

ASHP Statement on the Pharmacist's Role in the Care of Patients with HIV Infection

Position

The American Society of Health System Pharmacists (ASHP) believes that pharmacists have a role in the care of patients infected with human immunodeficiency virus (HIV). Pharmacists have a responsibility to provide pharmaceutical care to these patients and, in states where it is authorized, can expand on that responsibility through collaborative drug therapy management.

Pharmaceutical care is the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life.¹ Pharmacists establish relationships with patients to ensure the appropriateness of medication therapy and patients' understanding of their therapy and to monitor the effects of that therapy. In collaborative drug therapy management, pharmacists enter into agreements with physicians who may authorize pharmacists to select appropriate medication therapies for patients who have a confirmed diagnosis and adjust them on the basis of patients' responses.²

Clinicians who provide these services are responsible for the quality of care, the satisfaction of patients, and the efficient use of resources, as well as their own ethical behavior.³ High-quality, coordinated, and continuous medication management for patients should be measurable as a result of the provision of these services. The potential benefits to patients include access to medication information, the prevention and resolution of medication-related problems, improved outcomes, and increased satisfaction.⁴ Pharmacists are able to use medication-related encounters with patients to provide information and either resolve problems or make a referral for health care needs.

The purposes of this statement are to promote an understanding of the various ways in which pharmacists can provide or contribute to the provision of care for patients infected with HIV in integrated health systems and to suggest future directions for pharmacists to expand patient care services.

Background

HIV infection, like many other chronic illnesses, affects nearly every organ system of the body. HIV is pathogenic in some instances, and superinfection by bacteria, other viruses, or fungi is common in the advanced stages of HIV infection. Unlike some other illnesses, HIV infection can be prevented by curbing high-risk behaviors,⁵ so the illness still carries a social stigma among some who believe that they are not at risk. Among those at high risk for HIV infection are intravenous drug users and the severely mentally ill,⁶ whose conditions may discourage testing for HIV infection or disclosure of HIV status and can also hinder treatment. Discrimination against HIV-infected individuals in housing and employment persists and may impede the delivery of health care by disrupting the stability of home and work life.

Our understanding of the basic pathophysiology and immunology of HIV infection continues to evolve on an almost-daily basis, and drug development occurs at a rapid pace. Since 1990, the Food and Drug Administration (FDA)

has averaged one new antiretroviral agent approval per year; several years have seen the approval of two or three new antiretrovirals.⁷ With these rapidly changing and complex therapeutic options, it is a challenge for many primary care providers to keep abreast of state-of-the-art strategies for managing HIV infection and provide comprehensive treatment for a relatively small population of patients. General practitioners know intuitively what has been shown in the literature: patients who are cared for by physician experts in HIV infection have better outcomes.^{8–10} The advent of effective antiretroviral therapies has increased the need for clinicians with a broad knowledge of and experience managing HIV infection's concomitant diseases. In addition, important drug–drug interactions exist between antiretroviral agents and drugs used to treat opportunistic infections, between antiretroviral agents and drugs used to treat non-HIV-related comorbidities, and among the antiretroviral agents themselves. Failure to recognize these drug–drug interactions may result in additional or exacerbated adverse effects, non-adherence, therapeutic failure, or irreversible drug resistance. HIV-infected patients require extraordinary counseling and education regarding their treatment, from the importance of adherence to ways to recognize and cope with long-term consequences of therapy. The complexity of pharmacotherapy for patients with HIV infection presents special challenges and opportunities for pharmacists interested in developing a specialized knowledge base about HIV treatment.

There are a range of places within integrated health systems where pharmacists are likely to interact directly with patients infected with HIV: outpatient pharmacies, ambulatory care clinics, inpatient settings, dialysis units, hospices, and home infusion and home health care companies. Pharmacists are often considered the most accessible health professional; they are frequently at the frontline in helping HIV-infected patients deal with barriers to medication access, managing adverse effects and drug interactions, and adhering to medication regimens. Because many HIV-infected patients feel disconnected from the community, compassion on the part of the pharmacist can forge a strong bond with the patient and perhaps enhance patient adherence to antiretroviral treatment.

Patients' ability to adhere to antiretroviral regimens is essential to achieving the goals of drug therapy. Although the exact degree of adherence needed to ensure successful outcomes from drug therapy is not known, one study found that patients must take 95% of their doses to maintain drug levels that will achieve viral suppression, prevent drug resistance, and avert treatment failure.¹¹ Lack of adherence is often cited as the most common cause of the development of drug resistance and reduced effectiveness or therapeutic failure.¹² Mutations that lead to resistance to one drug may confer resistance to other drugs in the same therapeutic class, severely limiting future treatment options.^{13,14}

Causes of nonadherence are multifactorial and differ greatly from patient to patient. In general, adherence has not been related to patient age, race, sex, education level, socioeconomic status, or history of substance abuse.¹⁵ The principal factors associated with nonadherence to antiretroviral

therapies appear to be patient-related, and include mental illness (particularly untreated depression), unstable housing, active substance abuse, and major life crises.^{16,17} Some patients stop or reduce the dosage of antiretroviral medication because of adverse effects.^{17–19} Other factors that have been shown to negatively affect adherence include inconvenient frequency of drug administration, dietary restrictions, and pill burden.¹⁷ A health care professional's assessment of a patient's ability to adhere to a medication regimen is a notoriously poor predictor of actual adherence.^{20,21} In one study, the most important predictor of a patient's lack of success with an antiretroviral regimen was the patient's inability to keep appointments with the health care practitioner.²²

Responsibilities

Pharmacists involved in the care of HIV-infected patients participate with other members of the health care team (e.g., physicians, physician assistants, nurse practitioners, nurses, dietitians, social workers, case managers, and pastoral care providers) in the management of patients for whom medications are a focus of therapy. The pharmacist's responsibility is to optimize the patient's medication therapy. Because of the rapid changes in HIV treatment, pharmacists involved in the care of HIV-infected patients should commit themselves to weekly if not daily education from journals or other sources. Pharmacy services should be designed to support the various components of the medication-use process (ordering, dispensing, administering, monitoring, and educating) as individual steps or as they relate to one another in the continuum of care. Pharmacists should evaluate all components of the medication-use process to optimize the potential for positive patient outcomes.² Particular care is needed in the prescribing and dispensing phases because the names of many antiretroviral agents sound and look similar, especially when they are handwritten, and some physicians continue to refer to antiretroviral agents by their chemical or investigational names. Verification of the appropriateness of the antiretroviral cocktail and its dosages is important because dosing recommendations change frequently as more becomes known about individual drug pharmacokinetics and because drug–drug interactions may be used clinically to simplify or increase the efficacy of drug regimens. Pharmacists should screen the medication profile for potential drug–drug and drug–food interactions. A number of antiretroviral drugs cannot be taken with certain foods, and it is the responsibility of the pharmacist to ensure that the patient and caregivers (dietitians, nurses, family members, and friends) are aware of these dietary restrictions.

Pharmacists are responsible for assessing patients' readiness to adhere to drug therapy, assisting in the design of therapeutic plans to increase the likelihood of adherence, assisting the patient in successful implementation of drug therapy, intervening when the patient states or intimates that he or she cannot or will not adhere to treatment, and providing ongoing monitoring of adherence. The public health implications of inconsistent adherence are much greater with antiretroviral agents than with other chronic medications. The pharmacist can promote patient adherence by considering the patient's history of adverse effects when recommending a regimen; helping to develop a daily medication administration schedule that accommodates the patient's sleep, work, and meal schedules; providing memory aids for medication

taking; recruiting an adherence coach; and educating and motivating patients and caregivers.²³ To ensure a consistent supply of antiretroviral medications, patients need to be counseled to plan for medication refills so they are never without these medications. Pharmacists, along with other health care professionals, are responsible for postmarketing surveillance of adverse drug events. Suspected adverse drug events should be reported to the patient's primary care provider and to FDA's MedWatch program. Many antiretroviral medications were marketed with scant data about their long-term effects because FDA's accelerated drug approval process allows certain drugs to be approved with only six months of clinical (Phase III) data. Pharmacists should also be aware of the potential for adverse events or drug interactions caused by dietary supplements and should report those as well.

Pharmacists' ability to recognize potential opportunistic infections or other HIV-associated complications and appropriately refer the patient for evaluation and management by a physician is critical. In addition, pharmacists have an obligation and an opportunity to educate members of the community about prevention of HIV infection and may be in a position to recognize persons undertaking high-risk behaviors. The pharmacist should recommend testing of persons at high risk for HIV infection and help educate patients infected with HIV about how to modify their behavior to prevent disease transmission.

The advent of effective antiretroviral therapies has made the treatment of hospitalized patients with acute HIV-related conditions more complex. Pharmacists still need to be prepared to recognize, prevent, and treat the acute opportunistic infections associated with advanced AIDS. The extended survival of those undergoing antiretroviral therapies introduces new comorbidities, such as diseases of the liver, malignancies, hyperlipidemia, and diabetes mellitus, which pharmacists must take into account as they provide pharmaceutical care.

Care for dying patients is also part of the continuum of pharmaceutical care that pharmacists should provide to patients. Pharmacists have a professional obligation to work in a collaborative and compassionate manner with patients, family members, caregivers, and other health care professionals to help fulfill the pharmaceutical care needs—especially nutrition support; the management of diarrhea, electrolyte imbalances, pain, and depression; and other quality-of-life needs—of dying patients.^{24,25}

When more than one pharmacist is involved in delivering care, practice standards for the group should be adopted and should serve as a guide for all. Pharmacists should also establish methods of communication among themselves in order to provide and ensure continuity of pharmaceutical care on behalf of the patients served.² Methods for referral to other health care providers should also be defined.

Functions. In general, pharmacists perform the following functions in collaboration with physicians and other members of the health care team²:

1. Perform patient assessment for medication-related factors.
2. Order or recommend laboratory tests necessary for monitoring outcomes of medication therapy and potential drug toxicities, and cancel unnecessary laboratory tests.

3. Provide drug information to physicians and other members of the health care team.
4. Identify potential and actual drug–drug interactions and make recommendations for dosage modification or alternative therapies, if appropriate.
5. Interpret data related to medication safety and effectiveness.
6. Initiate or modify medication therapy or patient care plans on the basis of patient responses.
7. Provide information, education, and counseling to patients about medication-related care.
8. Document the care provided in patients' records.
9. Identify any barriers to patient adherence to medication regimens.
10. Communicate with prescribers known instances of nonadherence to medication therapy and propose strategies to the prescriber and patient to improve the likelihood of success of subsequent regimens.
11. Communicate relevant issues to physicians and other members of the health care team.
12. Participate in multidisciplinary reviews of patients' progress. Hospice caregivers and volunteer community service organizations should be included in this review as appropriate.
13. Communicate with payers to resolve issues that may impede access to medication therapies.

Expanded Functions. In addition to the aforementioned functions, pharmacists practicing in some settings and with some interdisciplinary relationships may engage in the following activities:

1. Monitoring efficacy of the regimen by tracking CD4⁺ T lymphocyte counts and viral load and providing input about patients' response to therapy to other members of the health care team.
2. Providing individualized health promotion recommendations and disease prevention advice and activities, including administration of immunizations where authorized by law and institutional policies.
3. Assessing patient knowledge about HIV infection and its treatment and educating patients about the pathophysiology and natural history of HIV infection and progression to AIDS; the goals, mechanism of action, and duration of antiretroviral drug therapy; potential adverse effects from and interactions with antiretroviral drug therapy and ways to manage adverse effects; the concept of drug resistance and the importance of adherence to the therapeutic regimen; laboratory monitoring of therapeutic response to antiretroviral drug therapy; and therapeutic strategies for overcoming therapeutic failure.
4. Recognizing (using accepted guidelines) when patients are at risk for opportunistic infections, recommending initiation or discontinuation of prophylaxis, and intervening to ensure evaluation and management by a physician or other practitioner (e.g., physician assistant, nurse practitioner, or clinical pharmacist).
5. Performing limited physical assessment and supervising medication therapy with appropriate collaborative drug therapy management authority.
6. Assessing the indications for HIV drug-resistance testing, the appropriateness of timing for sample collection, interpreting test results, and designing a new

antiretroviral regimen in consultation with an expert in drug resistance.

7. Referring patients to other health care or social service providers, such as psychologists, psychiatrists, social workers, case managers, and chemical dependency providers or support groups (e.g., Alcoholics Anonymous or Narcotics Anonymous) in conjunction with the patient's primary care provider.
8. Educating the community about modes of HIV transmission and effective techniques for prevention of transmission.
9. Encouraging public policy decisions that reduce the risk of transmission of HIV, hepatitis B, hepatitis C, and other sexually transmitted diseases.²⁶
10. Performing research related to antiretroviral therapy (e.g., adherence, quality of life, pharmacokinetics).

Pharmacists' Scope of Practice. The pharmacist may have a range of practice privileges that varies in its extent of authority and responsibility. Pharmacists who participate in the collaborative care of patients with HIV should meet the health care organization's competency requirements to ensure that they provide appropriate quality and continuity of patient care. They should demonstrate required knowledge and skills that may be obtained through practice-intensive continuing education, pharmacy practice, and specialty residencies. The specific practice of pharmacists who participate in collaborative practice should be defined within a scope-of-practice document or similar tool or protocol developed by the health care organization. The scope-of-practice document should define activities that pharmacists would provide within the context of collaborative practice, as well as limitations when appropriate. The document should indicate referral and communication guidelines, including the documentation of patient encounters and methods for sharing patient information with collaborating medical providers.² Pharmacists participating in collaborative practice should remember that, although diagnosing is not within the pharmacist's scope of practice, the pharmacist must be able to recognize the manifestations of opportunistic infections and complications of HIV infection and treatment in order to know when to refer a patient to the appropriate practitioner. Also included in the scope-of-practice document should be references to activities that will review the quality of care provided and the methods by which the pharmacist will maintain continuing professional competency for functions encompassed by the scope-of-practice document. A process should be in place, and responsible parties identified, to review and update the scope-of-practice document as appropriate.

Description of Services Provided. The services offered by the pharmacist range from consulting with the health care team to providing direct support to the patient while working in collaboration with the health care team. The pharmacist provides medication therapy outcomes management as part of the patient's ongoing care. The level of intensity of services varies as the patient's needs change and the disease progresses. For patients who suspect HIV infection, the pharmacist should refer the patient for confidential or anonymous testing (anonymous testing is not available in every state in the United States). Pharmacists also have an important responsibility to ensure the availability of emergency antiretroviral therapy in postexposure prophylaxis and

provide counseling and education to the exposed person. For persons who are newly diagnosed with HIV infection, the pharmacist may facilitate access to medical care or refer a patient to a provider who specializes in the care of patients with HIV infection. The pharmacist may be called on to assess the patient's readiness and ability to adhere to antiretroviral therapy, provide initial or follow-up education on HIV-related disease and complications, as well as antiretroviral medications, and evaluate adherence to a therapeutic regimen. The pharmacist should maintain a current knowledge of antiretroviral therapy and may be called on to recommend and monitor the patients' antiretroviral therapy in collaboration with primary care providers or other members of the health care team. When collaborating with HIV specialists, the pharmacist is often asked to conduct follow-up visits with patients whose disease is stable or make an early follow-up telephone call or visit with patients just starting antiretroviral therapy. For patients with known HIV infection of longer duration, the pharmacist may be expected to ensure that the patient is monitored for long-term complications of antiretroviral therapy, such as diabetes mellitus or metabolic, cardiovascular, or hepatic complications. In the absence of a dietitian, the pharmacist may also monitor for changes in the patient's weight and appetite. The complexity of services provided varies according to the patient's needs and support from within the integrated health system, as well as the availability of other health care professionals on the team. In many situations, the pharmacist may play (or supplement) the role of financial counselor or social worker to facilitate access to medications. To deliver uninterrupted antiretroviral drug therapy, the pharmacist will often need to be knowledgeable about financial resources available to patients with HIV infection.

Documentation of Pharmacists' Care. The professional actions of pharmacists that are intended to ensure safe and effective use of drugs and that may affect patient outcomes should be documented in the patients' medical records.²⁷ Pharmacists in every practice setting should routinely document the quantity and quality of services provided and the estimated effect on patient outcomes.

Confidentiality of medical data is protected by common law and by constitutional rights to privacy. Confidentiality for the HIV-infected person is a critical issue because of the stigma that is sometimes still associated with the illness. Pharmacists should always take extreme care in discussing drug therapy to ensure that confidential medical information is not overheard by other individuals. Information about medications should be disclosed only to appropriate individuals and only with authorized consent from the patient, preferably in writing. Before counseling anyone other than the patient about medications, the pharmacist needs to ascertain that the person with whom he or she is speaking has been authorized by the patient. Pharmacists are urged to explore their local and state laws that may apply to the confidentiality of medical records.

Value of Pharmacists' Care. Methods for obtaining compensation or economic and professional credit for value-added services must continue to be addressed. Structures designed to measure the practitioner's effectiveness as part of an innovative team should be instituted. The pharmacy profession should embrace these activities in the form of well-structured research.² Integrated health systems, as well as other treatment settings, will need to receive adequate

support to expand the availability of pharmacists to provide pharmaceutical care as an essential component of the care of HIV-infected patients. Therefore, aggressive research must be pursued to demonstrate the importance and effectiveness with respect to outcomes of the pharmacist's role in educating the patient about his or her disease and medications.² Because many patients with HIV infection are eventually disabled and disenfranchised, few patients are able to pay out-of-pocket for drug therapy management services, as some patients do for diabetes education or smoking-cessation programs. Third-party payers who cover patients with HIV infection (e.g., private health insurance, state AIDS drug assistance programs, and Medicaid) must begin to cover the cost of patient education and adherence monitoring.

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Other Resources

Web Site Resources

General HIV Care and Treatment Information

- Healthcare Communication Group—Clinical Care Options for HIV (www.healthcg.com/hiv)
- U.S. Department of Health and Human Services AIDSinfo Web site (www.aidsinfo.nih.gov)
- Medscape-AIDS (www.hiv.medscape.com/home/topics/aids)
- HIV Insite Home (www.hivinsite.ucsf.edu)
- HIV Insite International AIDS Society (www.hivinsite.ucsf.edu/medical/iasusa)

Clinical Practice Guidelines and Recommendations

- *Morbidity and Mortality Weekly Report* (www.cdc.gov/epo/mmwr)
- U.S. Department of Health and Human Services AIDSinfo Web site (www.aidsinfo.nih.gov)

Drug Interactions

- Clinical Management of HIV–AIDS Drug Interactions (www.healthcg.com/hiv/treatment/interactions)
- Georgetown University Medical Center Division of Clinical Pharmacology (www.dml.georgetown.edu/depts/pharmacology)
- University of California at San Francisco (<http://arvdb.ucsf.edu>)

Clinical Trials

- U.S. Department of Health and Human Services AIDSinfo Web site (www.aidsinfo.nih.gov)

Hotlines

- University of California at San Francisco Warmline (800) 933-3413

HIV Certificate Programs

- SouthEast AIDS Training and Education Center, Atlanta GA
- Charlotte AHEC, Charlotte NC (800) 874-2417

This statement was reviewed in 2008 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

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