East African Drug Seller Initiative in Uganda

Stakeholders Meeting

June 17, 2008




MSH MANAGEMENT SCIENCES *for* HEALTH

CPM | Center for Pharmaceutical Management

A New Drug Seller Initiative

- October 2007, Gates Foundation awarded MSH a 3-year grant to continue its efforts to involve private drug sellers in enhancing access to essential medicines in East Africa .
- The East African Drug Seller Initiative (EADSI) builds on MSH's Strategies for Enhancing Access to Medicines (SEAM) Program.
- **EADSI Goal**: create a sustainable model to replicate and scale-up private-sector drug seller initiatives in developing countries that will ultimately operate independent of donor support.

SEAM's Program in Tanzania

- Bill & Melinda Gates Foundation funded Management Sciences for Health (MSH) to carry out the SEAM Program (2000-2005).
- 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.
  - Medicine quality unassured.
  - Poor pharmaceutical service quality.
- Results indicated that rural people lacked access to quality medicines and pharmaceutical services.

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 (e.g., access to loans, authorization to sell some prescription medicines).

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.

ADDO billboard at the bus stop in Songea fostered public awareness

ADDO Program Results

- 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 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.

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 some promise, but needs an adequate resources.
- Supervision and mentoring (distinct from regulation and inspection) are complex, time-consuming, and expensive, and pose challenges.

Post-SEAM ADDO Program Activities (1)

- After the successful ADDO pilot program in Ruvuma, the Ministry of Health and Social Welfare recommended that the program be scaled up nationwide by the year 2010/2011.
- Rollout ongoing in three additional regions: Morogoro, Mtwara, and Rukwa.
- In the four regions, over 890 ADDO shops have been established and more than 1,800 dispensers trained.
- By mid-2008, about 20% of the country will be covered.

Post-SEAM ADDO Program Activities (2)

Government and donors are expanding the scope of services that ADDOs provide by using them to strengthen community-based health care interventions—

- Child health component based on integrated management of childhood illness added to package of services
- HIV/AIDS prevention and palliative care information
- Distribution of subsidized artemisinin-based combination therapies (ACTs) and insecticide-treated nets.

Oshara Duka la dawa Baridi before conversion to ADDO

Oshara *Duka la dawa Muhimu* after conversion

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 replicate the ADDO model to scale in a another country and demonstrate the adapted model in one district.

Why Consider 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—opportunity for leveraging.
- MSH has an office and ongoing activities.

Major EADSI Activities in Uganda

- Conduct a situation and options analysis based on existing data on the Ugandan pharmaceutical sector and access to medicines.
- Seek government approval to move forward.
- Build key stakeholder consensus to introduce an ADDO-like model in Uganda.
- Develop an ADDO model and implementation plan.
- Implement and evaluate the Ugandan ADDO model in one district.
- If the pilot is successful, develop a rollout strategy, establish infrastructure, and solicit funding for nationwide implementation of the model in Uganda.

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 is necessary to promote support and identify 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 (see report bibliography).
- 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 (see Appendix 3).

Situational Analysis Next Steps

- Review situational analysis with stakeholders and identify information gaps.
- Review organizations and related activities to identify opportunities for collaboration/ leveraging.
- To fill information gaps, data collectors will conduct interviews with key informants in both the public and private sectors including with drug shop owners and dispensers.

Findings: How Medicines are Financed

- Government per capita expenditure on medicines = USD 0.72
- Donor per capita expenditure on medicines = USD 3.34
- Estimated per capita out-of pocket expenditure on medicines = USD 5.13
  - Out-of-pocket = 56%
  - Public (including donor) = 44%

Findings: Public Health Facilities 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

- 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%)

Findings: Distribution Facilities

Registered Pharmaceutical Distribution 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**

- 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.

Findings: Medicine Prices/Availability

- No differences in medicine prices between 32 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.
- Medicines more available in urban than rural facilities.
- Median medicine availability overall 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%).

(*Source*: HAI 2006)

Public Pharmaceutical Sector Challenges

- Scale-up of HIV/AIDS, malaria, and tuberculosis treatment and diagnostic programs.
- Deferrals of improvements in pharmaceutical management capacity; large number of pharmaceutical positions are unfilled.
- Underfunding, particularly at the Health Center IV level.
- Poor stock availability at the National Medical Stores 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.

(*Source*: MOH health sector assessment 2006/2007)

Findings: Regulatory Landscape

- 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, but their capacity for this is unclear.

Information Gaps: Inspection Capacity (1)

- Decentralized authority to regulate district health services
  - Does this include private sector? Pharmacy/drug shops?
  - What budgets and human resources are available for these tasks?
- Volunteer health workers at Health Center I
  - What do they do now? Who trains and oversees their work?
  - What drugs are they allowed to dispense?
  - Do they have a potential role in ADDOs—supervisory, inspection?
- Health inspectors in town councils and districts
  - Do they inspect only public health facilities? Regulate food outlets?
  - Potential role for ADDO inspection?

Information Gaps: Inspection Capacity (2)

- District assistant drug inspector (DADI) and NDA zonal inspectors
  - What are the most recent changes with these positions?
  - Potential role for ADDO inspections?
- MOH reports that > 3,500 drug shops were inspected in 2006/07
  - How was this accomplished?
  - What was the role of DADIs?
  - What was the role of other institutions/cadres?

Information Gaps: Inspection Capacity (3)

- Public Private Partnership in Health Strategy (HSSP II)
  - What is the role for district health management teams (DHMT)?
  - Do they have experience in overseeing/regulating private providers?
- Is there any potential for regulation without operational involvement of local or central government?

Information Gaps: Pharmacy Council

- What are its resources and capacity?
- How will it approach drug shop approval as per the new Pharmacy Bill?
- The Council is responsible for “community empowerment” for accessing quality medicines—are there any related materials or activities?
- The Council is responsible for “continuing education” for pharmacists. What does that entail?

Information Gaps: Labor Market (1)

- What is the status of labor market for staffing drug shops and ADDOs?
- Is the labor market reality in line with regulations on staffing qualifications for drug shops?
- Where are pharmacists, pharmacy technicians, and pharmacy assistants located geographically?

Information Gaps: Labor Market (2)

- What grade of staff work in primary health care facilities (e.g., nurse assistants, nurses)?
- What training do nurses/nurse assistants have to dispense medicines? How is their dispensing supervised/regulated?
- What is the role of the community drug vendor (reportedly supplying 70-80% of community-level medicines)? Is there a potential for collaboration with ADDOs?

Information Gaps: Training Capacity (1)

- What training institutions exist in Uganda for pharmacy/dispensing and for business management training?
  - Pharmacy schools
  - Health and non-health sector
  - Other public sector facilities
  - Private institutions
  - National Smallholder Business Center
  - Capacity elsewhere in East African Community

Information Gaps: Training Capacity (2)

- According to the MOH, The NDA's Drug Information Center sensitized 1,300 health workers on rational use of drugs, regulation, and pharmacovigilance in 2006/07.
  - Are any details available on these efforts (e.g., materials, methods, training, impact evaluation)?
- The MOH launched the Home Based Management of Fever initiative in 2002.
  - Are any detail available on the implementation of this program (e.g., reports, evaluations, materials and methods used)?

Information Gaps: Private Supply Chain

- How does the private importer/distributor/ wholesaling supply chain work?
- Information indicated that the Joint Medical Store entered into partnership with the Diocese Health Coordinator to contract out private transport for distribution to four zones. Did this activity ever happen?

Information Gaps: Drug Shop Standards/Performance

- What government requirements must drug shops meet to do business (e.g., license, regulatory approval, taxes)?
- Drug shops must pay a fee to the Pharmaceutical Society of Uganda. What is this for? Do all drug shops pay it?
- What are the overall motivations and problems of drug shop owners?
- What are the current standards and perceived performance for Class C shops?
  - Prices
  - Quality
  - Staffing
  - Ownership

Information Gaps: Drug Shop Financing

- Who are the potential partners for providing micro-loans to ADDO owners?
  - Summa Foundation's Uganda Private Providers Loan Fund
  - Uganda Microfinance Union
- What sort of requirements exist for microloans and financial assistance?
- What are the Community Health Fund and Community Based Health Financing Association?
  - Where are they located? How well are they functioning?
  - Are they potential ADDO customers?

Information Gaps: EAC Harmonization

- UNIDO report states that "regional distribution of medicines should be harmonized by January 2008" and that this "aims at a uniform regulation and a liberalized open market between Uganda, Kenya and Tanzania"
  - What does this mean in practice?
  - Any benefits for ADDOs?
    - Mutual recognition of drug registrations
    - Mutual recognition of wholesaling/distribution licenses (potential for expanding the supplier base for ADDOs in Uganda)
- Tanzania ADDO standards–any applicability in Uganda?

Possible Key Stakeholders (1)

- Ministry of Health
  - Clinical Services
  - Department of Planning
  - Health Services
  - IMCI Unit
  - National Malaria Control Program
  - Pharmacy Division
  - Private Sector Committee
  - Uganda AIDS Commission
- Regional and district authorities (e.g., district pharmacists)

Possible Key Stakeholders (2)

- National Drug Authority
- National Medical Stores
- Joint Medical Store
- Pharmacy Council
- Faith-based organizations
  - Uganda Catholic Medical Bureau
  - Uganda Muslim Medical Bureau
  - Uganda Protestant Medical Bureau

Possible Key Stakeholders (3)

- World Health Organization
- Professional societies
  - Medical Society of Uganda
  - Pharmaceutical Society of Uganda
  - Private Medical Practitioners Association
  - Uganda Association of Allied Health Professionals
  - Uganda National Association of Nurses and Midwives

Possible Implementation Partners

- Makerere University Faculty of Medicine/ Department of Pharmacy
- HEPS Uganda
- The Infectious Diseases Institute
- The Joint Clinical Research Centre
- Summa Foundation/Uganda Microfinance Union
- Uganda Community Based Health Financing Association
- National Smallholder Business Center
- International Network for the Rational Use of Drugs

Organizations Working in Related Areas (1)

- Johns Hopkins University Center for Communications Program's AFFORD Health Marketing Initiative/Uganda Health Marketing Group
- Living Goods
- Medicines for Malaria Venture
- Population Services International (e.g., ACTwatch)
- Minnesota International Health Volunteers
- Health Store Foundation (CFWshops)

Organizations Working in Related Areas (2)

- Academy for Educational Development (e.g., Netmark, A2Z)
- Banking on Health (Banyan Global)
- Family Health International (surveying drug shops to see whether they would be suitable outlets for providing injectable contraception)
- Health Action International