

Project Evaluation Plan

SEAM Tanzania Country Program: Accredited Drug Dispensing Outlets

Background: Duka la Dawa Baridis (DLDBs) constitute the largest network of licensed outlets for basic essential medicines in Tanzania. They are found in all districts in the country and their combined inventory turnover value is estimated to be greater than Ministry of Health expenditures on essential medicines for primary health care. It is estimated that there are more than 4,600 DLDBs in the country, which represents almost double the number of public health facilities. Given the absence of pharmacies in rural communities, and the extreme shortage of them in poor urban areas, DLDBs are often the most convenient retail outlet from which to buy medicines.

A variety of factors encourage people to self-diagnose and medicate at DLDBs before visiting a government health facility for common medical problems, such as malaria and diarrhea. Moreover, with out-of-stock rates of 20-30% in public primary health care facilities, patients will often turn to DLDBs to obtain medicines and supplies prescribed by the government health worker.

Although DLDBs play an important role in providing access to essential drugs for a significant proportion of the population, data from the 2001 SEAM country assessment indicated that they are characterized by a number of problems. These include:

- 1) Insufficient number of trained staff
- 2) Poor dispensing practices
- 3) No assurance of drug product quality, with few products in stock that are registered with the Tanzanian Food and Drugs Authority (TFDA)
- 4) Drug prices charged to patients tend to be higher than those charged at other types of facilities
- 5) Types of medicines available for sale at DLDBs do not meet consumer needs
- 6) Medicines found at DLDBs are often not authorized by the TFDA for sale in DLDBs

Each of these problems is exacerbated by:

- 1) Inadequate enforcement of regulations
- 2) Difficulty in finding reliable and legal sources of medicines and supplies
- 3) Limited list of authorized medicines to meet legitimate public health demands

The Accredited Drug Dispensing Outlet (ADDO) program was designed to address each of these problems. The goal of the ADDO program is *to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or peri-urban areas where there are few or no registered pharmacies*. In the context of the ADDO program, *affordable* means that the price of medicines and services are within the means of the population that is served whether that be through direct payment (e.g. cash, in-kind, credit) or through local health financing schemes. *Quality medicines* are those that are registered with the Tanzania Food and Drugs Authority and are therefore subject to national quality assurance programs and regulation. *Quality pharmaceutical services* are to be provided by certified, trained personnel according to national TFDA standards.

To achieve this goal it was necessary to approach the problems of DLDBs in a systemic fashion. All aspects of the DLDB enterprise – including the physical shop, stock maintained by the owner, consumer choices, interactions with dispensers, and recommended treatments – had to be improved. In addition, the larger systems in which DLDBs are embedded, which include licensing, supply, training, and inspection, involving ward, district, regional and national authorities, also had to be changed and strengthened.

The adopted strategy of converting DLDBs to licensed and monitored ADDOs sought to address these interlocking features. The approach combined changing the behavior of shop owners and dispensing staff through the provision of training and incentives, regulatory coercion, and efforts to affect client demand/expectation of quality products and services. The ADDO accreditation program was designed to include the following elements:

- Development and enforcement of practice standards and licensing requirements for ADDO shops, endorsed by the TFDA and MOH
- Training program for outlet managers and attendants in appropriate dispensing and stock management
- Enhanced supervision and reporting for performance monitoring and adherence

Access Dimensions for Evaluation: As the program works to improve access to essential medicines, it is necessary to define parameters for evaluating the results and outcomes. This evaluation will review the results in terms of the various factors that influence access to medicines. The main access gaps being immediately addressed are the **quality of services and products** and **availability of essential medicines**. In addition, the program addresses the **appropriateness of dispensing** of important products provided by the ADDOs. Consumer and ADDO owner **acceptability/satisfaction** will be reviewed to ascertain customer acceptance of the new approach and to identify reasons for conversion to the ADDO system among owners. In the absence of any mechanism to discourage increased prices charged to patients, it is possible that ADDOs may negatively impact on **affordability**, although competition, financing for working capital, and improved, locally based, wholesaling services are expected to mitigate any such effect. Appropriate business performance indicators and data availability are under review and will be included in the assessment as available.

Evaluation Design:

The evaluation report will provide:

- A description of the Accredited Drug Dispensing Outlet Model/Program
 - Objectives
 - Model/Program components and roles and responsibilities of the various stakeholders
- A review of the Model/Program approach and implementation process
 - Model/program design and involvement of stakeholders
 - Conversion from DLDBs to ADDO (model/program marketing, micro-financing sources, training, number of facilities converted to ADDOs, number of facility personnel trained, etc.)
 - Supervisory processes designed to maintain standards of service and quality
 - Enablers and constraints to Model/Program implementation

- Measures of ADDO Model/Program impact on:
 - Characteristics of services and products
 - Appropriateness of dispensing
 - Quality of drug products and dispensing services
 - Access dimensions:
 - Availability of essential medicines on site
 - Affordability of products
 - Acceptability/satisfaction (with the ADDO program)
- A discussion of lessons learned and conclusions
- Recommendations/implications for roll-out/practice and/or further research

The review of the implementation approach and process will provide a detailed description of the implementation process. In-depth interviews of project implementers and stakeholders (shop owners, national and local authorities) and review of project records will provide insight on perceived benefits, enablers, and sustainability of the program.

The evaluation of outcomes (for availability, affordability, quality of products and services), will be based on pre-post change analysis for both intervention and control groups along with an analysis of the current status of services at the newly-formed ADDOs. Baseline measures have been collected and will be repeated in a sample of intervention and control DLDBs.

The evaluation of appropriateness of dispensing (product recommendation relative to health problem/diagnosis) will use a pre-post comparison of ADDOs (Ruvuma region) with non-converted DLDBs (Ruvuma) and non-intervention region DLDBs (Singida), for a malaria dispensing scenario, as described above. A post-only comparison of ADDOs (Ruvuma region) with non-converted DLDBs (Ruvuma) and non-intervention region DLDBs (Singida) may be conducted for one additional dispensing scenario. An additional analysis of dispensing practices is being considered that would use a detailed review of ADDO dispensing records. An analysis of business performance indicators will likely be included, and the availability of such data is under review.

Each analysis will be conducted using data from a sample of facilities. The ADDO model was introduced in three districts that were identified as having met pre-requisite criteria for “readiness” in the Ruvuma region (Songea Urban, Songea Rural and Namtumbo districts). As of February 2004 approximately 67 DLDBs have converted to ADDOs, while approximately 20 in the same region have remained DLDBs. Singida Region DLDBs were selected as the control group. The performance of a sample of 50 ADDOs in the Ruvuma region will be compared with (1) up to 20 DLDBs in Ruvuma region that do not adopt the model and (2) 50 DLDBs in comparable districts in Singida region (Iramba, Singida Urban and Singida Rural districts). The comparison groups and sample sizes are summarized in Table 1 below.

Table I. Comparison groups and sample sizes

Intervention Group	# facilities *	Comparison Groups	# facilities *
ADDOS in intervention districts of Ruvuma region (Songea Urban, Songea Rural and Namtumbo districts)	Total #: 67 Sample #: 50	DLDBs in control districts in Singida region, pre- and post-intervention	Total #: ~ 60 Sample #: 50
		DLDBs located in Ruvuma region that did not convert to ADDOs	Total #: up to 20 Sample #: up to 20

* Note: The number of facilities to be surveyed is estimated based on projections of participation as of 1/04

Evaluation Data Collection Techniques: A number of data collection techniques are being employed to track changes, supervise, and to conduct the final assessment of the ADDO program. They are summarized below:

Pre-intervention baseline data collection techniques (data gathered March 2003)

- Facility surveys (key informant interview, facility and stock/shelf inspection/observation),
- Simulated client

Post-intervention data collection techniques (data collection planned for October-December 2004)

- Facility surveys (key informant interview, facility and stock/shelf inspection/observation)
- Simulated Client (baseline data to be used for comparison)
- Review of ADDO transaction/dispensing records (Note: feasibility of electronic processing and analysis of ADDO dispensing records is under review)
- Exit Interviews to measure customer satisfaction among clients

Outcome Measures: The table below describes the outcome indicators that will be applied to evaluate the results of the ADDO program. Each proposed indicator is listed along with the source of the data and the comparison groups.

Service Characteristics & Access Dimensions	Proposed Indicators	Data Source (Instrument)	Baseline	Comparison Design	Comments
<p>Quality of services (Appropriateness of Recommendations)</p>	<p>% encounters where appropriate antimalarial for chloroquine-resistant malaria was sold (alternatively, it could be expressed as % encounters where inappropriate antimalarials were recommended)</p>	<p>Simulated Client (malaria scenario)</p>	<p>March 2003</p>	<p>ADDO group pre-post comparison with:</p> <ul style="list-style-type: none"> • Control region (Singida) DLDBs • Intervention region (Ruvuma) non-converted DLDBs 	<p>Supplementary indicators from baseline:</p> <ul style="list-style-type: none"> • % encounters where patient is prescribed an antimalarial consistent with STGs in sufficient quantities to complete a full course of treatment. • % encounters where attendant asked for more information about the condition presented • % encounters where the attendant refers the client to a to a doctor or clinic
<p>Quality of Services (Appropriateness of Recommendations)</p>	<p>% encounters where an antibiotic was sold for a selected condition</p>	<p>Simulated Client (antibiotic scenario to be determined)</p>	<p>N/A</p>	<p>ADDO group comparison with:</p> <ul style="list-style-type: none"> • Control region (Singida) DLDBs • Intervention region (Ruvuma) non-converted DLDBs 	<p>Alternative indicators:</p> <ul style="list-style-type: none"> • % encounters where an antibiotic was sold for an acute respiratory infection complaint (no pneumonia) • % encounters where an antibiotic was sold for a case of acute diarrhea • % encounters where oral rehydration salts were sold (or recommended) <p>Supplementary indicators:</p> <ul style="list-style-type: none"> • % encounters where attendant asked for more information about the condition presented • % encounters where the attendant refers the client to a to a doctor or clinic

Service Characteristics & Access Dimensions	Proposed Indicators	Data Source (Instrument)	Baseline	Comparison Design	Comments
<p>Quality of Services (Dispensing Communications)</p>	<p>% encounters where attendant provided instruction to patient/caregiver on how to take/give medication</p>	<p>Simulated Client</p>	<p>March 2003 (only for malaria scenario)</p>	<p>For malaria scenario: ADDO group pre-post comparison with:</p> <ul style="list-style-type: none"> • Control region (Singida) DLDBs • Intervention region (Ruvuma) non-converted DLDBs <p>For other scenario: ADDO group comparison with:</p> <ul style="list-style-type: none"> • Control region (Singida) DLDBs • Intervention region (Ruvuma) non-converted DLDBs 	<p>Supplementary indicator:</p> <ul style="list-style-type: none"> • % encounters where attendant gave information on possible problems with medications (danger signs)
<p>Quality of Products</p>	<p>% of items sampled that are registered with the TFDA</p>	<p>List of Products Sold form</p>	<p>March 2003</p>	<p>ADDO group pre-post comparison with:</p> <ul style="list-style-type: none"> • Control region (Singida) DLDBs • Intervention region (Ruvuma) non-converted DLDBs 	<p>For ADDOs and DLDBs this would be the indicator for product quality. Data on performance of TFDA product quality initiative will supplement product quality assessment (relative to antimalarials and other priority pharmaceuticals targeted under the inspection, sampling and TLC testing activities).</p>

Service Characteristics & Access Dimensions	Proposed Indicators	Data Source (Instrument)	Baseline	Comparison Design	Comments
Affordability	Average % difference in price to patients between ADDOs and DLDBs, for a set of tracer items	Survey: Availability/ Price sheet	March 2003	ADDO group pre-post comparison with: <ul style="list-style-type: none"> • Control region (Singida) DLDBs • Intervention region (Ruvuma) non-converted DLDBs 	Alternative indicator: <ul style="list-style-type: none"> • Average difference in price between the comparison groups, post-only. Complementary indicator: <ul style="list-style-type: none"> • Average # of hours (or days) worked to pay for standard course of selected essential medicines (using lowest government monthly salary and the monthly average per capita income in Ruvuma and Singida)
Availability	% of a set of tracer items in stock	Facility survey – Inventory	March 2003	ADDO group pre-post comparison with: <ul style="list-style-type: none"> • Control region (Singida) DLDBs • Intervention region (Ruvuma) non-converted DLDBs 	Supplementary indicator: <ul style="list-style-type: none"> • % tracer item-months in which tracer items were dispensed (From ADDO dispensing registers only. Note that if drug was not dispensed, it does not necessarily indicate that it was not in stock.)
Acceptability/ Satisfaction	% of customers who express satisfaction with service	Client exit interview	N/A	ADDO group comparison with: <ul style="list-style-type: none"> • Control region (Singida) DLDBs • Intervention region (Ruvuma) non-converted DLDBs 	To ascertain customer perception of service based on fulfillment of pre-determined criteria.