3 The Certificate of the dispenser

4.1.4 A letter of commitment from the supervising pharmacist

4.1.5 A letter of commitment from the dispenser

4.1.6 A complete list of the products to be manufactured and their registration status.

5. Requirements for an Application for Large Scale Pharmaceutical Manufacturing

5.1 In addition to the general requirements, the applicant should submit also the following:

5.1.1 The Certificate of Practice of the Production Pharmacist

5.1.2 Commitment letter from the production pharmacist

5.1.3 The Certificate and letter of commitment of the Head of Quality Control/Assurance

5.1.4 A complete list of the products to be manufactured and their registration status

6. Payment of License Fees

6.1 All applicants for licenses to operate pharmacies and drug shops ***(except those in the South Western and Western Regions with Headquarters in Mbarara and Hoima respectively)*** should pay the relevant fees through a branch of **Stanbic Bank** within their area using NDA Banking slips. ***No license fees, except in the South-Western and Western Regions, should be paid to the DADI or any other Inspector.***

6.2 The NDA Banking slips *(in quadruplicate)* should be collected from any of the following offices nearest to you:

- District Assistant Drug Inspector (DADI) based in the office of the DDHS in every district
- Regional office located at the following locations:
  - **Central Region: -** Premier Complex, Nakawa.
  - **South Eastern Region: -** Stanley Street, Jinja.
  - **Eastern Region: -** Bukedi Cooperative Union Building, Tororo,
  - **Northern Region: -** Erute road, Lira.
- NDA Headquarters, Plot No. 46-48, Lumumba Avenue, Kampala.

6.3 During payment, the banking slip should be filled in quadruplicate and should clearly show the name of the drug shop or pharmacy and amount paid. ***Each of the 4 copies shall be originally signed and stamped by the bank***.

6.4 The ***Yellow*** copy shall be ***retained by the Bank*** to be used to send returns directly to NDA.

6.5 The ***White***, ***Blue*** and ***Pink*** copies shall be returned to the payee/applicant who shall attach the ***Blue*** and ***Pink*** copies onto the application forms and hand-over the set to the inspector/DADI. The ***White*** copy shall be ***retained by the applicant*** as evidence of payment.

6.6 The Inspector/DADI shall deliver the ***Blue*** copy to the Regional Office to be issued with a receipt in exchange. ***NDA shall issue a receipt only on receipt of a Blue copy originally endorsed by the Bank.***

6.7 The Inspector/DADI shall forward the receipt to the applicant.

For further information on these and any other drug regulatory issues contact NDA Officials at the above addresses (Sections 1.1 and 6.2).

SCHEDULE OF FEES 2007

A) LICENSE FEES

Herewith listed are NDA fees applicable for the Licenses for the year 2007 until further notice. **Please note that there has been no change in fees.**

Note: All fees are in Uganda shillings except where otherwise stated.

1) Drug Shop

Type of Fee	New Applications			Renewal Applications		
	Kampala	Municipal	Rural	Kampala	Municipal	Rural
Inspection + Forms	12,000	12,000	12,000	12,000	12,000	12,000
Suitability of premises	80,000	50,000	35,000	40,000	25,000	20,000
Operating License	80,000	50,000	30,000	80,000	50,000	30,000
Total fees payable	172,000	112,000	77,000	132,000	87,000	62,000

2) Retail Pharmacies *(Outside Kampala District)*

Type of Fee	New Applications		Renewal Applications	
	Municipal	Rural	Municipal	Rural
Inspection + Forms	30,000	30,000	30,000	30,000
Suitability of Premises	200,000	200,000	100,000	100,000
Operating License	100,000	100,000	100,000	100,000
Total Fees Payable	330,000	330,000	230,000	230,000

3) Wholesale Pharmacies (*Outside Kampala District)*

Type of Fee	New Applications		Renewal Applications	
	Municipal	Rural	Municipal	Rural
Inspection + Forms	35,000	35,000	35,000	35,000
Suitability of Premises	200,000	200,000	100,000	100,000
Operating License	200,000	200,000	200,000	200,000
Total Fees Payable	435,000	435,000	335,000	335,000

4) Wholesale Pharmacies *(Kampala District)*

Type of Fee	New Applications		Renewal applications	
	Central division	Other divisions	Central division	Other divisions
Inspection + Forms	35,000	35,000	35,000	35,000
Suitability of Premises	500,000	400,000	250,000	200,000
Operating license	500,000	400,000	500,000	400,000
Total fees payable	1,035,000	835,000	785,000	635,000

5) Retail Pharmacies *(Kampala District)*

Type of fee	New Applications		Renewal applications	
	Central division	Other divisions	Central division	Other divisions
Inspection & Forms	30,000	30,000	30,000	30,000
Suitability of Premises	500,000	400,000	300,000	250,000
Operating license	300,000	200,000	300,000	200,000
Total fees payable	830,000	630,000	630,000	480,000

6) Small-Scale Manufacturers

Type of Fee	New Applications	Renewal Application
Inspection + Forms	70,000	70,000
Suitability of Premises	300,000	250,000
Operating License	250,000	250,000
Total Fees Payable	620,000	570,000

7) Large-scale Pharmaceutical Manufacturers

Type of Fee	New Applications	Renewal Applications
Inspection + Forms	130,000	130,000
Suitability of Premises	500,000	500,000
Operating License	500,000	500,000
Total Fees Payable	1,130,000	1,130,000

Notes on Parts (1 to 7)

a) The cost of the relevant set of application forms, which have been quoted together with inspection fees:

Drug shops	**2,000/=**	Retail Pharmacy	**5,000/=**
Wholesale Pharmacy	**10,000/=**	Small Scale Manufacturing	**20,000/=**
Large scale manufacturing	**30,000/=**		

b) The term "Municipal" includes areas covered by Town Councils which will pay similar fees

c) A surcharge of 50% of the total fees payable will be charged on all **late application** and/or **late payment** of the relevant fees. All license fees are payable within 30 days from the date of the invoice or letter notifying the applicant of the approval of the license. For administrative convenience, the fees for ***renewing drug shops*** are payable at the time of application.

d) The Pharmaceutical Society of Uganda (PSU) Annual Fees are:

- Drug Shop: **5,000/-,** Retail Pharmacies **40,000/-**, Wholesale Pharmacy **120,000/-,** Small Scale Manufacturing **150,000/-,** Large-scale Manufacturers: **200,000/-**.

- In the case of Drug Shops this will be collected by the relevant District Assistant Drug Inspector (DADI) on behalf of the PSU.

e) Other Fees:

- Change of premises from the licensed location shall be subject to payment of the fee for suitability of premises for new applicants for the respective outlet**.**
- change of ownership/management of a pharmacy: **500,000/-**
- change of pharmacist: **100,000/-**
- change in professional Auxiliary staff: **50,000/-**
- change drug shop in-charge: **50,000/-**
- change of management for a drug shop: **100,000/-**

Please note that as per the National Drug Policy and Authority Act Cap. 206, it is an offense ***to operate without a license or to operate in premises without a Certificate of Suitability of Premises*** or not to inform NDA of a change in the ownership/management of a pharmacy or drug shop.

B) DRUG REGISTRATION FEES

a) REGISTRATION AND RETENTION	Fees	b) AMENDMENTS	Fees 2004/5
1. Registration (initial)	$1,000	1. Change in formulation (Inactives)	US$ 500
2. Retention (annual)	$300	2. Change in manufacturing site	US$ 500
3. Locally manufactured medicine registration (LSM)	$200	3. Change in Local Technical Representative (LTR) **(For all the products) Lump-sum**	US$ 1,000
4. Locally manufactured medicine retention (LSM)	$100	4. Extension of shelf life	US$ 200
5. Locally manufactured medicine registration (SSM)	150,000/=	5. New scientific information/literature	US$ 200
6. Locally manufactured medicine retention (SSM)	75,000/=	6. Finished product specification	US$ 200
7. EDLU item, LCV, not currently registered, registration	$250	7. Trade name change	US$ 100
8. EDLU item, LCV retention	$125	8. Change in name of manufacturer	US$ 100
9. OTC/PIM medicines, LCV registration	$1,000	9. Additional pack size	US$ 100
10. OTC/PIM medicines, LCV retention	$300	10. Pack design – Primary pack – Secondary pack	 US $ 50 US$ 50
11. Registration (with commercial value) Traditional (Herbal) Medicines	$500	11. Change in packing material	US$ 100
12. Notification of Traditional (Herbal) products (local)	10,000/=	12. Additional accessories	US$ 50
13. Notification of Traditional (Herbal) products (foreign)	$250	13. Change of label design	US$ 50
14. Notification of Food supplements (local)	20,000/=	14. Change of license holder	US$ 500
15. Notification of Food supplements (foreign)	$20	**c) PUBLICATIONS**	
16. Notification of Public Health products (local)	20,000/=	1. Drug Register(Human)	15,000/=
17. Notification of Public Health products (foreign)	$50	2. Drug Register(Veterinary)	5,000/=
18. Retention Traditional (Herbal) Medicines (foreign)	$150	3. Drug Registration Application forms plus guidelines	Free

KEY

LTR	Local Technical Representative
LSM	Large Scale Manufacturers
SSM	Small Scale Manufacturers
EDLU	Essential Drug List of Uganda
LCV	Low Commercial Value
OTC	Over the Counter
PIM	Pharmacist Initiated Medicine

C) IMPORT CONTROL AND cGMP FEES

Description	Fees
1. Annual Import or Export Permit	300,000
2. Provisional Import or Export Permit (*Per consignment*)	100,000
3. Verification fees for commercial consignments and donations to commercial organizations and Government Ministries, Departments, Projects, Programmes and Institutions	2% of FOB Price
4. Verification fees for donations to non-profit making charitable NGOs	50,000
5. Fine for a consignment of drugs **imported (which arrives at the port of entry) before the drugs registration amendments are applied for and approved**♠	$1000

♠*Such consignments shall only be inspected for release on condition that the amendments have been approved and the fine has been paid.*

D) LABORATORY SAMPLE ANALYSIS FEES

Description	Fees
1. Routine analysis of one batch in the NDA Lab (*the first 3 batches of a particular product per routine consignment shall be analyzed at NDA's cost and any extra batch shall attract a fee. This though shall not apply to consignments to projects that import large numbers of batches at a go which require mobilization of extra resources and shall be billed on case by case basis*)	100,000
2. Male Latex Condoms per batch	$280
3. Long Lasting Insecticide Treated Nets (LLINs), per batch of size up to 30,000 nets and every 30,000 nets.	$200
4. Samples analyzed at laboratories outside NDA	cost + 10% service charge
5. Re-analysis of a sample at owner's or importer's request	$1000
6. Detailed Certificate of Analysis at the request of the owner/Importer	150,000/=

E) GMP INSPECTION FEES FOR ROREIGN PLANTS

	Processes at the site	East Africa	Rest of Africa	Outside Africa
1	Site with all processes at one site	$2,000	$3,000	$4,000
2	Additional Sites in the same country as main site:			
	• Warehousing of raw materials up to finished bulk product	$1,500	$2,000	$3,000
	• Final packaging, quality control and final release	$1,000	$1,500	$2,000
	• Quality control and final release	$500	$750	$1,000

NB: ***Cancellation of inspection by the applicant after confirmation of schedule shall lead to forfeiture of the inspection fees.***

F) PRICES FOR NDA PUBLICATIONS:

Name	Cost	Name	Cost
1. Set of statutes	10,000	6. Prescription Drug Book	8,000
2. Purchase Order Book	10,000	7. List of licensed drug outlets	10,000
3. Classified Book	10,000	8. GMP Audit Checklist	30,000
4. Delivery Book	10,000	9. Guideline for Site and Product Master File	30,000

G) MISCELLANEOUS

Description	Fees	Description	Fees
1. Screening of Promotional materials per language:		2. Medical/Pharmaceutical Representative Permit	150,000
▪ Written materials	50,000		
▪ Audio/video + written Scripts	70,000		
▪ Posters/Bill boards	100,000	3. Supervision of specialized tasks e.g. Drug destruction (per hour)	50,000
▪ Posters on Vehicles	100,000		
▪ T- shirts	100,000		

THE FOLLOWING IS THE POLICY ON EQUITABLE DISTRIBUTION OF PHARMACEUTICAL SERVICES IN UGANDA, EFFECTIVE OCTOBER 2006
(First Published in November 2004)

INTRODUCTION

One of the mandates of NDA is to put in place policies to ensure that safe, efficacious and good quality drugs are available to the entire human and animal population of Uganda. To achieve this, the distribution of pharmaceutical services/drug outlets is controlled by the National Drug Authority under the provisions of section 6(a) of National Drug Policy and Authority Act, Cap. 206 ***through encouraging their equitable distribution***. This has been achieved by implementing a policy of:

- Charging **reduced fees** for applicants from **up country towns** and **Rural areas**,
- **Restricting the opening up of new drug outlets** in certain defined areas considered to be sufficiently served compared with other areas that are under served.

Consequently, a number of pharmaceutical outlets have ***opened up in hitherto underserved*** areas of the Country, hence improving the accessibility of pharmaceutical services to the rural population of Uganda.

The strategy of equitable distribution was ***first tried in 1998 by banning the opening of new drug outlets in Kampala Central Division and subsequently piloted in Jinja District in 2003***. The guidelines were subsequently discussed with stakeholders and first published in January 2004. Since the initial implementation, a number of improvements on the guidelines have been found necessary. These have been discussed and agreed upon with the stakeholders and the guidelines updated to this version. They shall, until notified otherwise, be used in assessing new applications and applications for relocating drug outlets.

A) The Policy:

1) The National Drug Authority, in collaboration with the Relevant Professional Councils, shall be responsible for ensuring equitable distribution of pharmaceutical/drug/medicines outlets.

2) Methods used to control the distribution of the outlets shall take into account, the prevailing situation ***(human & animal population density and patterns, existing drug outlets and infrastructure)*** in particular parts of the Country.

3) ***In accordance with section 15(1)(b) of the NDP/A Act, Licensed Sellers (Class C Drug Shops) are considered interim drug outlets which may no longer be licensed once the area is sufficiently served by other more comprehensive drug outlets.***

4) No persons shall open up any pharmaceutical/drug/medicine outlet anywhere without the prior approval of National Drug Authority. ***An application for pre-inspection of the location of the proposed premises should be submitted to NDA prior to any financial or legal commitment to the premises and the approval should be obtained in writing following a pre-inspection***. This is to avoid loss in case of rejection of application ***based on these and any other guidelines***. ***NDA shall not be obliged to license premises opened without following these procedures and shall not be liable to any claims of resultant financial loss.*** This approval shall be valid for a period of 3 months and, if not implemented, the location may thereafter be allocated to a new applicant.

5) These policies and related strategies shall apply to wholesale pharmacies, retail pharmacies, drug shops and any other outlet handling pharmaceuticals/drugs/medicines, both for ***human*** and ***veterinary*** use.

6) If a drug outlet (pharmacy or drug shop) ***does not renew its license for a period of one year***, it shall, ***on re-application***, be considered as a new applicant ***with respect to location and fees***.

B) Strategies and Guidelines:

1) Distribution of pharmaceutical/drug/medicine outlets shall be based on the particular location of a proposed outlet, the population living in that area and the distance of the proposed outlet from existing licensed outlets.
2) The allowed minimum distance between pharmacies shall vary according to the infrastructural development of the different towns as follows:

2(a) ***Kampala Central Division****;* No more ***new outlets for human drugs (Pharmacies and Drug Shops)*** shall be licensed to operate in ***Kampala Central Division***. ***New veterinary pharmacies*** may be considered for Kampala Central Division, **other *than "Container Village" Nakivubo Place, Kampala which is already sufficiently served by existing pharmacies***, but they must be ***at-least 300m*** from existing vet pharmacies. Consideration shall also be given to new pharmacies in new malls in accordance to strategy ***No. 4 below*** of these guidelines.

2(b) ***Other divisions of Kampala district***; new pharmacies may be licensed but they must be ***at-least 200m*** from existing licensed pharmacies and no new drug shops shall be licensed in Kampala District.

2(c) ***Municipal towns***; a minimum distance allowed between pharmacies shall be ***150m***. This shall apply to the following municipalities.

Kabale	Mbarara	Kasese	Masaka	Tororo
Jinja	Mbale	Soroti	Lira	Mukono
Gulu	Arua	Hoima	Fortportal	Masindi

2(d) ***Small towns and suburbs***; in small towns and suburbs with high population density, the minimum distance of ***100m*** shall be allowed between pharmacies. The criteria of population shall also be applied to determine the maximum number of pharmacies allowed in the suburb or town. Towns shall include the following:

Iganga	Bushenyi	Rukungiri	Apac	Kamwenge
Kyenjojo	Rakai	Lyantonde	Kamuli	Palisa
Kumi	Bugiri	Busia	Ntungamo	Mubende

2(e) No Pharmacies for human drugs shall relocate into Kampala Central Division from outside the division. Pharmacies in Kampala Central Division may relocate within but ***the new location must be at least 300m from existing Pharmacies.*** Drug outlets in other

areas may relocate but the new location must meet ***the relevant minimum stipulated distances from existing drug outlets.***

3) a) **Class 'C' drug shops** shall have a minimum separation distance of ***500m from any existing retail pharmacy or drug shop.***

b) Existing Class "C" drug shops which are located ***within 500m*** from a licensed retail pharmacy shall be given an opportunity to ***upgrade to a pharmacy, re-locate as per equitable distribution guidelines*** or ***wind up*** operation within one calendar year from the commencement of these guidelines (first published in January 2004) or from the time a new retail pharmacy starts operation in the location.

c) ***Drug shops upgrading to a pharmacy shall not be subjected to restriction on distance provided the current premises are suitable for a pharmacy business***. However, if the current premises do not meet the requirements for a pharmacy and they re-locate, the new location must comply with the guidelines on minimum distance. Since no place, other ***than "Container Village" in Kampala***, is currently congested with veterinary pharmacies, ***veterinary drug shops upgrading to pharmacies, in areas other than "Container Village", shall not be subjected to distance restriction even when they relocate from current premises to more suitable premises in the same areas.***

d) ***Implementation of 3(b) and (c) shall be in a phased manner.*** It started with a pilot in Jinja in 2003 and it was extended to Kampala District starting with sensitization in 2005. Implementation in Kampala started January 2006 and will continue in 2007. Sensitization shall begin in Mbarara and Mbale in 2007 for implementation starting in January 2008.

e) No wholesale license shall be issued for Class 'C' drug shops ***and a drug shop shall not engage in Wholesale business of drugs.***

4) ***Shopping malls****:* A shopping mall can be defined as a mercantile establishment consisting of a carefully landscaped complex of interrelated shops representing leading merchandise. It is designed to have most of the services in one place. It is a modern version of the market place or town in one building. ***For the purpose of these guidelines, a shopping complex shall be considered to be a mall if it has a minimum of 50 shops and new pharmacies shall only be allowed in if it is located in an area not served by other general shops, i.e. no pharmacy within the prescribed minimum radius.*** For the distribution of pharmacies in such shopping malls, the following guidelines shall be followed.

- Pharmacies shall not be allowed in **shopping malls** located in areas which are already sufficiently served by existing Pharmacies. For the purpose of these guidelines, ***the area bordered by Kampala-Bombo roads, Entebbe Road, Nakivubo Road, Namirembe Road, Martin Road and Kyagwe Road is considered sufficiently served.***
- ***For a mall with 50 - 100 shops, one pharmacy may be allowed; a mall with 100 - 200 shops, two pharmacies may be allowed; a mall with more than 200 shops three pharmacies may be allowed***.
- The minimum ***walking distance between the pharmacies within the mall*** shall be ***50m***, except for a mall with different floors where a distance of ***less than 50m*** shall be allowed if the pharmacies are ***on different floors***.
- The location of such pharmacies shall be in such a way that the pharmacies are not congested in one location.
- ***For new Pharmacies on the street side of the mall***, existing pharmacies neighboring the shopping mall shall be considered and ***the minimum prescribed distance between pharmacies for the area***, as outlined in section (2) above, shall be put into consideration and be applied.

5) Any other strategy approved by the National Drug Authority from time to time to promote provision of improved public health.

For further information please contact NDA Headquarters, the NDA Regional offices or District Assistant Drug Inspectors in the respective district.

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ANNEX 4. EADSI DATA COLLECTION METHODOLOGY IN KIBALE AND MPIGI DISTRICTS

MSH contracted with a company to use a global positioning system to map health facilities in Kibale and Mpigi. Based on the mapping exercise, the following facilities were chosen as targets for data collection—

Kibale

- A random sample of 56 Class C drug shops
- All 9 public health centre IIs
- A random sample of 15 private clinics

Mpigi

- A random sample of 45 Class C drug shops
- All 14 public health center IIs
- A random sample of 14 private clinics

In the drug shops, data collectors interviewed owners and dispensers to gather information on operations and performance. They interviewed staff in the health clinics regarding labor availability and qualifications. In addition to interviews with facility personnel, data collectors posed as clients and presented symptoms to dispensing personnel in Class C drug shops to document prescribing/dispensing behavior. Also, data collectors conducted exit interviews with patients receiving prescriptions from health facilities; however, because too few clients were available in the time allotted for data collection, data were incomplete and are not included here.

A measure of access includes availability of essential health commodities needed to treat or prevent a community's key public health problems. By identifying key conditions and treatments, a list of associated tracer medicines can be used to track availability in health facilities. Products on the tracer list should reflect standard treatments and be included on the country's essential medicines list, and we based this list on medicines commonly used at the lowest primary health care level (health center II). However, we also included a few medicines used at health center III because they are commonly prescribed as per the *Uganda Clinical Guidelines*. We also included chloroquine to evaluate how many facilities were still dispensing this outdated medicine for malaria. The table below lists the tracer medicines used in this survey as well as its associated health condition.

Data collection commenced on August 13, 2008 with two teams of data collectors—one team per district. In Mpigi, data was collected from a total of 49 drug shops, 15 private clinics, and 13 public health center IIs, while in Kibale data collectors hit 57 drug shops, 19 private clinics, and 9 public health center IIs.

General Information on Class C Drug Shops

Position of Persons Interviewed

Position of contact person	Mpigi (n = 49)	Kibale (N = 57)
Owner	16	22
Seller	33	35

Number of Employees in the Drug Shop

Number of employees	Mpigi (n = 49)	Kibale (N = 57)
1	10	20
2	33	35
3	6	1
4	0	1

Number of years the shop has been opened

Number of years	Mpigi (n = 49)	Kibale (N = 57)
< 1	3	4
1	8	12
2	7	14
3	4	4
4	6	3
>4	17	15
Don't Know	4	5

Tracer Medicine List

Condition	Key medicines	Level of care
Malaria	Artemether/lumefantrine tablet	HC 2
	Chloroquine 300 mg (150 mg base) tablet	HC 2
	Sulfadoxine + pyrimethamine 500 mg+ 25 mg	HC 1
	Quinine inj 300 mg/ml	HC 3
Acute respiratory tract infections	Co-trimoxazole tablet 480 mg	HC 2
	Co-trimoxazole syrup 240 mg/5ml	HC 2
	Amoxicillin tablet/capsule 250 mg	HC 2
	Amoxicillin syrup 125 mg/5ml	HC 2
Skin infections	Clotrimazole cream 1%	HC 3
	Benzoic/salicylic acid ointment, 30 g	HC 2
Protozoa infestations	Metronidazole tablet 200 mg	HC 2
Urinary tract infections	Erythromycin tablet 250 mg	HC 2

	Doxycycline tablet 100 mg	HC 2
Fungal infections	Nystatin oral susp 100,000 IU/ml	HC 2
	Nystatin pessary 100,000 IU	HC 3
	Ketoconazole 200 mg tablet	HC 3
Pain	Ibuprofen tablet 200 mg	HC 2
	Paracetamol tablet 500 mg	HC 1
	Acetylsalicylic Acid tablet 300 mg (aspirin)	HC 1
Conjunctivitis	Tetracycline eye ointment 1%	HC 1
Worm infestations	Albendazole tab 200mg	HC 2
	Mebendazole tab 100mg	HC 2
Diarrhea	Oral rehydration solution (ORS)	HC 1
	Zinc tablet 30mg	HC 2
Others	Benzylpenicillin inj (PFR) 1MU	HC 2
	Procaine penicillin forte 4 mu	HC 3
	Glucose infusion 5%	HC 2
	Sodium chloride infusion 0.9%	HC 2
	Combined contraceptive pill	HC 2
	Condoms	HC 1

Annex 5. Summary of Interventions to Build Capacity of Private Sector Drug Sellers in Uganda

Greer et al. 2004. Improving Management of Childhood Malaria in Nigeria and Uganda by Improving Practices of Patent Medicine Vendors. Arlington, VA: BASICS II Project. Tawfik et al. 2006. Negotiating improved case management of childhood illness with formal and informal private practitioners in Uganda. *Tropical Medicine and International Health* 11 no 6 pp 967–973.

Location: Four sub-counties in Luwero district

Intervention dates: September 2003–?

Implementation partners: Academy for Educational Development's Support for Analysis and Research in Africa (SARA) project and BASICS II Project. Funded by USAID Africa Bureau and later by BASICS II.

Targets: 104 lower-skill-level providers from drug shops and private clinics

Approach: Education, negotiation, and persuasion model is built on obtaining specific information on current practices among the target group and using that as a point for negotiating changes to correct inappropriate practices. This is then formalized with a "contract" stating that the participant accepts the new practices. The Uganda intervention was based on negotiating behavior change for malaria, acute respiratory infection, and diarrhea in children under five years of age. Activities included—

1. Conducting simulated visits to gather information on practices.
2. Providing information on case management to providers, in a 3-day workshop.
3. Providing feedback to providers regarding their current treatment practices as documented by simulated visits.
4. Negotiating a contract with the provider, through which providers select practices among those recommended that they can comply with. Negotiation sessions were the intervention to improve the providers' quality of management of childhood illness.
5. Monitoring provider compliance with the contract using supportive supervisory visits.

The District Assistant Drug Inspectors (DADIs) and Integrated Management of Childhood Illness District Focal Persons (IMCI-DFPs) not only served as assistant trainers and supervisors, but also assisted with data management for the inventory.

Results: Two months after the negotiation sessions with the drug sellers, the simulated visits were repeated. Post-intervention result showed that the quality of case management for childhood diarrhea, acute respiratory infection, and malaria was generally better, although certain practices appeared resistant to change. A summary of the results related to malaria are in the table below.

	Simple Malaria			Complicated Malaria		
Private providers who:	**Baseline N=57**	**Evaluation N=66**	**P**	**Baseline N=61**	**Evaluation N=72**	**p**
Asked about the age of the child	100%	97%	.23	98%	99%	.68
Asked if the child had cough/cold	82%	87%	.42	21%	35%	.07
Advised to sleep under an insecticide-treated bednet	0%	5%	.04	0%	24%	<.01
Gave or recommended medicine	98%	73%	<.01	85%	57%	<.01
Gave or recommended correct medicine	2%	73%	<.01	2%	90%*	<.01
Gave correct dose	0%	68%	<.01	2%	47%	<.01
Explained how to give the drug	8%	66%	<.01	70%	61%	.27
Asked if the child had convulsions	21%	23%	.76	NA	NA	
Advised on signs for immediate care	0%	34%	<.01	NA	NA	
Advised on referral	NA	NA		16%	33%	.03
Asked about the duration of illness	NA	NA		13%	99%	<.01
Asked about previous medication	NA	NA		54%	82%	<.01

NA = Practice not applicable or not measured for the condition presented.
Private providers were advised to refer complicated cases immediately; correct medicine here is the same as for simple malaria.

Summary: Study authors felt results were encouraging, although because the evaluation was only two months after the intervention, the achievements might not have been sustained. The report included a summary of costs (estimated at about USD 58 per provider in the Greer report and USD 21 per provider in the Tawfik report). Authors also indicated that modifications to the pilot intervention would be needed for a large-scale implementation, such as involving community-based organizations and local nongovernmental organizations to maintain ongoing communication with providers. In addition, authors suggested that the government needs to simplify registration procedures and reduce associated fees to encourage private providers to register and be included in a large-scale intervention.

No indication if this intervention was to move forward.

Mbonye et al. 2008. Intermittent preventive treatment of malaria in pregnancy: a new delivery system and its effect on maternal health and pregnancy outcomes in Uganda. *Bulletin of the World Health Organization* 86:93–100.

Location: Mukono district

Intervention dates: May 2003–February 2005

Implementation partners: Ministry of Health, University of Copenhagen (DBL-Institute of Health Research and Development)

Targets: 51 community people (adolescent peer mobilizer, community reproductive health worker, drug shop vendor, traditional birth attendant—numbers of each not stated) identified to deliver sulfadoxine-pyrimethamine (SP) intermittent treatment to pregnant women (IPTp)

Approach: One week of training for community resource people to distribute IPTp in 21 parishes. Training covered dangers of malaria in pregnancy, malaria prevention in pregnancy, the benefits of SP and its side effects, taking blood samples, weighing the baby and estimating gestational age. The community workers collected data from pregnant woman at recruitment, before receiving the second dose of SP and at 36 weeks or at delivery. The control group comprised women who accessed IPTp exclusively from public health units in four parishes.

Results: 67 percent of the pregnant women recruited (n=2081) through the community intervention received two doses of SP compared with 39.9 percent of those receiving care at the health unit (n=704). The prevalence of malaria episodes decreased from 49 percent to 17.6 percent with the community intervention, but decreased to 13.1 percent in the health units. There was a lower proportion of low birth weight with the community intervention than the health units.

Conclusions: The new approach was associated with early access and increased adherence to IPTp. Health units were more effective in reducing parasitemia and malaria episodes. The authors noted that scaling up the approach would have policy implications: the community resource people would have to be trained, monitored, and linked to the health units to get SP, supplies, and supervision. The results of the study need to be disseminated to policy-makers and program managers in the MOH and the district and sub-country managers to gain consensus on results.

The CORE Group and Minnesota International Health Volunteers. 2004. Improving Malaria Case Management in Ugandan Communities: Lessons from the Field. Washington, DC: CORE Group.

Location: Ssembabule district

Intervention dates: September 1996–August 2000

Implementation partners: Minnesota International Health Volunteers. The bulk of the funding was from USAID; MIHV contributed matching funds from a variety of sources including the Child Health Foundation, the Conservation, Food, and Health Foundation, the Scandia Foundation, and Rotary International.

Targets: 167 drug shop attendants

Approach: The project trained 50 drug sellers (out of 300 identified in the district) in an initial three-day training, which focused on proper care and referral of malaria followed by subsequent one- to two-day trainings, which took place every three to four months.

Specific training objectives included the basics on malaria transmission, identifying at least three signs and symptoms of malaria, describing three danger signs and symptoms of malaria that require immediate referral, dispensing age-appropriate doses of chloroquine tablets for malaria treatment (in accordance with national guidelines), listing four ways in which drugs can be abused or misused, explaining four possible ways of preventing malaria, and describing drug sellers' role in the community. The training also addressed the practice of providing partial courses of chloroquine, which was seen as a problem in drug shops and also addressed the need to refer serious cases. As part of training, the project stressed that it is acceptable for professionals to refer cases and to advise clients when they can be better served by a trained health care provider. The project also stressed that it is not good for business to give clients inaccurate advice. The study authors concluded that while drug vendors already knew this about referral, it was important to discuss this issue openly and to reinforce professional norms.

The district health team was involved in developing and administering training as well as in quarterly monitoring and supervision. Many drug shop sellers had been community immunizers, so already had a working relationship with health units. Drug sellers kept records of how much chloroquine they dispensed and to whom (who the client was, how old the client was, the course of treatment sold, any follow up or referrals made), which were reviewed during these monitoring visits. The project provided drug sellers with calendars and posters that displayed age-appropriate dosage information. Tools developed included supervision tools, an instrument for referrals, and a record-keeping tool.

As part of the initial training, participating drug vendors of their own initiative established a chartered Drug Vendor Association to provide support and supervision to district drug vendors. Using government standards, the association began working with the District Health Team to register and govern the activities of drug vendors in the district. Representatives go out with project or health unit staff to conduct drug seller monitoring visits. The Association also holds meetings for its 100 members and makes recommendations to the District Health Team regarding additional training needs. By working closely with district and clinic staff and communicating professional norms to its members, the Association played a critical sustainability and quality-assurance role.

Results: Drug vendor trainings were highly successful, and motivation within the group was high. Turnout at the trainings was usually 95–100 percent. When comparing their pre- and post-test results, 85 percent of all shopkeepers had correctly learned how to properly treat malaria and when to refer severe cases. Although drug vendors were not paid a stipend, and lost money whenever they closed their shop to attend trainings, they attended because they valued the information and skills learned in the training.

Conclusions: The authors concluded that with adequate resources, many of the approaches and tools developed in the project could be adapted for replication in other districts in Uganda and/or scaled up to the national level; however, there is no indication that the project was rolled out to any other districts.

Tumwikirize WA, Ekwaru PJ, Mohammed K, Ogwal-Okeng JW, Aupont O. 2004b. Impact of a face-to-face educational intervention on improving the management of acute respiratory infections in private pharmacies and drug shops in Uganda. *East African Medical Journal Suppl:* S25-32.

Location: Kampala District

Intervention dates: 2000

Implementation partners: Department of Pharmacology and Therapeutics, Makerere University

Targets: 191 registered drug shops (164) and pharmacies (27)

Approach: An experimental group received three face-to-face training sessions and educational materials on mild and severe acute respiratory infection in children, and the control group received no training. Data on the practices in the drug outlets from both groups were collected at two time points: seven months before the intervention, and at one-month after the intervention.

Results: The study found that despite the training, the assessment of the child's condition remained inadequate in both groups, where the child's age was the only question asked in more than 90 percent of cases. High levels of inappropriate dispensing practices for both mild and severe ARI were still persistent in both groups after the intervention. Antibiotic prescribing for both conditions was very common, and barely any advice or instruction was given with dispensed drugs. Client demand for particular drugs, competition among drug outlets, and inability of most clients to afford the recommended treatments were the main reported barriers that emerged from the focus group discussions with the counter attendants.

Conclusions: The evaluation of the practices one month after the face-to-face educational intervention showed that the management of acute respiratory infection did not improve in the drug outlets. While study design issues may have contributed to such findings, there are many other factors not related to knowledge and education that may indirectly hamper the promotion of appropriate dispensing in the private pharmacies and drug shops in Uganda. It is possible that a combination of interventions may contribute to improved management of respiratory infection by counter attendants in the private drug shops and pharmacies in Uganda.

Walker et al., 2001. The quality of care by private practitioners for sexually transmitted diseases in Uganda. *Health Policy and Planning*; 16(1):35–40.

Location: Masaka district

Intervention dates: November 1996–unknown

Implementation partners: London School of Hygiene and Tropical Medicine, Medical Research Council Programme on AIDS, Uganda Virus Research Institute, Boston University School of Public Health, World Health Organization.

Targets: 11 workers from private sector clinics or drug shops
Approach: Private sector providers were defined as a person working in a clinic or drug shop. The trial involves three groups, each covering six parishes: People living in the parishes in arm A receive information, education and communication (IEC) activities aimed to increase public awareness with respect to sexually transmitted infections (STIs) and AIDS. Parishes in arm B receive the same IEC interventions together with training and supervision for private sector providers in treatment of STIs. Private sector providers were interviewed in all three arms (12 in arm A, 11 in arm B, and 13 in arm C), but only the 11 providers in arm B received the training n the syndromic management of STIs and supply of drugs and regular supervision. The 11 providers in Arm B attended the British Medical Council training course on the syndromic management of STIs.

The trial was designed to last five years and the effectiveness of the interventions was to be measured by the rates of HIV-1 sero incidence in the study parishes. The first survey (round 1) was completed in November 1996.

Results: Providers in the intervention arm of the trial, who had attended meetings dealing with the syndromic management of STIs, referred to syndromes 82 percent of the time compared with 12 percent in the control arms, a mean difference of 70 percent ($p < 0.001$); stocked locally appropriate antibiotics 76 percent of the time compared with 52 percent, a mean difference of 24 percent ($p < 0.001$); and are more likely to prescribe appropriate drugs 82 percent of the time compared with 27 percent, a mean difference of 55 percent ($p < 0.001$) (Table 1). Providers applied mark-ups ranging from 67–300 percent on drugs (based on costs available at the district wholesaler).

Table 1. Percentage of correct drugs mentioned for certain STI syndromes

	Intervention group	Control group	Control group	Total
Syndrome	**Arm B (n = 11)**	**Arm A (n = 12)**	**Arm C (n = 13)**	**(n = 36)**
Penile discharge	88	28	12	39
Abnormal vaginal discharge	89	43	19	50
Genital ulcers	78	37	32	47
Lower abdominal pain in women	71	26	21	38
Total for all syndromes	82	33	21	44

Conclusions: Practitioners and patients felt that the private sector provided more convenient and confidential care and had easier access due to more facilities and longer opening hours. However, treatment was expensive and often results in the prescription of a partial course of antibiotics. Providers who had received training had reasonable stocks of appropriate antibiotics,\ and were also more likely to prescribe the drugs appropriately.

No indication that the study was ever completed beyond this initial evaluation.

The following papers are useful summaries of drug seller and other private sector provider interventions in a variety of countries in addition to Uganda.

Brieger W, Unwin A, Greer G, and Meek S. 2005. Interventions to Improve the Role of Medicine Sellers in Malaria Case Management for Children in Africa. London, UK and Arlington, Va., USA: the Malaria Consortium and BASICS for the United States Agency for International Development; prepared for Roll Back Malaria's Sub-group for Communication and Training and Malaria Case Management Working Group.

Abstract: This document reviews 15 interventions to improve child health and malaria-related activities of medicine sellers or patent medicine vendors in Africa. Medicine sellers are a major source of health care for many communities in sub-Saharan Africa. Reports in the literature on the use of medicine sellers in sub-Saharan Africa during recent child illnesses range from 15–82 percent with a median around 50 percent. These statistics in themselves do not justify the use of medicine sellers, but indicate the importance of ensuring that medicine sellers have the capacity to provide safe and appropriate medicines in correct amounts in the communities they serve. This review addresses those capacity-building questions. The review is part of the work of the Roll Back Malaria Subgroup for Communication and Training within the Malaria Case Management Working Group. The Private Provider Task Force of this Subgroup was charged with the goal of providing guidance and recommendations to the Roll Back Malaria partners via the Working Group on promising and appropriate strategies for engaging the medicine sellers to improve management of malaria in children. An annotated bibliography with all project documents is included in the annexes.

Goodman, C. W. Brieger, A. Unwin, A. Mills, S. Meek, G. Greer. 2007. Medicine Sellers and Malaria Treatment in Sub-Saharan Africa: What Do They Do and How Can Their Practice Be Improved? *American Journal of Tropical Medicine and Hygiene* 77(6 Suppl): 203–218.

Abstract: Medicine sellers are widely used for fever and malaria treatment in sub-Saharan Africa, but concerns surround the appropriateness of drugs and information provided. Because there is increasing interest in improving their services, we reviewed the literature on their characteristics and interventions to improve their malaria-related practices. Sixteen interventions were identified, involving a mixture of training/capacity building, demand generation, quality assurance, and creating an enabling environment. Although evidence is insufficient to prove which approaches are superior, tentative conclusions were possible. Interventions increased rates of appropriate treatment, and medicine sellers were willing to participate. Features of successful interventions included a comprehensive situation analysis of the legal and market environment; buy-in from medicine sellers, community members, and government; use of a combination of approaches; and maintenance of training and supervision. Interventions must be adapted to include artemisinin-based combination therapies, and their sustainability and potential to operate at a national level should be further explored.

Tawfik et al., 2002. Utilizing the Potential of Formal and Informal Private Practitioners in Child Survival: Situation Analysis and Summary of Promising Interventions. Washington, DC: Academy for Educational Development/Support for Analysis and Research in Africa (SARA) Project.

Abstract: This paper analyzes interventions to improve private practitioners' case management of childhood diseases. It concludes that most interventions have only been tested on a small scale; few been adequately documented or evaluated. This review found that interventions that only address practitioner knowledge are unlikely to succeed. Yet, realistic interventions that focus on improving a limited number of key practices, consider the multiple factors influencing practitioners' practices, use local entities that are trusted by the targeted practitioners, and treat practitioners as health "partners" are more likely to succeed. National health policies should allow for interventions that improve the quality of practice of both formal and informal private practitioners. Further testing of pilot interventions to improve the effectiveness of private practitioners' case management of childhood illnesses should be conducted. Interventions should be conducted with sustainability and large-scale implementation in mind. Thus, these interventions need to mobilize locally available resources and avoid, to the extent possible, injecting temporary resources. Adequate evaluation and documentation are needed to assess the impact of interventions in achieving a lasting change in the practice of private providers. This paper offers guidance for designing effective strategies to maximize child survival by improving the ability of private practitioners to provide effective treatment, counseling, and referral of sick children.