CHAPTER 32

Drug seller initiatives

SUMMARY

Retail drug shops tend to constitute the largest group of recognized outlets for medicines in developing countries, and they are often seen as playing an important role in the community's health. Typically, however, drug sellers are untrained, regulations of shops are unenforced, and the quality of pharmaceuticals that shops sell is not assured.

Systematically improving the services and products offered by drug shops can significantly contribute to national and regional goals for improving public health. If drug shops have legal access to quality pharmaceuticals and well-trained dispensers, and regulatory standards are enforced, shops can help improve access to and appropriate use of medicines and other health care–related products to treat common conditions, particularly among underserved populations.

To develop a program that improves retail drug shops and their operations, an integrated approach is needed that is supported by national and local authorities as well as shop personnel. Certain components are also needed to establish shop standards, ensure pharmaceutical and service quality, improve the availability of essential medications, and establish mechanisms for monitoring adherence to program standards.

An integrated approach to improving retail drug shops using the accreditation model would typically include—

- Development of regulatory standards defining requirements for shop premises, personnel, and dispensing practices
- Training in dispensing and the medicines used for commonly presented medical conditions; continuing education for shop personnel to improve customer service and appropriate medicine use
- A list of essential medicines that can be dispensed legally by an appropriately trained drug seller, along with strict adherence to the standards, established with input from stakeholders, for the quality and types of medicines that are permitted to be stocked
- Incentives such as business training for owners
- Access to loans for improvement of shop premises and expanded inventory
- Establishment of record-keeping systems to allow shop owners to monitor sales, inventory, costs, and profits
- Improved monitoring and supervision mechanisms, including self-monitoring, and regular shop inspections by authorities for regulatory enforcement
- Consumer education to promote the appropriate use of medicines and public demand for quality medicines and competent services from recognized shops

Any approach to strengthen the quality of services offered at retail drug shops must focus on providing safe, affordable, appropriate, and effective pharmaceuticals to populations in need.

A website (http://www.drugsellerinitiatives.org) shares experiences and tools from drug seller initiatives to provide a resource for those in any country with an interest in improving access to quality pharmaceutical services and products provided by drug sellers.

32.1 Popularity of retail drug sellers in developing countries

Most people in developing countries get their medicines from retail drug sellers, which are often the most convenient source—for example, in Ghana, the chemical seller shop; in Uganda, the Class C drug shop; in Tanzania, *duka la dawa baridi* (DLDB). Although pharmacies in developing countries may have strong professional identities and well-trained staff to sell prescription medications, both pharmacies and trained pharmacy personnel are limited in number. Retail drug shops, in contrast, tend to be more numerous. They typically constitute the country's largest group of recognized (although historically unaccredited and often unregulated) outlets for nonprescription medicines. 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.

As small businesses, retail drug shops spring up to meet illness-related needs in their communities, providing over-the-counter medicines and other popular items. For example, caretakers often treat children at home, and retail drug sellers may be their only contact regarding their children's health (Gyapong and Garshong 2007). A review of literature looking at the role of drug sellers in Africa reported that the use of retail drug outlets during child illnesses ranged from 15 to 83 percent, with a median around 50 percent, and that caretakers used retail outlets even when cheaper alternatives existed, such as village health workers (Goodman et al. 2007).

32.2 Problems with retail drug shops

A problem with having retail drug sellers deliver health care is that they are often untrained, and therefore, customers are not counseled on or sold the proper medicines or dosages to treat common ailments. In addition, these shops frequently sell prescription medications that should be legally distributed only by licensed health centers or pharmacies. Not only is this practice unlawful, but it also likely results in incorrectly or inappropriately stored and dispensed medicines. As a result, consumers may receive medicines that are ineffective or dangerous for their condition. A 2001 assessment of Tanzania (CPM 2003b) found that few dispensers at DLDB dispensed malaria treatment according to guidelines, and other studies have found similar results (for example, Abuya et al. 2007).

Although governments recognize these dangers to public health, actions to shut down or punitively regulate retail drug shops have been almost universally unsuccessful. Most drug shops are seen as playing an indispensable role in their community's health system, especially in areas without licensed pharmacies. An increase in the number of drug sellers who legally dispense common medicines in an appropriate way would have the potential to help many people in many countries.

Overall, estimating precisely how many people could benefit from improving the quality of products and services through enhanced retail drug seller interventions is difficult; however, retail drug outlets are clearly far more accessible to populations in need than pharmacies or public health facilities. Country assessments (CPM 2003a, 2003b) estimated that Tanzania had more DLDB than all other health facilities—public and private—combined (4,627, compared with 4,288); Ghana had almost 1,000 pharmacies, located almost exclusively in urban areas, with almost 8,000 registered chemical sellers and possibly 2,000 more that were unregistered. A 2008 analysis of the pharmaceutical sector in Uganda estimated that the country had nearly 4,000 Class C drug shops (EADSI 2008). This scenario is common in many developing countries, and it illustrates the potentially broad effect of improving the quality of products and services in retail drug outlets and the huge impact closure of these shops would have on access to medicines.

Systematically improving the services and products offered by drug shops can contribute significantly to national and regional goals for improving public health. If drug shops can legally sell selected prescription medicines and have access to quality pharmaceuticals and better trained dispensers, and if regulatory standards are in place and enforced, then shops can improve access to and appropriate use of medicines and other health care–related products, particularly among underserved populations.

32.3 Strengthening the role of retail drug shops

Health managers, drug regulators, or policy makers who would like to expand access to quality pharmaceuticals should consider what role retail drug shops can play in the population. Licensed pharmacies need not be the only acceptable alternatives for improving access to and rational use of medicines. Although retail drug shops are often unregulated, consumers with longstanding habits of buying from these shops will continue to turn to them, even when such consumers have other choices to access medicines.

Taking a course of action and encouraging participation

Any approach to strengthen the quality of services offered at retail drug shops must focus on providing safe, affordable, appropriate, and effective pharmaceuticals to populations in need. The program must establish standards and requirements related to physical premises and operations before existing shops can be upgraded or new shops opened. Community-level input will help determine how to develop a drug shop initiative that best fits the specific context.

An integrated program to establish retail drug shops as a source for quality medicines must work with current drug shop owners to improve or upgrade existing retail drug shops. Consider the number of drug retail shops in the area and the quality of the services they offer, and explore incentives that may motivate existing owners to participate in a program. Many owners favorably perceive opportunities for developing new business and improving the quality of services. In addition, observing the successful conversion of an existing shop provides a powerful incentive for owners to join in. In a drug seller accreditation program in Tanzania, every DLDB owner in the pilot region of Ruvuma participated in the conversion process.

Relying on single-focus interventions for improving drug shops

Efforts to improve retail drug shops and increase access to quality medicines often rely on single-focus interventions. For example, some programs may try to improve access by educating people who dispense medicines. Others could focus on improving owners' management practices, strengthening regulations or regulatory agencies, or using social marketing for particular products. Some examples of the successes and limits of each type of intervention follow.

Educating dispensers. Educational interventions have trained dispensers to improve their knowledge and skills so they can provide appropriate treatment. Yet many factors

other than knowledge guide dispensers in the private sector (for instance, the desire to make a profit from selling drugs). To improve their effectiveness, some educational interventions have used persuasive face-to-face discussions that focus on particular problem behaviors in interactions between dispensers and consumers, such as unclear messages about when to stop taking a medicine. Some interventions have successfully included peer group discussions to educate participants on standards set by regulatory bodies or professional societies. Country Study 32-1 describes some drug seller education approaches and results in Africa.

Establishing regulations. Regulatory interventions may attempt to ban shops from selling prescription medicines without legally approved prescription authority. These efforts can prove counterproductive, especially in communities where unauthorized or unregulated shops pro-

Country Study 32-1
Retail drug seller education approaches and results in sub-Saharan Africa

Kenya

Approach: Conducting workshop training for groups of drug retailers combined with community information activities in rural Kenya. The initial drug seller training lasted four days, with annual one-day refresher workshops over the following years. Successful sellers were awarded certificates of satisfactory training in public ceremonies, and posters were displayed outside their shops showing that they had been accredited by the Ministry of Health. Public information activities to create awareness of the program focused on identifying trained retailers and giving information on the importance of early effective treatment for malaria in children, changes in malaria treatment policy, and situations for referrals. Trainers attended public gatherings (women's groups, school groups, and so on), handed out posters, and showed the program logo; local dance and drama groups conveyed program messages.

Results: The proportion of over-the-counter antimalarial medicines sold in an adequate dose rose from 8 percent to 64 percent in the intervention areas. In addition, the proportion of shop-treated childhood fevers receiving an adequate dose of a recommended antimalarial within twenty-four hours rose from 1 percent to 28 percent.

Approach: Training and equipping pharmaceutical wholesalers, both mobile drug vendors and wholesale counter attendants, to serve as volunteer outreach educators of new malaria guidelines to their drug retailer clients during normal business interactions ("vendor-to-vendor"). Components of the program included a shopkeeper job aid for a retailer to consult when selling antimalarial medicines; a client awareness poster to hang near the entrance of the outlet to generate consumer demand for the five approved brands of sulfadoxine-pyrimethamine (SP) and to communicate that SP was now available over the counter; orientation of wholesale owners; training and equipping of mobile vendors and wholesale counter attendants; and monitoring. Each wholesaler trainee received a receipt book to record the names of the recipients of posters and to obtain their agreement to comply with the new guidelines. At the end of the training, all wholesalers received caps and shirts with the malaria dosage chart on the front.

Results: During the first six months, approximately 450–500 private drug outlets were reached. The intervention affected stocking patterns, malaria knowledge, and prescribing practices of shops and kiosks significantly, but not consistently for other types of outlets. About 32 percent of shops receiving job aids prescribed the approved first-line treatment, SP, compared to 3 percent of the control shops.

Nigeria and Uganda

Approach: The Basic Support for Institutionalizing Child Survival project designed an intervention in Nigeria that combined a short, highly focused training for patent medicine vendors with the promotion of age-specific, color-coded, prepackaged antimalarials for children under five. These activities were supported by a comprehensive social marketing and behavior change strategy, which included mass media promoting the new prepackaged antimalarials and display of shop identifiers from the training by patent medicine vendors. More than 800 medicine vendors were trained in a two-month period at the relatively low cost of about 8 U.S. dollars each. Training materials focused on immediate treatment of children under five with fever, using an appropriate dose (preferably prepackaged) of an antimalarial.

Results: Examples of postintervention assessment results showed that the number of patent medicine vendors giving the correct antimalarial and dose increased from 9 percent to 53 percent after the intervention. Also, knowledge of patent medicine vendors about the need to use insecticide-treated nets tripled (21 percent to 65 percent) between pre- and postintervention surveys.

Sources: Marsh et al. 2004; Tavrow, Shabahang, and Makama 2003; Greer et al. 2004.

vide the only available access to medicines. National or regional authorities can unilaterally introduce regulations, but enforcement may be sporadic, in part because limited resources often keep regulatory efforts from being consistent or sustainable.

Program managers need a balanced approach to developing regulations that will maintain consistent, reliable, and verifiable quality services. Program managers can create incentives that encourage shop owners to abide by regulations while making sure the owners understand what will happen if they do not comply.

Social marketing. Social marketing of condoms, contraceptives, and bed nets often uses techniques such as advertising campaigns to introduce new products through retail drug shops. For example, interventions have been used to help prevent the transmission of HIV by promoting the use of condoms and to help prevent malaria infection by encouraging the use of bed nets.

Although frequently implemented, single-focus interventions typically are less effective than programs that weave together multiple interventions as part of an integrated, holistic approach (Shah, Brieger, and Peters 2011).

32.4 Improving drug shops through an integrated approach

To develop a program that improves retail drug shops, an integrated approach that is supported by national and local authorities as well as shop personnel is needed. The program can include the proven single-focus practices that are consistent with the goals and resources available. Certain components are also needed to establish shop standards, ensure pharmaceutical and service quality, improve the availability of essential medications, and establish mechanisms for monitoring adherence to program standards.

Identifying the components of an effective integrated approach

An integrated approach to improving retail drug shops would typically include—

- Development of regulatory standards defining requirements for shop premises and dispensing practice
- Training in dispensing and the medicines used for commonly presented medical conditions; continuing education for shop personnel to improve customer service and appropriate drug use
- A list of essential medicines that can be legally dispensed by an appropriately trained drug seller, along with strict adherence to the standards, established with input from stakeholders, for the quality and types of medicines that are permitted to be stocked
- Incentives such as business training for owners to improve business practices, inventory control, marketing, and profitability
- Access to loans for improving shop premises and expanding inventory
- Availability of and training on the use of forms to help ensure accurate record keeping to allow shop owners to monitor sales, inventory, costs, and profits
- Improved monitoring and supervision mechanisms, including self-monitoring, and regular shop inspections by authorities for regulatory enforcement
- Consumer education to promote the appropriate use of medicines and public demand for quality medicines and competent services from recognized shops

National versus program standards

Many countries use a national drug regulatory authority or the ministry of health to establish national standards for essential medicine lists, treatment guidelines, and appropriate medicine use. If standards for pharmaceutical premises exist in a country, they should define the minimum required to operate a drug shop under the law. A national effort to strengthen drug shops and sellers to ensure expanded provision of quality products and services to the community would require review and revision of existing laws and regulations. For example, an accredited drug seller initiative might require new standards for training and shop premises that would have to be met and that would be enforced. Failure of a drug shop to comply would result in loss of accreditation or shop closure.

Individual shop owners or franchisees of shops can go beyond the minimum level required by law and regulations to set their operations and services apart from the competition. Individual or franchise standards, however, need to be consistent with existing national standards.

Stakeholder engagement

An integrated approach should include engagement not only with drug shop owners, dispensers, consumers, and health care providers, but also with other stakeholders concerned with public health issues, such as local government officials. Stakeholders need to work together to find ways to make drug shops and sellers effective and reliable partners in national health care delivery efforts. A successful program should seek to change the behaviors and expectations of individuals and groups that use, own, work in, or regulate drug shops.

Best practices

An integrated approach needs to encourage owners and dispensers to apply the following best practices.

Country Study 32-2
The drug shop accreditation process in Tanzania

The following example describes an integrated accreditation approach, adopted by a food and drug authority and ministry of health, that has improved retail drug shops and enhanced the availability and quality of the medicines that these shops sell.

The Tanzania Food and Drugs Authority (TFDA) had a plan to license nonpharmacy drug shops to improve public access to basic over-the-counter drugs in areas with few registered pharmacies. However, the drugs authority lacked the human and financial resources to make the plan succeed. Many drug shops, known as *duka la dawa baridi,* sold prescription drugs illegally; their dispensing staff often lacked basic dispensing training; and many operated without valid licenses from authorities.

Assessment of DLDBs

The Ministry of Health and Social Welfare assessed the DLDB in 2001 with assistance from the Strategies for Enhancing Access to Medicines (SEAM) Program (CPM 2003b) and found that the DLDB prices tended to be higher than those in all other outlets. Drugs in stock were frequently unregistered or purchased from unlicensed suppliers, so quality could not be assured. Many DLDB owners purchased illegal stock, including pharmaceuticals diverted from the public sectors of Tanzania and neighboring countries. Nonetheless, DLDB flourished. They were convenient, registered pharmacies were absent, and public health centers had stockout rates of 20 to 30 percent.

New approach

The TFDA and Ministry of Health and Social Welfare decided to explore new approaches to improve access to affordable, quality pharmaceuticals and services in rural or periurban areas. A pilot program, developed in collaboration with the SEAM Program, aimed at establishing a regulated system of accredited drug-dispensing outlets (ADDOs) to provide a limited list of essential prescription medicines in addition to nonprescription medications and other health supplies. The list of prescription medicines they could sell was based on the medicines authorized for public primary health care facilities.

The program formulated an integrated approach for the ADDOs to—

- Improve shop premises to provide better customer service and to ensure adequate storage and security for the expanded list of medicines approved for sale
- Help ensure access to financial resources, if needed, to improve shop premises and increase inventory
- Train dispensers in good dispensing practices, treatment guidelines, communication skills, and quality control
- Provide training in business skills, regulations, and business ethics for shop owners and dispensers
- Strengthen the ward, district, and regional systems under which all the drug shops operate, which include systems for processing accreditation applications, scheduling regular inspections, and reporting to TFDA

Use of formative research

Before any ADDOs opened, the program conducted research among consumers, shop owners, shop staff, community leaders, health care providers, and political authorities.

For owners—

- Provide quality medicines at affordable prices that are appropriate to local market needs.
- Meet all premises standards required, including maintenance of adequate storage facilities.
- Hire licensed, trained, and skilled dispensers (or work in the shop yourself as a licensed, trained, and skilled dispenser).
- Facilitate access to refresher training to upgrade dispensers' skills.
- Maintain accurate records of pharmaceuticals, financial transactions, patient information, and other useful data.
- Meet all regulatory, accrediting, and licensing standards and fulfill reporting obligations.
- Meet ethical standards and responsibilities.
- Work to ensure that essential, quality medicines are available at all times.

For dispensers—

- Listen to the customer's request, and serve or advise him or her appropriately, following established protocols.
- Provide appropriate information or advice about the medicines dispensed or, if needed, referral to a clinic for needed care.

The results indicated almost unanimous concern about the quality and origin of drugs sold by the DLDBs. All stakeholders wanted trained dispensers who could provide quality medications at reasonable prices. However, the owners preferred limited regulation by the government.

SEAM sponsored formal and informal discussions and consultations to foster broad support for the ADDO program strategy as well as ownership and partnership in the change process. Based on research and discussions, the final ADDO components balanced program objectives with measures to encourage DLDB owners' participation.

ADDO program components for standards and incentives

Component	Process or requirements
Accreditation application process	A Council Food and Drugs Committee is responsible for a four-part application process for shops: an application form, initial inspection of the existing facility, reinspection after any structural changes required for accreditation, and ongoing inspection after accreditation.
Incentives for owners	Owner incentives focus on improved shop profitability and approval to sell a range of prescription medications. Incentives for owners who commit to standards include access to microfinancing for stock purchases, a marketing campaign encouraging consumers to buy ADDO-provided products and services, and more reliable sources of affordable, quality wholesale pharmaceuticals.
Building/infrastructure	The standards provide instructions for premises, layout, identification, dispensing and services areas, storage, and security.
Staff qualifications	The minimum entry-level training for ADDO dispenser candidates is currently that of a nurse assistant, with plans to expand the qualifications to any secondary school graduate.
Medicine quality	The list of products approved for sale by ADDOs includes the full range of over-the-counter medicines and a limited list of prescription medicines, including common antibiotics and oral contraceptives. ADDOs may sell only those products registered with and approved by the TFDA.
Training and continuing education	All dispensers must be accredited by the TFDA, display their accreditation certificate at their place of employment, and wear their photo identification when working. Accreditation involves completing a TFDA-approved, module-based dispensers' course. Training topics include information on medicines that are authorized to be dispensed by ADDOs; symptoms of commonly encountered medical conditions and protocols for handling patients presenting with symptoms, including referral, when needed; treatment dosages, side effects, and patient information; laws governing dispensers' work; basic business management, record keeping, and ethics; and communication skills. Continuing education is a part of maintaining dispenser accreditation. Training for ADDO shop owners focuses on ethics, regulations, and improvement of business management skills.
Record keeping	ADDOs must account for all prescription drugs sold and their selling prices, financial and sales records, and expired medications. These records may be used for supervision purposes and must be available for review by inspectors.
Regulation, inspection, and sanctions	Local government officials receive a basic inspection training course from the TFDA and are certified as local TFDA inspectors. TFDA conducts a minimum of two inspections of each shop per year, and local inspectors inspect quarterly.
ADDO-restricted wholesalers	Approved wholesalers can receive a license to sell nonprescription and ADDO-approved prescription drugs under the supervision of a full-time pharmaceutical technician.

- Provide appropriate information or advice for self-care if a medicine is not required or recommended.
- Appropriately promote associated products or services connected to the customer's needs (for example, recommend insecticide-treated nets to families at risk of malaria).
- Refer customers to a qualified health provider for services beyond the scope of the shop.
- Communicate effectively with customers who demand inappropriate services or medicines by being firm and providing explanations as to why the service or product should not be used.
- Maintain a customer-oriented attitude that meets ethical standards and responsibilities.

32.5 Borrowing from accreditation and franchising

How can shop owners be encouraged to adopt best practices and cooperate with an improvement program? Accreditation and franchising can offer shop owners some positive incentives. Within the community context, consider elements from these approaches and incorporate the elements that best fit into the program.

Accreditation

Accreditation of drug shops includes certifying or licensing dispensers, identifying shops as members of a group that

meets accreditation standards, and monitoring their ongoing adherence to standards. Accredited shops may become more acceptable to consumers than nonaccredited shops, but acceptance should be encouraged with a marketing campaign to inform consumers which shops are accredited and why this is important to them.

For example, the Tanzania Food and Drugs Authority (TFDA) and the Ministry of Health and Social Welfare developed a pilot program to establish a regulated system of licensed retail drug outlets, known as accredited drug-dispensing outlets (ADDOs), which has now been scaled up nationwide. The government accredits ADDOs to provide an expanded selection of drugs, including some prescription medicines, and other supplies. The program has provided ADDOs with links to organizations and agencies that provide financial support and reliable access to sources of quality wholesale goods. Country Study 32-2 describes this example in more detail.

Franchising

Franchising encourages existing or potential shop owners to invest in shops to meet franchise standards as well as government licensing criteria. Shop owners gain the right to operate under the franchise name as long as they meet and maintain the franchise standards. Box 32-1 describes how a franchise program works.

In Ghana, a for-profit group established the CAREshop® franchise, which sets its own standards in addition to meeting government licensure and operational requirements. The franchisor provided franchisee training and supervision and negotiated with suppliers for quality medicines at competitive prices. Table 32-1 summarizes the CAREshop franchise standards; note that the CAREshop franchise is no longer active, although individual shops remain in operation.

In Kenya, a nongovernmental organization called the HealthStore Foundation® developed a drug shop and clinic franchise. It consists of a network of Child and Family Wellness Shops (CFWshops™) and clinics, which are owned and managed by Kenyan community health workers and nurses. The franchisor provides franchisees with training, supervision, and access to microcredit. The franchisor also procures quality, essential pharmaceuticals for resale to franchisees at affordable prices. Country Study 32-3 describes the program in more detail.

How accreditation differs from franchising

Accreditation and franchising are not mutually exclusive. Governments can establish accreditation programs to reach

Box 32-1
How a franchise program works

Requirements

Franchising programs for drug shops operate within government pharmaceutical standards and regulations, under the authority of the ministry of health and other agencies charged with licensing and overseeing legal requirements for health care facilities and products. In addition, all franchising programs require—

- Commitment to performance standards that have been agreed upon and established so customers find quality pharmaceuticals and services in every shop
- Compliance with established standards, with monitoring through a system that reviews adherence and gradually increases self-regulation, which the franchisor verifies through periodic checks
- Fees for entering into the franchise and for remaining a member

Benefits to shop owners

In return for participation and fees, the franchisor provides benefits to owners and staff, including—

- Training, both initial and ongoing, for drug shop workers, supervisors, and owners
- Access to competitively priced quality drugs and health care supplies on a consistent basis
- Incentives such as business plans and franchisor backing that facilitates access to microfinancing and loans at market rates
- Designation as a franchise member
- Marketing of program standards and identity (brand marketing) that distinguish the quality of franchisee-provided medicines and services from those offered by competitors
- Opportunities for making a profit that is maintained or enhanced through ongoing participation and compliance

Benefits to consumers

Well-organized franchises of drug shops can benefit the public, particularly in underserved communities. Customers receive—

- Improved pharmaceutical services and steady supplies of medicine
- Quality, essential medicines at competitive prices

Table 32-1 Ghana CAREshop franchise standards and benefits

Operational area	Requirements	Benefits
Standards implemented by the shop owners in the franchise		
Building/infrastructure	• Paint exterior using the approved colors • Provide interior shelving and ventilation • Adhere to the cleanliness standards	• Franchise identification • Better customer service • Improved quality of services
Medicines in stock	• Procure only those drugs provided by the franchisor in compliance with the Pharmacy Council's approved list and have them delivered to the door	• Reduced cost of inventory • Assured availability of products
Minimum staff qualifications	• Meet all Pharmacy Council license requirements	• Better customer service • Improved rational drug use • Better pharmaceutical practices
Training and continuing education	• Complete a franchise training course in business, disease recognition, and record keeping • Participate in continuing education to maintain participation in the franchise	• Improved customer service • Improved rational drug use • Enhanced sustainability • New disease-related data for the ministry of health • Better business practices and improved services
Record keeping	• Keep standardized inventory, sales, and customer request records to track shop performance and create community health profiles	• Decreased stockouts of needed medicines • Improved profitability • Improved planning and decision making by the ministry of health
Standards implemented by the franchisor		
Medicine availability and quality	• Conduct quantification and tendering with suppliers on behalf of all shops • Buy only government-approved products from reliable sources	• Quality products at a competitive price • Consistent availability of drugs • Enhanced profitability
Supervision and inspection	• Supervise and inspect the shops to maintain the quality of services and ensure compliance to franchise standards	• Provision of quality care and products • Identification of problem areas • Improvement of performance

targeted areas underserved by pharmacies, while the private or nongovernmental organization sector can establish a franchising network for new or improved retail drug shops. In this way, both approaches can help fulfill the public health goals of access to and rational use of affordable, quality medicines.

Accreditation has many of the same requirements and benefits that franchising has, but with some important differences. Unlike franchisee shops, accredited shops generally remain small, independent businesses. They do not pay fees to a franchisor, nor do they receive the benefits of being part of a larger franchise system. The franchisor generally provides training and training updates to shops belonging to a franchise, whereas training for nonfranchise shop owners and dispensers to meet accreditation standards would have to come from outside organizations such as schools of pharmacy and regional training centers that offer routine, planned courses. Some franchise shops may seek additional training from outside agencies to address specific needs. Training agency courses typically are certified by an appropriate authority, and students pay course fees either directly or indirectly through their employer.

32.6 Taking steps to improve retail drug shops

A successful, integrated program requires that stakeholders' needs, interests, and expectations be taken into account. Typical stakeholders for drug shop accreditation or franchising programs include consumers, shop owners, shop dispensers, community leaders, health care leaders, and political and civic leaders. The availability of funding, partnerships, training, communications, and other resources must be determined. This section outlines the major steps involved in developing an improvement program including identifying stakeholder needs, expectations, and potential roles and formulating appropriate program components for the context.

Use formative research

As a first step, conduct research to gather local data for program planning and implementation. Formative research, which engages stakeholders through focus group discussions or other qualitative methods, can help gather information from stakeholders while involving them in the change process from the start. Failing to learn about stakeholder

Country Study 32-3
Improving pharmaceutical access and quality using franchising in Kenya

The majority of Kenyans living in rural areas get their basic essential medicines from shopkeepers in nearby markets. The Bamako Initiative established village pharmacies run by community health workers (CHWs) in certain districts. The high attrition rate in CHWs has been attributed to the difficulties they have in maintaining their activities without external support, including lack of sustained supervision or continuing education and the high cost of medicines they must purchase at wholesale pharmacies.

The Sustainable Healthcare Enterprise Foundation (now the HealthStore Foundation) established the Child and Family Wellness Shops (CFWshops™) in Kenya to engage CHWs and nurses working in their rural communities to provide access to essential health care commodities and services in a sustainable manner. The network targets the five to ten diseases causing 70 to 90 percent of morbidity and mortality among children and their families, while also providing basic health services and other products. It combines microenterprise and franchise principles to enable qualified CHWs and nurses to own and operate drug shops and medical clinics in underserved areas.

The franchise system provides standardized training in business and franchise management, medicine and client services management, and public health interventions in the community, including child survival interventions for malaria and acute respiratory infection. The franchisees receive a microloan that covers the costs of four-week training, initial pharmaceutical stock, and equipment and shop infrastructure. Once trained, the franchisees run drug shops or clinics in easily accessible market centers and receive ongoing supervision and mentoring support from field-based supervisors employed by the CFWshops organization. The franchisees are required to purchase their pharmaceutical supplies through the HealthStore Foundation to ensure quality and to adhere to franchise rules for service delivery. The franchisees are licensed by the Kenyan Ministry of Health and also receive continuing education from the HealthStore Foundation to adhere to national treatment guidelines.

The first eleven shops opened in April 2000, and by 2010, 76 shops had opened and served almost 500,000 patients that year. In 2003, the HealthStore Foundation added its first medical clinic to the network of CFWshops. The clinics are franchised like the drug shops but are owned and operated by nurses who can supply a wider range of medicines and health services than provided by the drug shops.

The franchised outlets provide their communities with a reliable source of quality-assured essential medicines, delivered by a trained health worker who adheres to certain standards of service prescribed by the franchise agreement. The franchisee runs a for-profit enterprise on a full-time basis, which provides him or her with an income that ensures sustainability of the initiative. Ongoing supervision support and continuing education also contribute to the sustainability of the venture.

See http://www.healthstore.org for more information.

interests not only can discourage stakeholder interest in joining or collaborating with the program, but also can handicap understanding of what is going to be required to make the program work and ultimately undermine adherence to any new or existing standards.

The keys to formative research are keeping an open mind and using good listening and recording skills to gather data. Formative research is a two-way street: learning from stakeholders while involving them in the improvement process. Stakeholders may be engaged several times during the research and planning process. A sample formative research process includes—

- Interviewing a few key individuals to learn their points of view
- Presenting preliminary ideas to small focus groups of stakeholders to hear what they think of your initial program proposal
- Developing broad stakeholder commitment to improvements by sharing the program design and implementation process through dissemination workshops

Focus group discussions are particularly effective for gathering information from stakeholders while at the same time raising awareness about health and related issues, such as licensing drug shops. A focus group typically brings together a group of five to twelve people who have something in common, for example, groups of consumers, pharmaceutical professionals, or new mothers. Information from

focus group discussions can provide the basis for designing improved systems to meet as many different expectations as possible and developing communications and marketing plans to educate stakeholders and promote consumers' use of improved shops.

Establish key components with stakeholders

The second step of the design phase involves exploring with stakeholders the key components of the program, such as drug shop standards, incentives for shop owners, and ways to monitor and supervise drug shops' quality.

Every shop improvement program needs to establish standards in the following areas—

- Building/infrastructure
- Essential medicines lists
- Product quality
- Staff qualifications
- Training and continuing education
- Record keeping
- Regulation and inspection

Building/infrastructure. All participating retail drug shops in accreditation and franchising enterprises should arrange for the prominent display of signs and the logo of the enterprise. Some programs require owners to paint their shops with specific colors. Standards for the shops' interior and storage areas must include level of cleanliness and specifications for shelving, counters, and other physical requirements.

Essential medicines lists. National health authorities usually have an established list of essential medicines for primary health care centers, which can form the basis for a program list. If shops are to stock an expanded list of medicines, such as common antibiotics, close work with public health and regulatory authorities will be necessary to meet their regulations and standards and change the regulation, if necessary. For example, the program may need to train retail drug shop dispensers in the rational use of medicines and treatments for common illnesses and regularly supervise and monitor dispensers' performance to meet standards to dispense certain medicines. An understanding of how essential medicines are distributed is also required. In addition to keeping accurate records on essential medicines, the program should get a baseline estimate of how many and what types of unregistered health products are being sold.

Product quality. All programs require participating shops to purchase their medicines and supplies from approved sources of supply. Franchisees must purchase from the franchisor, while accredited shops need to purchase from licensed wholesalers. Programs should provide owners and dispensers with training in pharmaceutical procurement and inventory management. Adhering to program standards and training is very important.

Staff qualifications. Although the ideal dispensers at retail drug shops are trained pharmacy providers, the program will need to consider local labor markets and other factors. Different programs may adopt various minimum certification requirements for dispensers that depend on their education, in-service training, the drugs they will dispense, and the level of skills that are generally available in the labor market. For example, in Tanzania, because of the shortage of pharmaceutical personnel, ADDO dispensers are required to be trained nurse assistants at a minimum. The program may want certification by a recognized board or authority. Most accredited programs insist that all dispensers display their accreditation certificate at work and may require them to wear identification cards with photographs.

Training and continuing education. Improvement programs need to provide training for both dispensers and owners. Data from focus group discussions can help develop training and continuing education programs that will encourage owners to join the program and improve their services and profitability. A professional organization, such as a school of pharmacy, or a regional training center may provide training. Programs ideally provide periodic continuing education and require participation for reaccreditation or ongoing franchising approval. Some programs tie continuing education topics and requirements to the results of supervisory visits.

Conveying good business practices to shop owners as well as what sort of price markups are commonly applied throughout the distribution system, from wholesalers to products for sale to consumers, is helpful. A simple price survey can compile pricing data.

Record keeping. Standards should include a record of drugs sold, with an emphasis on prescription medicines. Other data collected may include basic demographic information about customers, expired medicines, and medicine purchase and sale prices. Programs generally use standardized forms for recording all required information and train owners and dispensers in filling them out.

Regulation and inspection. Designing and implementing regular supervision and inspection helps motivate owners and dispensers to maintain the required standards, ensures a consistent level of quality across the network, and inspires customer loyalty. Inspection needs to cover all drug shops, not just accredited shops, to prevent nonaccredited shops from selling prescription medicines and undermining the incentive for accredited shops to maintain standards. All owners need to know that they will be inspected regularly and that they will suffer sanctions for violations.

Incentives. In a comprehensive program, a balance is necessary between standards, with which shop owners must comply, and incentives, which can motivate drug shop

owners to participate in an improvement program, whether for accreditation or as part of a franchise. Make these incentives clear when recruiting owners to join the program.

Financial management. The most powerful retail incentives for shop owners are those that improve profitability, give the shops a competitive edge, and are exclusive to the shops. Shop owners can benefit from a more complete understanding of distribution systems and pricing methods. They also need to know the financial dimensions of related incentives, including—

- Legal approval to sell a range of prescription drugs
- Training for owners and dispensers
- Access to financing to purchase stock or implement building improvements
- A marketing campaign that promotes brand recognition and encourages consumers to buy drugs from network shops
- Access to convenient and reasonably priced wholesale services
- Reassessment of taxes and license fees, combined with fair and even-handed enforcement and collection, to accurately reflect shop revenue

Business ethics. Fulfilling a community social mission may motivate some owners. They may find that owning a business that provides a valuable service to the local population can give them status and a sense of personal satisfaction. Formative research will indicate whether this type of incentive will attract potential participants to the network. Over the long term, however, shop owners will remain in the network only if the financial benefits of participating are greater than the perceived costs. If their participation increases sales, customer volume, and technical skills while improving access to quality medicines without significantly increasing medicine costs, then the owners will be more likely to continue their participation.

Monitoring and supervision. Monitoring the performance of the drug shops participating in the network may be the most important supporting element of the program. It can foster a consistent level of excellence in the products and services at each shop. Monitoring or supervision activities that reinforce tangible improvement and practical training are less likely to be perceived by owners as burdensome or intrusive. Monitoring and supervision efforts in which inspectors, owners, and dispensers work together to identify problems and find solutions are more effective than efforts focused exclusively on identifying errors or noncompliance. At an accredited drug shop in Uganda, the drug seller said, "We used to run away from the inspectors because they used to come and close our shops and remove the medicines that we were not supposed to have. . . . Now that the National Drug Authority allows us to have antibiotics and other medicines, we don't keep these medicines hidden away or run from the inspectors like we used to do."

Marketing and communications

The last major step for developing the program requires planning ongoing communication with stakeholders, including shop owners and customers, who can help market the program and educate consumers. The program needs to motivate shop owners to join, to maintain established standards, and to monitor their own performance. Local monitors of the Accredited Drug Shop program in Uganda reported that owners and sellers in accredited shops were now watching out for and reporting unlicensed shops to authorities. The program also needs to motivate consumers to recognize the program's quality brand and purchase their medicines through "branded" shops. Educating consumers on what constitutes quality in retail drug shops and why visiting a branded shop can make a difference to their health is important to success.

Develop and implement a communication plan for general consumer awareness and the program's brand by carrying out a market analysis, developing key communication messages for different groups of customers, and identifying and implementing communication activities using print and other media, such as radio announcements and billboards.

Sustaining the quality of drug shops and services

As a comprehensive drug shop improvement program that uses accreditation or franchising measures is developed, a foundation should be laid to sustain the shops over the long term. If the program is successful on a small scale, pressure will arise to not only sustain the current operations but also to expand the program model. It is logical to assume that problem areas experienced during a pilot program will loom larger during scale-up. Consider sustainability within the context of growth, and prepare the program for the future by following through on carefully planned actions. These actions may not guarantee the program sustained success and growth, but they will put the program in a strong position to face future challenges. The following actions will help sustain the program—

- Touch base with stakeholder groups periodically and use their feedback to make program adjustments.
- Review lessons learned from the training program once a year, and revise materials as needed.
- Put reporting mechanisms in place to help track performance, and give feedback and support in a timely manner if performance fails to adhere to standards.
- Closely monitor the financial performance and stability of individual shops, including increases in

Box 32-2
Drug Shop Provider Association tool kit

As part of a project funded by the Rockefeller Foundation, Management Sciences for Health developed a tool kit to facilitate the expansion of ADDO associations in Tanzania; however, the tools can be adapted for use in any context. The tool kit was finalized through a consultative stakeholder workshop. It includes seven operational and management tools, which are available in English and Kiswahili—

- Roles, responsibilities, and benefits of ADDO provider associations
- How to form and register an ADDO provider association
- Basic components of a model constitution for ADDO provider associations
- How to plan and manage activities for ADDO provider associations
- How to mobilize financial resources for ADDO provider associations
- Institutional networking and coordination mechanisms for ADDO provider associations
- How to document, monitor, and evaluate activities

In addition, the tool kit includes additional promotional and orientation materials—

- Advocacy guide for the national-, regional-, and district-level stakeholders
- Promotional banners
- Presentation slides for provider association orientation
- A DVD produced by a local consultant, MediaNet, that ADDO providers can view to become familiar with the association concept

The tool kit is available in Appendix C of the project report: http://www.drugsellerinitiatives.org/DSI-PDF-Documents/upload/40-Rockefeller-ADDO-Association-Final-Report-MSH-Dec-2010.pdf.

profitability and the timeliness of meeting payment schedules.
- Develop solid wholesale operations or link to reputable established operations that will allow shops to more easily access affordable, quality pharmaceuticals, pass on savings to the consumer, and stay financially stable.
- Continue to use communication activities to influence consumer behavior and encourage shop owners and dispensers to adhere to standards.
- Solicit long-term support for networks of drug shops by encouraging providers and medical authorities to recognize the vital role that retail drug shops play in ensuring access to quality pharmaceuticals and services in areas that would not otherwise be served.
- Promote the establishment and strengthening of owner and dispenser associations as a mechanism to increase product and service quality and promote sustainability. Box 32-2 provides information on a provider association tool kit.

Country Study 32-4 describes how multiple national and international stakeholders contributed to the successful expansion of the ADDO program in Tanzania.

Management Sciences for Health (MSH) has put together a website (http://www.drugsellerinitiatives.org) whose purpose is to share initiative experiences and tools of drug sellers and others to provide a resource for those with an interest in improving access to quality pharmaceutical services and products provided by drug sellers in other countries. A drug seller initiative tool kit is a major component of the website. The tool kit identifies program components, such as regulation and monitoring, and then links tools and resources related to those components from experiences in Tanzania and Uganda. Stakeholders interested in initiating a drug seller initiative are encouraged to adapt the tools and resources for their own use. ■

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Country Study 32-4
Multistakeholder contributions to ADDO program expansion

Many people in rural Tanzania seek health care and medicines from retail drug shops, called *duka la dawa baridi,* for reasons such as convenience. Historically, the TFDA authorized DLDB to provide nonprescription medicines. However, a 2001 assessment showed that many shops sold prescription medicines illegally and that the drug sellers were generally unqualified and untrained. In response, the SEAM Program collaborated with TFDA to develop and launch the ADDO program in 2003. The goal was to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in areas where few or no registered pharmacies exist. To achieve this goal, SEAM took a holistic approach that combined training, accreditation, business incentives, and regulatory enforcement with efforts to increase consumer demand for quality products and services.

By the end of the SEAM Program in 2005, the TFDA had accredited more than 150 shops in Ruvuma. Results of the pilot in the Ruvuma region provided proof that ADDOs could improve access to quality medicines and pharmaceutical services. The next year, the Danish Agency for International Development Assistance (Danida) funded an independent evaluation of the program and confirmed SEAM's findings. Based on the SEAM and Danida evaluations, the Ministry of Health and Social Welfare approved a plan to roll out the ADDO concept to mainland Tanzania.

As the program has taken off, many have recognized the potential of ADDOs not only to increase access to essential medicines, but also to serve as a platform for community-based public health interventions, such as improving child health. As a result, numerous organizations and programs have played a role in expanding both the services that ADDOs provide and their geographic reach—about 1,300 ADDOs are currently serving eight regions.

To be successful, nationwide scale-up of initiatives such as the ADDO program in Tanzania requires creative partnerships and solid commitment to productive collaboration. The following timeline illustrates the range of partners who have contributed to the success of Tanzania's ADDO program.

Tanzania ADDO timeline

2003	The SEAM Program and TFDA design and launch the ADDO program in the Ruvuma region.
2005	SEAM and TFDA evaluate the pilot program in Ruvuma.
2006	Danida sponsors an independent evaluation of the ADDO program in Ruvuma.
2006	The government of Tanzania, through the Ministry of Health and Social Welfare, approves a TFDA plan to roll out ADDOs throughout the Tanzanian mainland.
2006	The U.S. Agency for International Development, through MSH's Rational Pharmaceutical Management (RPM) Plus Program, funds the ADDO rollout in the Morogoro region using resources from the U.S. President's Emergency Plan for AIDS Relief.
2006	The government of Tanzania funds rollout in the Mtwara and Rukwa regions.
2006	The RPM Plus Program collaborates with the Basic Support for Institutionalizing Child Survival Project to add a child health component to ADDO services.
2006	The National Malaria Control Programme adopts the ADDO concept as part of its national strategy to increase access to malaria treatment.
2007	Tanzania's National Health Insurance Fund initiates a plan that allows members to fill prescriptions at ADDOs.
2007	MSH's Strengthening Pharmaceutical Systems Program uses President's Malaria Initiative funds to provide subsidized artemisinin-based combination therapy (ACT) through ADDOs.
2007	The Global Fund to Fight AIDS, Tuberculosis and Malaria agrees to fund ADDO rollout in six to eight high-impact malaria regions to improve access to ACTs for children under five; Danida also contributes funding for rollout.
2007	The Bill & Melinda Gates Foundation funds the East African Drug Seller Initiative to work with TFDA to review and revise the existing ADDO model to make nationwide scale-up more cost-efficient and to help ensure the long-term sustainability of ADDOs.
2008	The Gates Foundation provides the East African Drug Seller Initiative with supplemental funding to evaluate ADDO rollout in Tanzania and long-term sustainability in existing ADDO regions.
2008	The Prime Minister's Office for Regional Administration and Local Government mandates local governments to incorporate ADDO program implementation into their planning and budgets.
2009	The Rockefeller Foundation funds MSH to develop a strategy to promote program sustainability and quality through the establishment of ADDO owner and dispenser associations.
2009	Local governments in Arusha, Iringa, Kagera, Kilimanjaro, and Tabora mobilize to obtain funds to introduce ADDOs.
2009	The government of Tanzania starts rolling out ADDOs to six of the eight Global Fund– and Danida-supported regions and developing a strategy to open ADDOs in urban areas.
2009	The Clinton Foundation funds initial implementation activities in Shinyanga and Dodoma.
2009	A government of Tanzania regulation is revised to phase out unaccredited drug shops (*duka la dawa baridi*) by January 2011.

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