

Expanding the Role of Pharmacy Staff in Antiretroviral Therapy

Helena Walkowiak and Douglas Keene

Rational Pharmaceutical Management Plus (RPM Plus) Program, Management Sciences for Health, United States

THE PHARMACY DEPARTMENT HAS A pivotal role to play in the provision of quality antiretroviral therapy (ART) care, through both ensuring an efficient supply of medicines and delivering patient-oriented services to promote appropriate use. Studies in the developed world have found that support from pharmacists can positively affect adherence¹ and that clinical pharmacists appear to have a strong impact on promoting positive clinical outcomes in patients starting ART, particularly in economically disadvantaged areas.² In many developing countries, initiatives to scale up ART have focused attention on the pharmacy and on making better use of pharmacists, whose skills and training are often underutilized. Currently, the role of the pharmacist and other pharmacy staff in supporting the ART program varies considerably between and within countries as managers explore different models of service provision and pharmacists embrace the opportunity to expand their role in ART care.

Pharmacy practice takes place at different levels³: the system (national, provincial, or district), the facility (including the health-care team), supply management, the individual patient, and the community level. Substantial gaps exist in the scope and performance of pharmacy practice at all levels in

most resource-limited settings. The introduction of an ART program can serve as an entry point to strengthening practices and expanding patient care activities at the pharmacy to benefit all health-care programs. The ART program is refocusing attention on the importance of traditional pharmacy activities, such as dispensing, including checking prescriptions, labeling medicines, and medication counseling. Increasingly, pharmacy responsibilities are expanding to include a wider range of patient care activities, specifically adherence monitoring, medication-related problem monitoring, and identifying and following up on defaulting patients. Supporting nonmedical staff and community caregivers in the distribution and appropriate use of medicines is another important undertaking.

Estimates of the number of pharmacy staff needed to support ART scale-up range from less than one to three staff per 1,000 patients, depending on how responsibilities for dispensing and especially counseling are allocated between cadres.⁴ In one study, Kenya was estimated to need a 50% increase from 2005 levels in the number of public sector pharmacy “specialists” to meet the U.S. President’s Emergency Plan for AIDS Relief target of supporting 250,000 ART patients by 2008.⁵ However, many countries,

especially in sub-Saharan Africa, have a severe shortage of pharmacists. Ethiopia, Mozambique, Rwanda, Tanzania, and Uganda have three or fewer pharmacists per 100,000 people, compared with the United States, which has 88 pharmacists per 100,000.⁶ Migration of pharmacists overseas is a major cause of shortages in many resource-limited countries. In Ghana, almost two-thirds of the 140 pharmacy school graduates migrated out of the country in 2003.⁷ Furthermore, pharmacists tend to be concentrated in the private sector and in urban areas. For example, in Uganda, 90% of the pharmacist workforce is located in just one of four regions of the country.⁷ Given the inadequate supply of pharmacists to support scale-up and the move to decentralize ART services to the primary health-care level, where pharmacists are few, the role of the pharmacist in ART needs to be redefined and reoriented to maximize the efficient use of the most skilled cadre of staff. In addition to pharmacists, other pharmaceutical service staff may include pharmacy technologists, technicians, or assistants; nursing staff; and other health-care workers who have been given responsibilities for dispensing or managing medicines. These other cadres of workers must learn new skills and take on new roles, thereby releasing pharmacists to focus on more specialized functions and supportive supervision.

This chapter highlights experiences in expanding the role of pharmacists and other pharmacy staff to support the introduction and scale-up of ART in developing countries.

SUPPORTING ART INTRODUCTION AND SCALE-UP AT THE SYSTEM LEVEL

At the national, provincial, or district level, the pharmacists and other health workers of the ministry of health responsible for managing pharmaceuticals

make important contributions to planning and managing the introduction and scale-up of ART, including developing enabling legislation, regulations, and policies. In several countries, the national-level staff responsible for pharmaceutical services work closely with the national AIDS control committee and donors to coordinate ART procurement, financing, and distribution (see chapter in this section entitled “Managing Medicines and Supplies for HIV/AIDS Program Scale-Up”). Pharmaceutical management staff also work increasingly with other government departments and programs to maximize efficiency in capacity-building activities. Other important functions include contributing to proposal development and, particularly, to developing the procurement and supply management plan for applications to the Global Fund to Fight AIDS, Tuberculosis and Malaria. Other evolving roles for national-level pharmacy staff that can serve as a starting point for strengthening good pharmacy practices for all health programs include the development of pharmacy practice standards for facilities dispensing antiretroviral drugs (ARVs), national standard operating procedures (SOPs) for ART pharmacy services, and accreditation guidelines and audit tools.

Involving pharmacists responsible for implementing ART at the national and local levels in ART medicine selection committees enables them to contribute to developing treatment guidelines that are easier to put into practice. A number of countries have identified pharmacists to work with the national, provincial, and, in some cases, district AIDS control teams to tackle ART-related pharmaceutical issues and to support sites in introducing and scaling up ART services. Given the shortage of pharmacists, future considerations may include expanding the responsibilities of these staff to support implementation of all health-care programs, especially where ART programs are integrated into existing systems.

To support ART scale-up in settings where pharmacists are in short supply, the national pharmacy department will need to work with ART program managers to decide on the optimal role for each cadre of pharmacy staff and the number of each cadre needed for ART scale-up. Preservice curricula and in-service training materials for pharmacists and other levels of pharmacy staff will also need to be aligned to match competency standards with the recommended scope of practice for each cadre.

SUPPORTING ART INTRODUCTION AND SCALE-UP AT THE FACILITY LEVEL

Involving the pharmacy staff at the facility at early stages of planning and throughout implementation is crucial to a successful start-up and also promotes ownership and sustainability. As countries move to decentralize ART services to the primary health-care level, where pharmacists are scarce, the identification of pharmacists at the provincial or district level who can provide technical oversight and support to pharmacy staff at new ART sites is an important step. For example, in South Africa, almost all provinces have a pharmacist providing oversight of HIV/AIDS pharmaceutical service activities. Furthermore, initiatives to explore ARV dispensing and counseling by pharmacy assistants in primary health-care clinics and identify effective mechanisms for supervision are under way. Approaches to enabling pharmacists to fulfill this new role are discussed later in the chapter. Ideally, the pharmacists should have experience in introducing ART and managing scale-up and be able to anticipate constraints and recommend strategies to address problems that commonly occur.

The primary role of the pharmacists providing technical oversight will be to train and mentor the staff that will be responsible for managing and

dispensing ARVs at new sites. In addition, they can assist pharmacy staff and the ART team to do the following:

- Assess the functionality of existing pharmaceutical management systems
- Develop implementation plans that prioritize and address gaps
- Quantify ARV and other supply needs
- Calculate storage needs for ART start-up and expansion
- Adapt and test SOPs, job aids, and recording and reporting forms
- Introduce tools to monitor adherence
- Identify needs for information resources—for example, ART guidelines and drug information for medication counseling
- Implement monitoring and reporting of medication errors, suspected adverse reactions to medicines, and other medication-related events
- Address emerging problems as patient numbers increase

PHARMACY STAFF AS MEMBERS OF THE ART HEALTH-CARE TEAM

Pharmacists and other pharmacy staff are essential members of facility ART committees or multidisciplinary teams and make important contributions to decision making on program management issues and clinical aspects of patient care. In developing countries, the role played by pharmacy staff, and particularly their degree of clinical involvement, varies considerably depending on the cadre of staff that participates and their individual capabilities and motivation. Pharmacists providing technical oversight to sites without pharmacists can mentor and assist the pharmacy staff to contribute more broadly to the ART team.

Experience has shown that including pharmacy staff in the ART team enables them to manage medicines and supplies more efficiently. For example, the team can assist the pharmacy staff

to quantify ARV needs by identifying potential changes in prescribing practice and developing and validating assumptions for expansion. Constraints at the pharmacy that may limit scale-up, such as staff shortages or lack of storage space, can be communicated to the team early on. Furthermore, health provider roles in the ART program—for example, in ART counseling—can be reviewed to identify gaps and eliminate unnecessary duplication to improve efficiency. Other benefits include improving cross-departmental coordination for the program, such as through streamlining the management and follow-up of clients who present for postexposure prophylaxis. As countries work to strengthen pharmacy systems and collect, analyze, and report data, the pharmacy role in providing information to other members of the health-care team (for example, on ARV consumption or prescribing practices, including characteristics of patients) is increasingly appreciated. One of the key challenges is to present the data in a format that is useful to others without overwhelming the workload of existing staff.

In many resource-limited countries, the clinical role of pharmacists is evolving, allowing them to make important contributions to decision making on treatment and care and case reviews, as well as to provide scientific updates and reviews of rational ARV use, including adherence. However, their level of involvement is generally uneven among facilities. Emerging activities include reviewing the incidence of ART-related adverse events at the facility, coordinating medication event reporting, and contributing to operations research. Pharmacists are very often the link between the ART team and the facility Pharmacy and Therapeutics Committee (PTC) and play an important role in providing information for PTC decision making on facility formularies and lists.

To be recognized as full members of the health-care team, pharmacists and other pharmacy staff

need to increase their competencies but also adopt new attitudes.³ These requirements are discussed later in this chapter.

MANAGING MEDICINES AND SUPPLIES AT ART SITES

Supply management activities, including procurement and distribution, continue to be important functions for pharmacy staff, and the adequate and continuous availability of quality ARVs is critical to the success of any ART program. In many resource-limited countries, pharmacists still devote much of their time to supply management; however, given the shortage of pharmacists discussed earlier in this chapter, some of these responsibilities are now being delegated to other cadres of pharmacy staff. In countries where responsibilities are being realigned, pharmacists still play a key role in supervising supply management activities, problem solving, assisting in complex tasks such as ARV quantification, and developing new methodologies, tools, and approaches to improve supply management practices.

THE ROLE OF THE PHARMACY IN SUPPORTING PATIENTS ON ART

Since the mid-1970s, the focus of pharmacy practice has been shifting from dispensing and inventory management to the provision of services and functions—some traditional and others new—that serve individual patients.³ In most developed countries and some developing countries, the pharmaceutical profession is working to implement patient-centered services or pharmaceutical care, namely, “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve or maintain a patient’s quality of life.”⁸ Successful medication therapy requires individual therapeutic decisions, reaching agreement with the patient on outcomes and how to achieve them, and patient monitoring.³ These are all activities

to which pharmacists increasingly contribute. In resource-limited settings, pharmaceutical care has, until recently, been mainly limited to pharmacists providing clinical pharmacy services in hospitals. However, the introduction of the ART program is increasingly serving as a gateway to strengthening practices and expanding patient care activities at all levels of the health-care system, often to the benefit of other health-care programs. Pharmacists and other pharmacy staff are progressively attaining the training, tools, resources, and supportive supervision needed to empower them to expand their role in ART care.

Key roles of the pharmacy staff include the following:

- Monitoring ART prescriptions for appropriateness and discrepancies
- Dispensing ARVs in appropriate packaging with clear instructions
- Providing medication-related counseling, including reinforcing adherence and advising on potential side effects and drug-drug interactions
- Providing drug information to providers and patients on request

Evolving roles include the following:

- Monitoring adherence to ARVs; working with patients and other providers to address difficulties
- Identifying and following up on patients who do not return for refills of their ARVs
- Working with providers and patients to identify, manage, and report adverse drug reactions and drug interactions
- Active dissemination of drug information to patients and providers
- Contributing to decision making on treatment and care for individual patients

PREPARING PHARMACY STAFF FOR A NEW ROLE

Early experiences in expanding the role of pharmacists in ART at the facility level identified training, adequate staffing levels, and access to up-to-date information as essential requirements for success.⁹ As countries move to reorient the role of the pharmacist and other cadres and to standardize and institutionalize these changes, additional policy and human resource issues need to be addressed.

Policies and Legislation

A legislative framework, together with supporting policies and procedures that define the new structure and describe how the reallocation of tasks for pharmacy staff will work, is required to standardize practices and enable each level of the health-care system to implement the changes. Policymakers will need to decide the optimal role for each cadre and the appropriate skills mix needed at each level and develop a structure to provide supportive supervision and technical oversight as staff take on new responsibilities. Legislative changes may need to be made—for example, to enable pharmacy staff other than pharmacists to dispense certain medicines.

Human Resources

Job descriptions need to be updated to reflect new responsibilities and, along with SOPs, are important for effective technical oversight and supportive supervision. Adequate staffing levels are essential to enable staff to take on new roles, such as adherence monitoring or technical oversight at other sites. An important first step in determining staffing levels is to ascertain the ratio of each cadre to the number of tasks to be completed or patients to serve.⁴ Eliminating unnecessary tasks and duplication of efforts in order to increase the efficient use of existing staff can also facilitate the reallocation of tasks.

SUPPORTING THE EXPANSION OF ART SERVICES IN SOUTH AFRICA

IN SOUTH AFRICA, THE GOVERNMENT is working with partners and stakeholders to down refer patients who are stabilized on ART from hospitals to primary health-care (PHC) clinics. In addition to reducing the patient load for the hospital's pharmaceutical service, this strategy can also reduce transportation costs for patients returning to collect prescription refills. However, the shortage of pharmacists at PHC clinics has led to the increased use of the pharmacy's assistants and nurses to support the expansion of the ART program and ensure that patients can get their medication. A number of different approaches are being explored.

In one approach, prescriptions are prepared at a nearby hospital and delivered to a PHC clinic closest to the patient's home or place of work. Prescriptions are packaged with appropriate information by hospital pharmacy staff and delivered to the local clinics. At the clinic, pharmacist's assistants or nurses dispense the ARVs and review patients' treatment progress. The PHC clinic returns progress reports and uncollected medication to the hospital.

There is also a movement toward the initiation of ART by nurses at the PHC level. In some PHC clinics, nurses who have dispensing

licenses and have been trained on HIV/AIDS dispense ARVs to patients who have been on ART for longer than six months and have been down referred to continue treatment. The nurses reinforce adherence at every visit, monitor patients for adverse events, and refer them for management of adverse events should they occur. Some changes to the applicable legislation and the National Essential Drugs List are needed to support this initiative.

In the Western Cape Province, an initiative is under way to develop a model in which pharmacist's assistants dispense ARVs in PHC clinics under the indirect supervision of a pharmacist. Additional training is being provided to the assistants, and job descriptions, SOPs, and monitoring tools are being developed to set the standards for pharmacy practice and facilitate effective oversight.

Another model in use in South Africa is one in which a pharmacist visits the PHC clinic once a week to dispense prescriptions for ARVs or to check prescriptions that have been prepared by a pharmacist's assistant. Prescriptions may be handed to the patient by either the pharmacist or nurses working in the PHC clinic.

Sources: Management Sciences for Health, Rational Pharmaceutical Management Plus, South Africa; Shanila Nair, MBBS, BSc, Technical Advisor, Elizabeth Glaser Pediatric AIDS Foundation, South Africa.

SHIFTING TASKS TO ADDRESS SEVERE SHORTAGES OF PHARMACISTS

IN 2003, MÉDECINS SANS FRONTIÈRES and the Nelson Mandela Foundation, in partnership with the Department of Health of the Eastern Cape, initiated a program to provide ART through primary health-care clinics in Lusikisiki, South Africa. Because of a shortage of skilled health-care workers, tasks were shifted to make the best use of available human resources. The traditional functions of the pharmacist in HIV/AIDS care include managing the supply of medicines

and overseeing prescriptions, while pharmacy assistants have a limited role and dispense medicines only under the supervision of a pharmacist at a hospital. The Lusikisiki program, however, utilized a hospital pharmacist to provide coaching to pharmacy assistants, whose responsibilities included managing the medicine supply, dispensing prescriptions, and, in some cases, checking adherence.

Source: Médecins Sans Frontières.¹⁰

Capacity Building

Pharmacy staff will require training or retraining to build their skills and knowledge and to adopt essential attitudes to successfully take on new responsibilities and expand their role in ART. Training curricula will need to be aligned with new competency standards and scopes of practice for each cadre of pharmacy staff. Pharmacists will need good leadership, management, budgeting, and communication skills to mentor and assist other cadres to take on new responsibilities for the ART program. For effective medication counseling, staff need good communication and problem-solving skills to assist patients to achieve and maintain high levels of adherence. In addition to preservice and in-service training to capacitate pharmacy staff to take on new roles, they will need a mechanism to stay up-to-date with scientific advancements and changes in recommended practices. Pharmacists will need to be visible, responsible, and committed to maintaining competencies in order to play a larger role in the ART health-care team.³ Required changes in attitudes for all staff will include a commitment to

confidentiality and patient-oriented, rather than task-oriented, practices.³

Resources

An essential requirement for providing pharmaceutical care to ART patients is an information system that collects patient-specific data and documents interventions and medicines dispensed at the pharmacy. Pharmacists and other pharmacy staff need access to up-to-date information, SOPs, and job aids (e.g., pediatric ARV dosing tables) to assist them to take on new tasks. Other requirements include a confidential counseling area and validated measurement tools for monitoring adherence in resource-constrained settings.

SUMMARY

Experiences to date have shown that pharmacists and other pharmacy staff have an important role to play in ART care in resource-limited settings by promoting appropriate use and ensuring availability of quality and efficacious medicines. To make the most efficient use of available staff, the roles of

the pharmacist and other pharmacy staff will need to be realigned. However, policymakers may need to be convinced of the value of an expanded role for pharmacy staff and will want to know the cost implications and the feasibility of implementing the

necessary changes. Operations research to develop scalable models, answer important questions, and document benefits such as increasing the job satisfaction of pharmacists to slow down migration to the private sector and overseas is urgently needed.

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