Ugandan Private Sector Drug Seller Initiative Stakeholders' Workshop

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MANAGEMENT SCIENCES *for* HEALTH
a nonprofit organization strengthening health programs worldwide

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About MSH

Management Sciences for Health is a private, nonprofit organization, dedicated to closing the gap between what is known about public health problems and what is done to solve them. Since 1971, MSH has worked with policymakers, health professionals, and health care consumers around the world to improve the quality, availability, and affordability of health-related services.

MSH has helped strengthen public and private health programs in more than 100 countries by providing technical assistance, conducting training, carrying out research, and developing systems for improving program management. MSH's staff of more than 1,000 work in its Cambridge, Massachusetts, headquarters; offices in the Washington, DC, area; and field offices throughout the world.

We provide long- and short-term technical assistance through four technical centers: Country Programs, Health Outcomes, Leadership and Management, and Pharmaceutical Management. Areas of assistance include maternal and child health, HIV/AIDS, tuberculosis, malaria, community-based services, supply chain management, and health reform and financing. Our publications and electronic products augment our assistance in these areas.

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ACRONYMS

ADDO	Accredited Drug Dispensing Outlets
DADI	District Assistant Drug Inspector
EADSI	East African Drug Sellers Initiative
MSH	Management Sciences for Health
MOH	Ministry of Health
NDA	National Drug Authority
PSU	Pharmaceutical Society of Uganda
SEAM	Strategies for Enhancing Access to Medicines (Program)
TFDA	Tanzania Food and Drugs Authority
WHO	World Health Organization

BACKGROUND

Similar to other developing countries, most people in Uganda buy medicines from retail drug outlets, referred to as Class C drug shops. These drug outlets dot the countryside, and for those who do not live in a city, they may be the only nearby place to buy medicines and get health advice on common illnesses such as malaria, acute respiratory infections, and diarrhea.

A problem with having retail drug sellers deliver health care is that they are largely untrained, and therefore, they may not provide appropriate counseling or sell customers the proper medicines, dosages, or quantities to effectively treat common ailments, including malaria, acute respiratory infections, and diarrhea.

Class C drug shops are far more accessible to the population than pharmacies. As of 2007, Uganda had 362 pharmacies located almost exclusively in urban areas, compared with almost 4,000 registered Class C drug shops. Thus, using the existing pool of drug sellers to dispense common medicines rationally has the potential to improve access to quality pharmaceutical products and services provided to people living outside of urban areas.

The East African Drug Seller Initiative (EADSI) aims to increase access to essential medicines and improve the quality of pharmaceutical services through the private sector. EADSI's goal is to create a sustainable model to replicate and scale up private-sector drug seller initiatives in developing countries that will help to meet their health-related goals and ultimately operate independent of donor support. EADSI builds on Management Sciences for Health's Strategies for Enhancing Access to Medicines (SEAM) Program, which, in collaboration with the government of Tanzania, launched that country's successful accredited drug dispensing outlet (ADDO) program. EADSI is funded by the Bill & Melinda Gates Foundation as a three-year grant.

As part of its activities in Uganda, EADSI is working with stakeholders to adapt the Tanzania ADDO model to address Ugandan needs and circumstances and to demonstrate the adapted model in Kibale district with Mpigi district serving as a control district. The first activity was to conduct a situational analysis on the Uganda pharmaceutical sector. The situational analysis report will serve as a key background document as we move forward with developing a specific strategy for Uganda.

To ensure that the right drug seller model is developed for Uganda, the National Drug Authority (NDA) in conjunction with the Ministry of Health Uganda (MOH) and MSH organized a one-day stakeholder meeting on November 14, 2008, at the Protea Hotel, Kampala, to discuss the Ugandan situational analysis and recommend the most appropriate options for a Ugandan model for improving access to essential medicines through the creation of a private sector accredited drug seller program. (See Annex 1 for a list of participants and Annex 2 for the meeting agenda.)

The workshop objectives were three-fold—

- Present the Ugandan pharmaceutical sector situation analysis
- Learn about Tanzania's experiences with their ADDO model

- Review and adopt the most appropriate model for a Ugandan private sector drug seller initiative

The stakeholder meeting was preceded by a one-day technical meeting held on November 13, 2008, which allowed participants to meet in small breakout groups to discuss five key topics critical to establishing a sustainable Ugandan private sector drug seller model. The options generated at this preparatory meeting were then presented to stakeholders at the November 14 meeting for discussion and consensus. The five topics included the following—

- Allowable products and services
- Human resources
- Service quality
- Institutional framework/stakeholder roles
- Sustainability

Annex 3 includes the background information and questions that each working group were asked to address.

WORKSHOP ACTIVITIES

Background Presentations

The meeting was opened by Mr. Martin Oteba, Assistant Commissioner, Pharmaceutical Division Ministry of Health, who represented Dr. Nduhura Richard, Hon. Minister of State for Health in charge of General Duties and delivered the Minister's speech. In his prepared remarks, the Minister underscored the government's commitment in involving the private sector to help meet its public health goals. He emphasized the importance of adopting the Tanzania ADDO model with careful consideration of the Uganda situation. See Annex 4 for a copy of the Minister's remarks.

A background of EADSI (see Annex 5) was followed by a session on the Tanzanian experience with the ADDOs (see Annex 6) that was presented by Margareth Ndomondo-Sigonda, Director General, Tanzania Food and Drugs Authority (TFDA). Her presentation gave an in-depth view of the ADDO program in Tanzania and illustrated how much work the program required.

MSH-Uganda Senior Program Associate, Aziz Maija, presented the Ugandan situational analysis, which was organized around the four dimensions of access—availability, affordability, acceptability, and geographic accessibility. See Annex 7 for the presentation slides.

Options for the Ugandan Model

In the preparatory workshop session, working groups drafted options related to the different components comprising a private sector drug seller model. Denis Mwesigwa of the National Drug Authority presented these options to the November 14 workshop participants. Specific issues that the working groups addressed along with their recommendations are presented below.

Pharmaceutical Sector Regulations and Laws

The accredited drug seller program involves allowing accredited shops to stock selected prescription-only medicines, which, by law, they are currently not allowed to stock. The related statutory changes will be time-consuming. Working group participants proposed that the program seek exemption on prescription medicines and auxiliary staffing for the accredited drug shop demonstration project. Depending on the success of the demonstration, there may be a need to review statutes and make permanent changes to the medicine schedules, staffing requirements, and premises requirements for accreditation of drug shops.

Development of Drug Seller Dispensing Practice Standards

The Pharmaceutical Society of Uganda (PSU), in collaboration with other councils, should establish minimum dispensing practice standards for accredited drug sellers, guidelines for referral, patient consultation and education, and ethical standards of practice in accredited shops.

Medicines List

Considering that the goal of accredited shops will be to improve access to essential primary health care medicines, NDA, in collaboration with PSU and other professional councils, should develop a list of essential medicines for both human and veterinary primary health care practice that accredited shops can sell. The list would be based both on what Tanzania adopted and on the current medicines used at the primary health care level in Uganda.

Reporting and Record Keeping

NDA should develop standards and materials for record keeping, including standardized supportive supervision forms. Standardized forms will help streamline supervision for other players, such as the district health teams. However, the information to be collected should reflect what is really needed to help ensure quality of service and protecting the public's health; forms should not be too complicated or require the collection of unnecessary or unused data.

The NDA zonal inspectors should act as the focal point for receiving reports on prescriptions, common diseases, and drug safety monitoring.

Human Resources

NDA and PSU should review the regulations for staffing drug shops, especially the qualifications of auxiliary staff in underserved and remote areas. The minimum background for accredited drug sellers needs to reflect the available pool of candidates and reality on the ground.

Considering the roles that PSU and other professional councils play in supportive supervision, working groups recommended that the MOH strengthen the PSU's capacity to oversee drug shop operations and practices.

Training and Accreditation of Drug Sellers

PSU and institutions that train health professionals should draw up a curriculum for training accredited drug sellers with NDA's input on the pharmaceutical-handling component. PSU should coordinate drug seller training during the demonstration project, which should be conducted by PSU, NDA, and training institutions.

PSU should have responsibility for accrediting trained drug sellers.

Monitoring and Supervision

In collaboration with other professional councils, PSU should coordinate efforts relating to monitoring and supervision of accredited drug shops and drug sellers. One option is the formation of accredited drug shop owner and seller associations, which could establish a process for self-regulation. Another option is to expand the mandate of district health teams to provide supportive supervision at private drug outlets in addition to public health facilities.

Inspection

The inspection model in Uganda should be built around the following administrative levels—

- Local council leadership at the lowest level
- District level—District Assistant Drug Inspector (DADI)/District Health Teams
- Zonal NDA inspectors
- NDA regional inspectors
- NDA head office

NDA should develop and review a standardized inspection checklist based on the agreed premises, record keeping, reporting, and drug seller qualification standards for the accredited drug shops.

Inspectors should conduct routine inspections and enforce actions for violations.

Drug Shop Financing and Business Training

Microfinancing institutions, local businesses, nongovernmental organizations, and private enterprises should be involved in—

- Developing business curriculum for owners
- Training owners in business management skills
- Providing owners with access to loans

Activities should be facilitated by establishing of accredited drug shop owner associations.

Private Sector Supply and Distribution of Medicines

To increase sources of medicines for retail outlets, the government should offer incentives to encourage pharmaceutical wholesalers to establish themselves in regions without wholesale pharmacies. Designing such incentives would involve the NDA, local government, etc.

Ongoing private sector initiatives should also be used as a source of medicines (e.g., Medicines for Malaria Venture and African Affordable Medicines) and technical assistance.

Consumer Awareness

Public health education programs at both the district and national levels should integrate information on services provided by accredited drug shops. In addition, local governments should sensitize the community about the accredited drug seller initiative.

Institutional Framework

For the demonstration project, the NDA will lead the Ugandan drug seller initiative in collaboration with MOH, PSU, and other stakeholders as needed, and with technical support from MSH.

Key Discussion Points

After hearing the working groups' options/recommendations presented above, the workshop stakeholders discussed a variety of issues that will affect the accredited drug shop model for Uganda. Following is a summary of their comments—

- The DADIs' dual responsibility to both the district and the NDA impedes their function of inspecting Class C drug shops, and as a result, some unlicensed drug shops continued to operate, especially in rural areas.
- NDA set an employment target of 21 zonal inspectors under three zones in each NDA regional office. The zonal inspectors will be fully accountable to NDA, which will improve NDA's inspection capacity.
- The prescription medicines that the accredited shops will be allowed to stock should remain as prescription-only medicines.
- Owners should be trained on ethical practices and the implications of unethical practices.
- The implementation plan should clearly delineate organizations' roles and responsibilities for the different activities.
- Pharmaceutical distributors also need to play a role in training owners and drug sellers.
- Local councils may not have the capacity to take responsibility for inspection and supervision activities. Their role should be limited to identifying shop owners/operators.
- The primary role of NDA is regulation and ensuring medicine safety. NDA's routine responsibility should not include implementing initiatives like this one—only overseeing such implementation.

- In Tanzania, the initial primary role of TFDA was to develop the ADDO system. TFDA has largely passed the ADDO implementation role to other organizations, both in the public and private sectors.
- Many consumers use the services of traditional healers. The initiative should not neglect these providers, especially as related to the care of children.
- Using a supervisory checklist would be very helpful in program implementation.
- It will be important for NDA to seek the advice of other health professional councils in developing the list of medicines that can be legally dispensed by accredited drug sellers.
- The definition of "underserved" should be agreed on through consensus.
- The organizations that will take the lead on curriculum development and training should be clearly defined. Both the PSU and the health professional schools need to be involved, but the leader of specific components should be recognized.
- The experience with ADDOs in Tanzania has shown that the creation of accredited dispensers and their associated career path has created a demand for these individuals in other health care settings, resulting in a shortage of accredited dispensers to work in the drug shops. This needs to be kept in mind. The system needs to be able to supply a continuous stream of new accredited drug sellers to ensure adequate numbers to fill the needs of drug shop owners. Incorporating a drug management and dispensing component into nurses' training curriculum could contribute to sustainability.
- The various health professions' councils should be involved with monitoring and supervision in collaboration with PSU. However, the government's task will be to strengthen these councils.
- Some districts already have drug shop associations, which are active in self-regulation. Perhaps NDA could provide guidance on how to establish these associations to promote rollout in all districts.
- Owners need to be cautious about seeking financing from microfinancing institutions, because paying back a loan requires discipline. Owners need to use viable microfinance institutions. In addition, owners need training on the ethical and legal requirements related to financing.
- There is a real problem with lack of information for consumers. NDA needs to work with partners in getting creditable information to the population on pharmaceutical services and products and appropriate medicines use. The District Health Officers should play a larger role in relation to this activity.

Points of Stakeholder Consensus

- Uganda would benefit from an accredited drug shop program. However, the model should be tailored to Ugandan needs.
- The National Drug Authority should take the lead in implementing the initiative.
- Sustainability must continuously be kept in mind as project planning and implementation move forward.
- The initiative must include a sound evaluation plan that will inform decisions on nationwide scale-up.

IMMEDIATE NEXT STEPS

- Hold further sensitization meetings with district officials and drug shop owners and sellers.
- Draft a private sector drug seller model for Uganda that considers the recommendations and consensus of the stakeholders' meeting.
- Develop an initiative implementation plan.
- Identify the key implementation partners with careful consideration of the recommendations from the stakeholders' meeting.
- Present the concept to the Ministry of Health's medicines working group.

ANNEX 1. LIST OF WORKSHOP PARTICIPANTS

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ANNEX 2. WORKSHOP PROGRAM

Program for the Ugandan Private Sector Drug Seller Initiative Stakeholders' Workshop

Date: 14th November 2008
Venue: Protea Hotel

Time	Activity	Discussant/Session Chairperson
08:00-08:30	Registration	
08:30-08:45	Introductions and welcome remarks	Mr. Denis Mwesigwa, NDA
08:45-09:00	Remarks from the Guest of Honour and official opening of the workshop	Hon. Dr. Richard Nduhura Minister of Health (presented by Mr. Martin Oteba, MOH)
09:00–09:15	Background to EADSI and conference organisation	Mr. Saul Kidde, MSH
09:15–09:45	The Tanzanian Experience with ADDOS	Ms. Margareth Sigonda, TFDA
09:45-10:15	Ugandan situational analysis	Mr. Aziz Maija, MSH
10:15-10.45	**Tea Break**	
10.45-12.45	Ugandan options/recommended model	Mr. Denis Mwesigwa, NDA
12:45–13:45	**Lunch**	
14:00–15:45	Discussion of recommendations	Dr. Lloyd Matowe, MSH (discussion facilitator)
15:45–16:00	**Break**	
16:00-1700	Final recommendations on the way forward for the Ugandan drug seller initiative	Dr. Lloyd Matowe, MSH (discussion facilitator)
17:00-17:15	**Closing remarks & invitation to a cocktail**	Mr. Morries Seru, MOH

ANNEX 3. BACKGROUND INFORMATION AND QUESTIONS FOR SMALL WORKING GROUPS

Group 1: Allowable Products and Services

Background information

- Class C drug shops are only allowed to sell medicines defined by law
  - Any change to the Class C medicine list would require a change in the law.
- Many Ugandans, particularly those in rural areas, use Class C shops as their initial source of health advice.
- To improve access and profitability, many Class C shops illegally sell prescription medicines or give injections and may provide other health-related services (e.g., wound/burn care). In Kibale and Mpigi:
  - 66% of shops offered injections; 40% stocked antibiotics; and 80% provided wound/burn care.

Discussion questions

- What are appropriate health conditions to address in accredited drug seller shops?
- What medicines should be available in accredited drug seller shops? What restrictions might apply?
- What other services might be made available?
  - Injections? Diagnostic tests? Wound/burn care?
- What laws/regulations would have to be changed or enacted to increase scope of products and services?
- What are potential barriers to expanding scope? Solutions?

Group 2: Human Resources

Background information

- The person in charge at Class C shops must be a clinical officer, pharmacy tech, or at minimum, a nurse.
  - In Kibale and Mpigi, 60-70% of the shops employed nurse assistants to dispense.
- The Ministry of Health does not recognize the cadre of nurse assistants; therefore, there is no defined training curriculum for this class of health worker.
- Professional councils are tasked with training and continuous education, but they have limited capacity.
- Less than 20% of drug sellers had organized training in malaria in previous 2 years, despite switch to ACTs.

Discussion questions

- Recognizing the current situation, what should the minimum entry-level qualifications for accredited drug shop dispensers be? Is there an adequate pool?
- What is a realistic training schedule for dispensers (e.g., length, frequency of offering)?
- Who should accredit and/or develop curricula and materials?
- Who should be in charge of training and where will it take place?
- Who should fund training? Owners? Dispensers?
- What institution should accredit dispensers?

Group 3: Service Quality

Background information

- For-profit facilities, including drug shops, are supposed to register with the government, but enforcement is limited and inspections sporadic.
- NDA has responsibility for inspecting drug shops through District Assistant Drug Inspectors…now replaced with zonal inspectors (3 hired; 5 advertised).
- There is little record-keeping in drug shops
  - 33% of shops in Kibale and Mpigi did not track the medicines sold.

Discussion questions

- What is the best inspection model for ensuring regular and ongoing inspections of accredited drug shops?
- Should all existing drug shops ultimately be forced to convert to accredited status?
- What record-keeping should be required? How can we be sure that the information collected will be effectively used to improve quality?
- What monitoring and supportive supervision options are most appropriate?
- How can consumers help assure service quality?

Group 4: Institutional Framework/Roles

Background information

- In Tanzania, the TFDA initially served as "owner" and implementer of its ADDO initiative.
- To increase sustainability, stakeholders recommended TFDA focus on its regulatory and enforcement roles + provide general oversight.
- Implementation has now been decentralized to the districts/regions with TFDA providing technical support as required.
- There is now increased reliance on the private sector for implementation.

Discussion questions

- What is the appropriate mix of public- and private-sector control for a private-sector drug seller initiative in Uganda?
- What should the coordination mechanism for such an initiative be? What would its role be? Where would it reside?
- Is there a need for accredited drug shop owner and dispenser associations? What role would such associations play? Would they contribute to sustainability?

Group 5: Sustainability

Background information

- Government set up the microfinance support center to provide wholesale credit to microfinance institutions for loans to their clients.
- Several nongovernmental organizations are involved in capacity building for small-scale enterprises—
  - Private Sector Foundation Uganda (PSFU) under its BUDS (Business development scheme) program
  - Enterprise Uganda
- Community-based financing schemes exist in Uganda, but appear limited.

Discussion questions

- Would existing micro-financing institutions take the risk of financing drug shops that want to convert to being accredited drug shops?
- What is the best approach to business training for accredited drug shop owners?
- Are there mechanisms/incentives that can be used to encourage drug shop owners and drug wholesalers to operate in remote districts?
- Can health insurance and community-based financing schemes play a role in the initiative?

ANNEX 4. REMARKS OF THE HONORABLE MINISTER OF HEALTH

Honorable Members of Parliament present
Senior Government Officials
Staff of the Ministry of Health
Invited Guests,
Ladies and Gentlemen.

I am delighted to be associated with this stakeholder's meeting in addressing one of the critical inputs in health care, access to medicines by the people of Uganda.
I am informed that this meeting will not only address itself to access to medicines, but also and most importantly their quality.

As you may all be aware, the Government is committed to the liberalization of the economy. Government is also committed to the full participation of the private sector in provision of health care through the public–private partnerships for health.

My ministry is happy to note that this meeting is aimed at addressing some aspects of such partnership and will be looking forward to the outcomes of the pilot. I pay tribute to the sponsors of the pilot to be conducted in Kibale District and appeal to the leadership of this district to support and work with the implementers of the pilot.

Ladies and gentlemen, malaria, diarrhoea, worm infestation and skin ailments like scabies are still a problem in some parts of our country. Collaboration like this one with support from prominent institutions such as MSH in this case is timely to support our strategies of taking care closer to the people and making this care as affordable as possible. You are aware that the government is running a health care that provides for universal coverage. However, cognizant of the fact that there will always be people who seek private health care, it is only imperative that such people's interests are taken care of at all levels.

Handling of medicines is a technical matter if we have to maintain quality of care even at the lowest level and rural settings. In this country, more than 80 percent of the pharmacies are located within urban settings. This leaves the rural population with almost no care except for the drug shops in the country side. I urge the NDA as the lead agency in this partnership and also the regulator of medicines to manage this extremely carefully and not to compromise its mandate of ensuring the highest quality of medicines are availed to all Ugandans. I call upon the pharmaceutical fraternity, especially the Pharmacy Council to work closely with the implementers of this pilot to ensure the best is availed to our people both in terms of quality and service.

I join you all in thanking the MSH through Mr. Keith Johnson, the Deputy Director, MSH Center for Pharmaceutical Management, for this support and call upon him to assure MSH of our appreciation and support. In the same vein, I thank the MSH country office for organizing this meeting and enabling the resources for this project gets through to Uganda. We look forward to a successful pilot in Kibale District.

May I now declare this meeting officially open.

I thank you.

ANNEX 5. BACKGROUND INFORMATION ON EADSI

East African Drug Seller Initiative
Uganda

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

Stakeholders Meeting
November 13, 2008

Introduction to EADSI

Saul Kidde
Management Sciences for Health

EADSI Objectives

EADSI's three main objectives are to—

1. Develop a regional strategy to support the implementation of sustainable private-sector drug seller initiatives.
2. Strengthen the ADDO model in use in Tanzania to facilitate scaling up and sustainability.
3. Develop a plan to adapt and replicate the Tanzanian ADDO model to scale in another country and demonstrate the adapted model in one district.

Why Uganda?

- The government has committed to involving the private sector to help meet its public health goals.
- The government is working to strengthen private-sector participation in public health, and political will is strong.
- Donor-funded organizations are implementing malaria-related projects involving the private sector—thus, there is an opportunity for leveraging among projects.
- MSH has an office and ongoing activities.

Completed EADSI Work in Uganda

- Conducted a situation and options analysis based on existing data on the Ugandan pharmaceutical sector and access to medicines.
- Reviewed draft report with stakeholders to identify information gaps.
- Mapped drug shops and health facilities and collected information to fill gaps in two study districts: Kibale and Mpigi.

Next Steps for EADSI in Uganda

- Build key stakeholder consensus to introduce an ADDO-like model in Uganda.
- Develop a model and implementation plan specific to the needs of Uganda.
- Implement and evaluate the Ugandan drug seller model in Kibale with Mpigi as a comparison district.
- If successful, develop a rollout strategy, establish infrastructure, and solicit funding for nationwide implementation of the model in Uganda.

ANNEX 6. TANZANIA EXPERIENCE WITH THE ADDO PROGRAM

East African Drug Seller Initiative
Uganda

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

Stakeholders Meeting
November 14, 2008

Tanzania's ADDO Initiative

Margareth Ndomondo-Sigonda
Tanzania Food and Drugs Authority

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2001 Tanzania Assessment

- 2001 SEAM assessment in Tanzania showed that retail drug shops (*duka la dawa baridi*) are common sources of medicines—especially in rural areas.
- However, identified problems included—
  - Limited list of legally approved medicines for sale.
  - Dispensers lack basic skills and qualifications.
  - Unassured medicine quality.
  - Poor pharmaceutical service quality.
- Results indicated that rural people lacked access to quality medicines and pharm.services.

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The ADDO Strategy in Tanzania (1)

Major program activities to create *Duka la Dawa Muhimu* ("essential drug shops") included—

- Developing accreditation based on Ministry of Health/Tanzania Food and Drugs Authority (TFDA)-instituted standards and regulations.
- Building business skills capacity in ADDO owners.
- Changing behavior of dispensing staff through training, education, and supervision.
- Providing ADDO owners commercial incentives, such as loans.

The ADDO Strategy in Tanzania (2)

Major program activities continued—

- Improving legal access to a limited list of basic prescription and nonprescription essential medicines.
- Focusing on regulation and inspection and improving local regulatory capacity.
- Increasing public awareness of quality and the importance of treatment compliance through marketing and public education.
- Pilot ADDO program in one region, Ruvuma, and compare to control region.

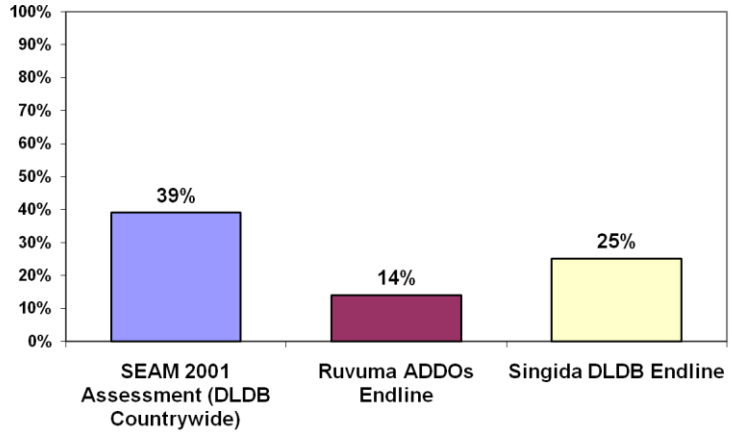
ADDO billboard at the bus stop in Songea fostered public awareness

ADDO Pilot Results (1)

- TFDA accredited first ADDO shops in August 2003—by August 2005, more than 150 shops were accredited across Ruvuma.
- SEAM Program evaluated the Ruvuma ADDO shops in late 2004, comparing them with a control group of *duka la dawa baridi* in the Singida region.
- Results showed significant improvements in accessing medicines, including –
  - The proportion of unregistered medicines (proxy for quality) reduced by factor of 13.
  - Malaria treatment encounters that included the sale of the appropriate first-line antimalarial increased 100%.
  - Fewer ADDO dispensers recommended antibiotics for upper respiratory infection.
- Results confirmed by an independent evaluation from Danida.

ADDO Pilot Results (2)

Percentage of simulated upper respiratory tract infection clients dispensed or recommended antibiotics



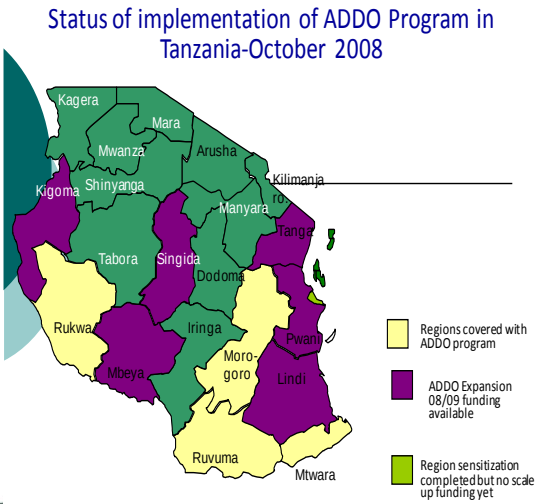
Lessons Learned in Tanzania (1)

- Pharmaceutical services in developing countries can be substantially improved through training, accreditation, and regulation of private sector drug sellers.
- The key to achievements has been the broad-based support from all stakeholders from the public and private sectors.
- Building in appropriate incentives to support commercial success is important for sustainability.
- Defining the appropriate mix of public- and private-sector responsibilities in a drug seller initiative is critical for timely scale-up and sustainability.

Lessons Learned in Tanzania (2)

- Owner, dispenser, and local regulatory/ inspector training is expensive and time-consuming.
- Decentralization of regulatory authority shows promise, but needs an adequate resources.
- Supervision and mentoring (distinct from regulation and inspection) are complex, time-consuming, expensive, and pose challenges.
- Success in a pilot program does not guarantee rollout success; a different implementation approach is needed.

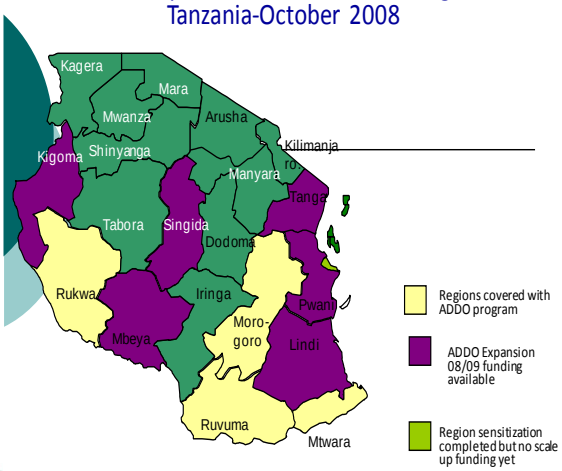
What's Happened Since SEAM? (1)



- Government recommended nationwide rollout by 2010.
- Roll out strategy document prepared (describing modality to roll ADDOs, resources, roles of institutions etc)
- Problems with Roll out strategy document: long time to complete roll out due to limited resources (financial, human etc)
- Rollout complete in Morogoro, Mtwara, and Rukwa.

What's Happened Since SEAM? (2)

Status of implementation of ADDO Program in Tanzania-October 2008



- Incorporated Public Health Programmes:
  - Child Health component based on Integrated Management of Childhood Illness (IMCI)
  - HIV/AIDS prevention & palliative care information
  - Distribution of subsidized ACT & Insecticide Treated Nets (ITN)

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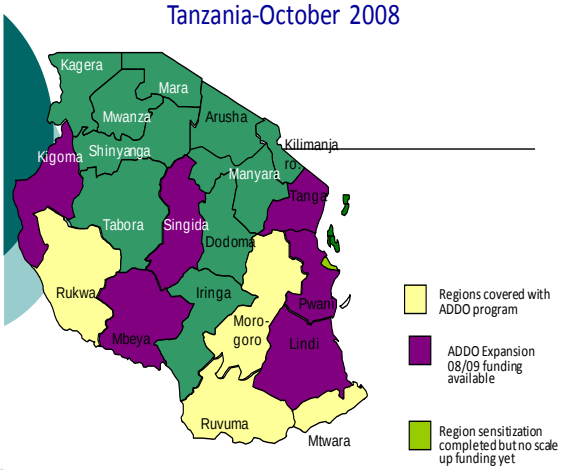
What's Happened Since SEAM? (3)

Status of implementation of ADDO Program in Tanzania-October 2008



- Revised ADDO Roll Out Package:

Delegation of Program activities to Local Government Authorities

Components of the Package

✓ ADDO Implementation Manual- A guide to Regions and Council

✓Training package: Dispensers, Owners and local inspectors manuals and facilitation guides for vet & human medicines

✓M&E Tool

✓Revised ADDO regulations in line with the Delegation of Power Regulations, 2006

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What's Happened After ADDO Roll Out Package Developed (1)

- TOT to create a pool of ADDO trainers country wide (190 new trainers (primarily pharmacists and veterinary surgeons)
- Over 1,400 dispensers and 828 owners have been trained.
- 660 district and ward-level inspectors have been trained in two regions.

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What's Happened After ADDO Roll Out Package Developed (2)

- Officers from 16 regional administrations and 83 councils were sensitized and inspectors trained on the ADDO program in Jan-Feb, 2008
  - Regional and district pharmacists key for rollout implementation plan.
- 753 accredited outlets are selling subsidized ACTs and 1,148 dispensers have been trained in the new treatment

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What's Next in Tanzania? (1)

- EADSI Program funding activities related to ADDO scale-up(system strengthening).
- July 2008 stakeholders meeting to develop and achieve consensus on a revised ADDO model to implement rollout whereby;
  - Modality on ADDO roll out in urban settings was added to the package
  - Incorporated other organizations/government agencies as "owners" of certain components e.g. training curricula
    - MoHSW Training Department
    - Pharmacy Council
    - NACTE

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What's Next in Tanzania? (2)

- Strengthening M&E Framework including reporting structure from the village to central level.
- Use revised model to rollout ADDO program to the six regions funded by Global Fund and other four regions whose Councils have incorporated ADDO activities in CCHP
- Develop an ADDO "tool-kit" based on Tanzania's implementation experience

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Oshara Duka la dawa Baridi before conversion to ADDO

Oshara *Duka la dawa Muhimu* after conversion

ANNEX 7. UGANDAN SITUATIONAL ANALYSIS PRESENTATION

East African Drug Seller Initiative
Uganda

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

Stakeholders Meeting
November 13-14, 2008

Situational Analysis: Access to Medicines in Uganda

Aziz Maija
Management Sciences for Health

Need for a Situational Analysis in Uganda

- SEAM experience taught that it takes a significant amount of data collection and analysis, options mapping, and stakeholder involvement to successfully introduce an ADDO-like initiative.
- Research on country context and stakeholders promotes support and identifies the principal advocate or lead organization.
- Such research reveals both barriers and opportunities for leveraging activities.

Conducted a Draft Situational Analysis

- Received permission from Uganda Ministry of Health to conduct situational analysis.
- Gathered and analyzed available information on Ugandan pharmaceutical sector related to Class C drug shops.
- Described the regulatory and organizational landscape of the country's pharmaceutical sector and how it relates to the population's access to medicines.
- Highlighted ongoing activities in the country related to access to medicines.

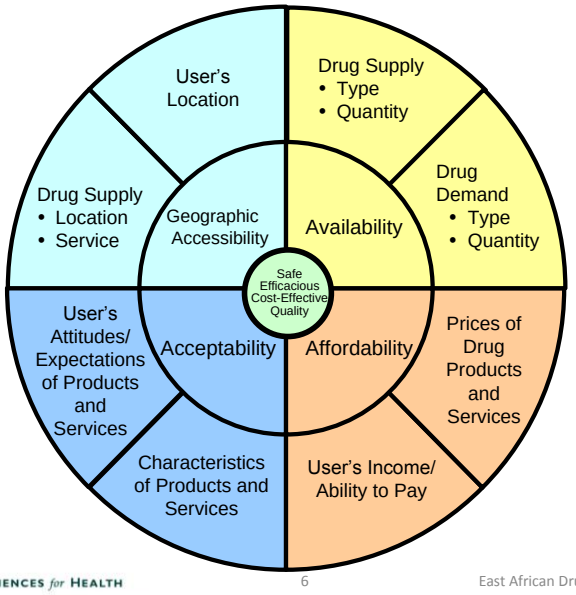
Finalized the Situational Analysis

- In June 2008, reviewed situational analysis with stakeholders and identified information gaps.
- To fill these gaps, data collectors conducted interviews with key informants in the public and private sectors, including drug shop owners and dispensers.
- Data collected in two districts:
  - Kibale
  - Mpigi

Data Collection: Kibale and Mpigi

- Mapping exercise of health facilities and drug shops
- Data collected in August 2008
- Facility-based survey questionnaires with tracer drugs
- Simulated client visits
- Patient exit interviews
- Mpigi: 49 drug shops (licensed and unlicensed), 15 private clinics, and 13 level-II public health centers
- Kibale: 57 drug shops (licensed and unlicensed), 19 private clinics, and 9 level-II public health centers

SEAM Access to Medicines Framework



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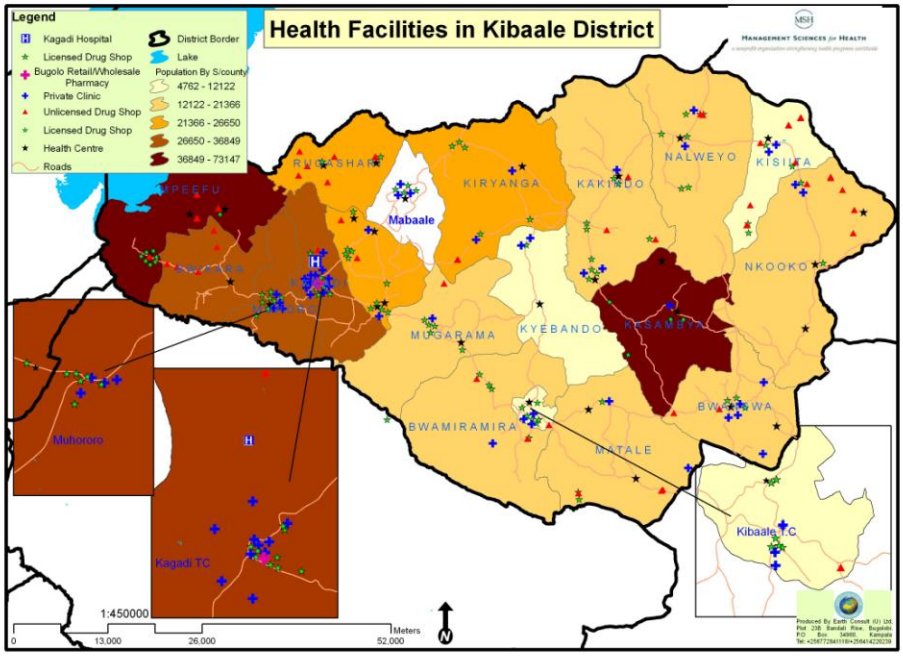
Accessibility

Accessibility

Registered Pharmaceutical Facilities 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**

- Total number of non-registered/non-licensed pharmaceutical outlets is unknown.
- Estimated sale of medicines through informal outlets is large.
- Other informal sources of medicine include traditional healers and mobile drug sellers.


Health Facilities in Kibaale District
Legend
Kagadi Hospital
Licensed Drug Shop
Bugolo Retail/Wholesale Pharmacy
Private Clinic
Unlicensed Drug Shop
Licensed Drug Shop
Health Centre
Roads
District Border
Lake
Population By S/county
4762 - 12122
12122 - 21366
21366 - 26650
26650 - 36849
36849 - 73147
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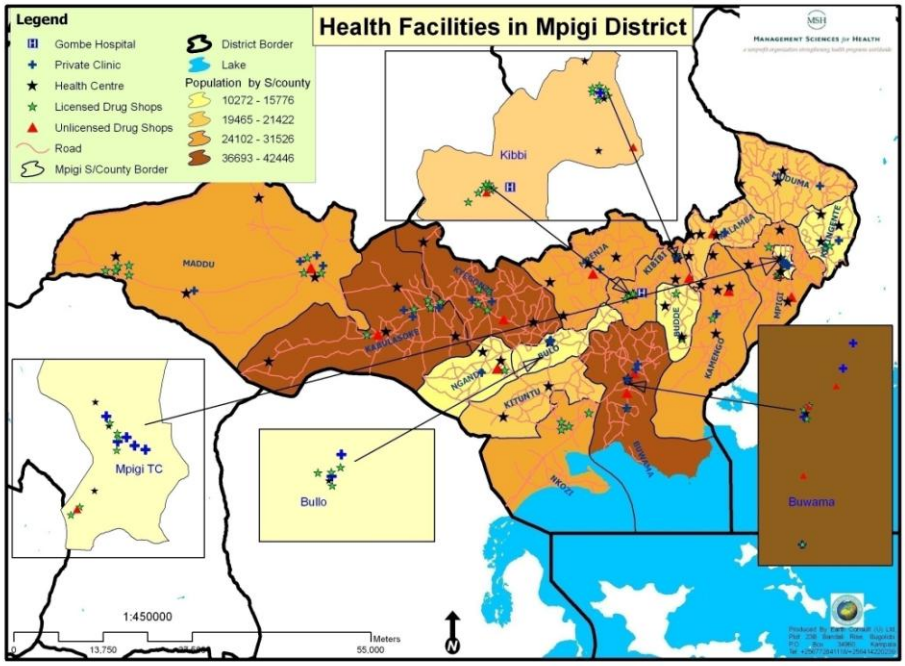
KIRYANGA
KAKUMIRO
NALWEYO
KISOJA
NKOOKO
KYEBANDO
BWAMIRAMIRA
MATALE
Mabaale
Muhororo
Kagadi TC
Kibaale TC
1:450000
0
13,000
26,000
52,000
Meters
N


Health Facilities in Mpigi District
Legend
Gombe Hospital
Private Clinic
Health Centre
Licensed Drug Shops
Unlicensed Drug Shops
Road
Mpigi S/County Border
District Border
Lake
Population by S/county
10272 - 15776
19465 - 21422
24102 - 31526
36693 - 42446
MANAGEMENT SCIENCES for HEALTH
Kibbi
MADDU
Mpigi TC
Bullo
Buwama
1:450000
0
13,750
55,000
Meters
N

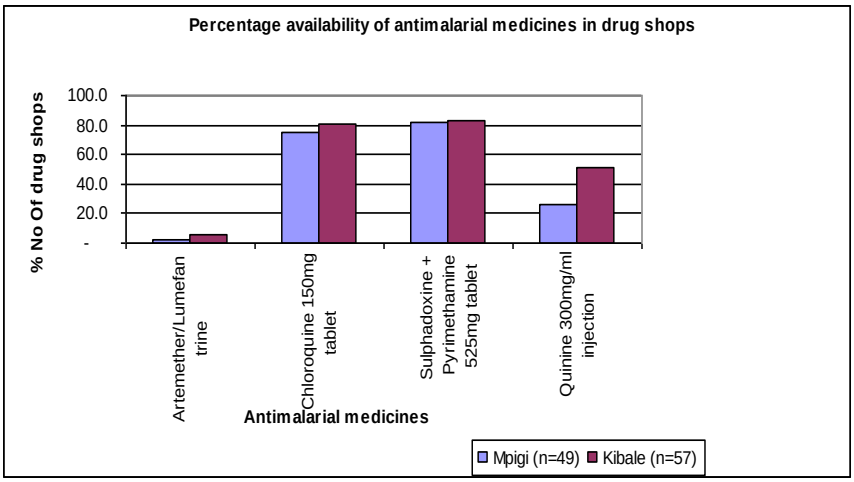
Availability

Availability (1)

- Medicines more available in urban facilities.
- Median medicine availability in 27 public facilities was 33%.
- Median availability in 14 mission facilities was 29%.
- Better availability in 32 private facilities at 58% overall, but urban higher than rural (70% vs. 33%).
- About 75% of 100 private sector dispensers interviewed in Nakasongola reported antimalarial stock-outs because—
  - Long distance to replenishment source
  - Lack of sufficient capital to restock
  - Unreliable suppliers
  - High demand during the rainy season

(*Sources*: HAI 2006; Batega et al., 2006)

Availability (2)



Affordability

Affordability (1)

- An estimated 56% of per capita expenditure on medicines is out-of-pocket in Uganda.
- No differences in medicine prices between 32 private urban and rural facilities.
- No significant differences in prices in 14 mission sector facilities compared with the private sector.
- Mission sector prices about 11% higher overall in urban compared with rural areas.
- Caretakers in Nakasongola reported the range of costs for first malaria treatment as UGX 100-120,000 with an average of UGX 5,781.

(*Source*: HAI 2006; Batega et al., 2006)

Affordability (2)

- A survey of 6 districts by MMV illustrated a wide range of prices for antimalarials, including ACTs which were 5 to 60 times more expensive than ineffective medicines such as chloroquine.
- It was noted that the average out-of-pocket cost for an average family's malaria treatment using ACTs for a year would range from UShs 85,000-148,750 or the equivalent of 91 days of income for the average household while it would require between 3 to 6 days' income for SP.

(*Source*: MMV 2008)

Acceptability

Acceptability (1)

- 2003 data indicate that people seek treatment from the following sources—
  - Private sector (53% of the time)
  - Public sector (24% of the time)
  - "Other" (4% of the time)
  - Do not seek care (19%)
- Caretakers in Nakasongola who preferred private providers cited proximity, availability of credit, and quick service.
- Caretakers expressed reservations about expired drugs, lack of record-keeping, and untrained dispensers.

(*Sources*: Xu et al., 2005; Batega et al., 2006)

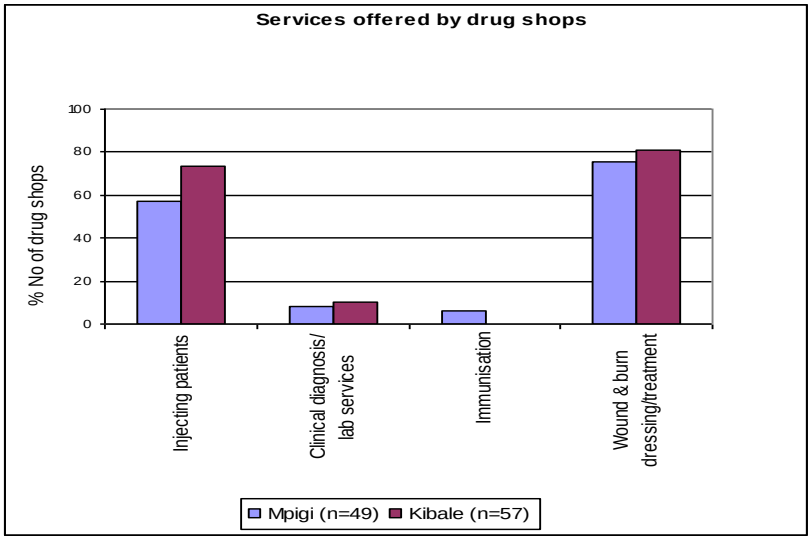
Acceptability (2)

"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'."

(***Source*: CORE Group and Minnesota International Health Volunteers, 2004)**

Quality of Products and Services

Quality of Products and Services (1)



Quality of Products and Services (2)

- Most of 100 shop dispensers in Nakasongola were knowledgeable about the general signs of malaria, although only 32% had been trained in some sort of health care.
- However, 35% thought pain relievers were the most effective treatment for malaria.
- Dispensers noted that most caretakers ask for a specific treatment and many did not want to buy a full dose.
- Dispensers either offered credit (45%) or gave them the dose they could afford (40%).

(*Source:* Batega et al., 2006)

Quality of Products and Services (3)

- Most drug shop and pharmacy attendants in Kampala District had medical or pharmacy training, but had little knowledge of acute respiratory infection and usually prescribed an unneeded antibiotic.
- Drug shops in areas of low malaria transmission dispensed quinine, which is only recommended as a second-line drug for severe malaria.
- 66% of shops in Kibale and Mpigi offered injections; 40% of shops stocked antibiotics.

(*Sources:* Ndyomugyenyi et al., 2007; Tumwikirize et al., 2004)

Issues Relating to Regulation and Capacity

Regulatory Issues

- Statutory changes needed to launch an ADDO-type program would be time-consuming, but an exception could be obtained for a pilot program in an appropriate district.
- According to the new Pharmacy Bill (pending in Parliament), the Pharmacy Council will take over some of NDA's responsibility for regulating pharmacy/drug shop operations.

Licenses and Inspection

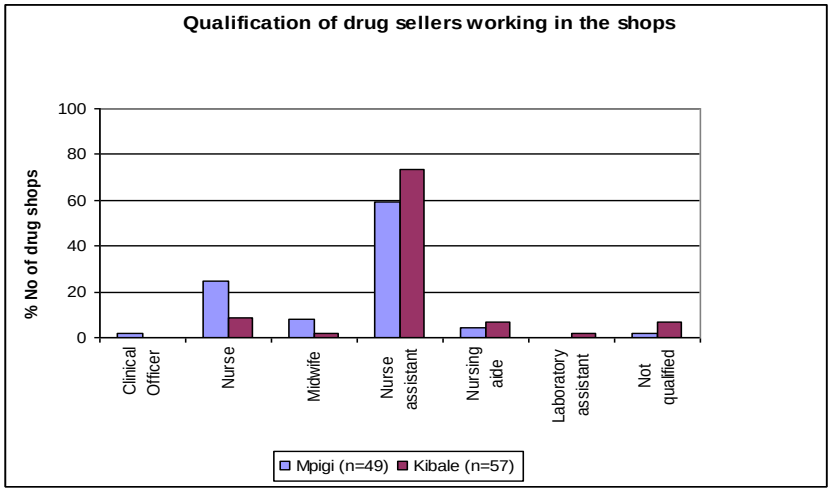
License for 2008	% of drug shops	
	Mpigi (n=49)	**Kibale (n=56)**
NDA license	44.9%	48.2%
Business license	67.3%	60.7%

Inspection status	% of drug shops	
	Mpigi (n=49)	**Kibale (n=56)**
Within the last year	67.3%	64.2%
Within the last 2 years	2%	0
Don't know	8.2%	9%
Never	22.5%	26.8%

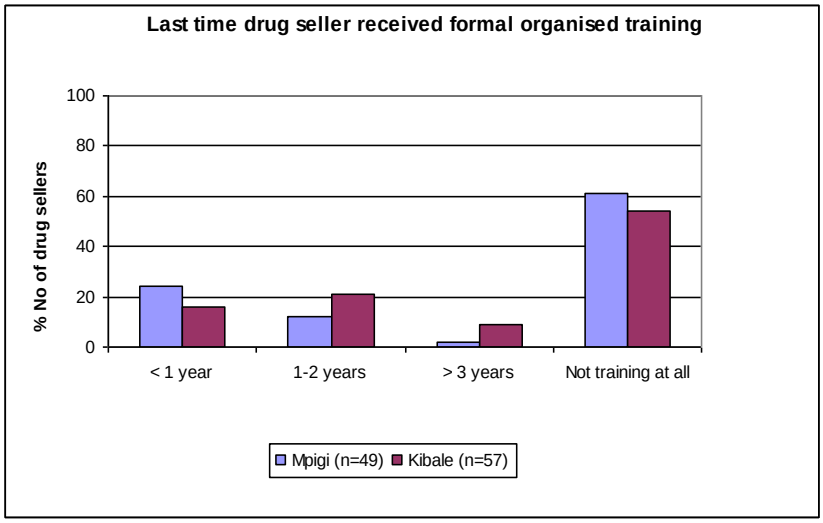
Inspection Capacity

- NDA has used District Assistant Drug Inspectors (DADIs) to inspect drug shops.
- NDA will replace DADIs with zonal inspectors.
- Currently, NDA has three zonal inspectors and is in the process of recruiting an additional five.
- Zonal inspectors will report to regional inspectors; each zone will comprise three districts.

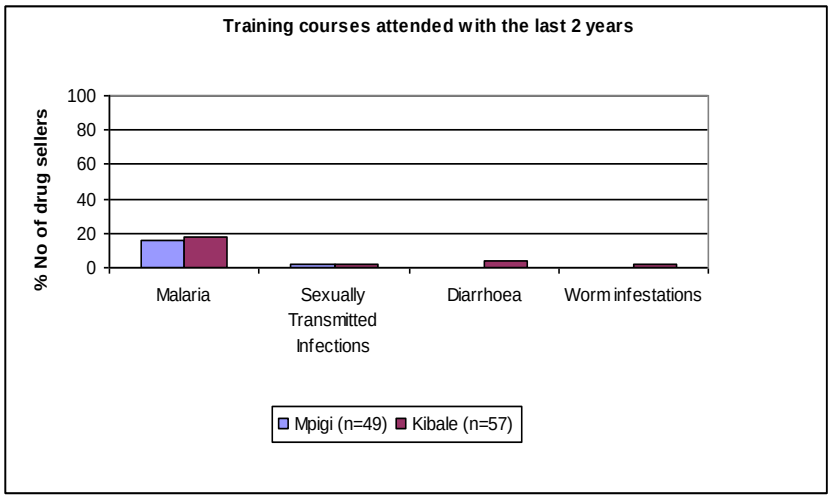
Drug Shop Dispenser Qualifications



Drug Shop Dispenser Training (1)



Drug Shop Dispenser Training (2)



Uganda Training Institutions

- Accredited nursing training institutions (36)
- Accredited allied health training institutions (9)
- Private training schools (14)
- Accredited physician training institutions (4)
- Accredited pharmacist training institutions (3)