# **Draft 2025 ASHP Guidelines on Pharmacist Involvement in HIV Care**

# Background and Purpose

- 2 Over the past four decades since the first human immunodeficiency virus (HIV) cases were
- 3 reported in the United States in 1981, both HIV treatment and the role of pharmacists in
- 4 managing the condition have seen remarkable advancements. What was once a fatal diagnosis
- 5 has now become a chronic, manageable condition, thanks to the development of modern
- 6 antiretroviral therapy (ART). This progress has significantly improved life expectancy for people
- 7 with HIV (PWH), who now face fewer hospitalizations for HIV-related complications and can often
- 8 manage their condition in outpatient settings. 1-3
- 9 As the landscape of HIV treatment evolves, so has the involvement of pharmacists. Their roles
- 10 have expanded beyond traditional boundaries, encompassing vital aspects of HIV prevention,
- 11 treatment, and patient support. Pharmacists in community and long-term care settings are
- 12 providing expanded care for PWH reflecting the changing demographics and needs of this patient
- population.<sup>4-5</sup> While the core principles of ART have remained stable, there have been significant
- therapeutic advancements, including new options for biomedical HIV prevention and the
- 15 introduction of long-acting ART formulations. Despite the fact that many pharmacists may not
- have received extensive training in HIV care, they are now expected to distinguish between
- 17 antiretrovirals used for prevention and treatment and to deliver personalized care to individuals
- 18 on ART, regardless of the setting.
- 19 Despite the therapeutic advancements, several gaps in HIV management persist, including
- 20 challenges in retention in care, adherence to ART, and the need for better integration of services.
- 21 Compounding these issues is the dwindling HIV workforce, characterized by an aging population
- of HIV-trained healthcare providers and high levels of burnout, which was amplified during the
- 23 COVID-19 pandemic. These developments underscore the critical role pharmacists hold in the
- 24 continuum of HIV care and highlight their potential to significantly impact patient outcomes and
- 25 contribute to the ongoing efforts to manage and ultimately end the HIV epidemic. 7-9 The Ending
- the HIV Epidemic (EHE) focuses on reducing HIV diagnoses through four key strategies: diagnose,
- 27 treat, prevent, and respond.<sup>10</sup>
- 28 Pharmacy practice in the United States is diverse, encompassing various roles and settings that
- 29 reflect the dynamic nature of healthcare. Pharmacists have made essential contributions via
- direct patient care, research, regulatory oversight, and work in community, hospital, ambulatory
- 31 care, specialty, regulatory, and academic settings. By fully integrating pharmacists into HIV care
- 32 teams, expanding their roles, and addressing existing barriers, pharmacists can harness their
- potential to drive significant progress in the fight against HIV. Pharmacists are expected to take
- 34 on more responsibilities in primary care, by managing chronic conditions, providing preventive
- care, and supporting mental health. This shift is largely due to the increasing need for accessible
- 36 healthcare providers.

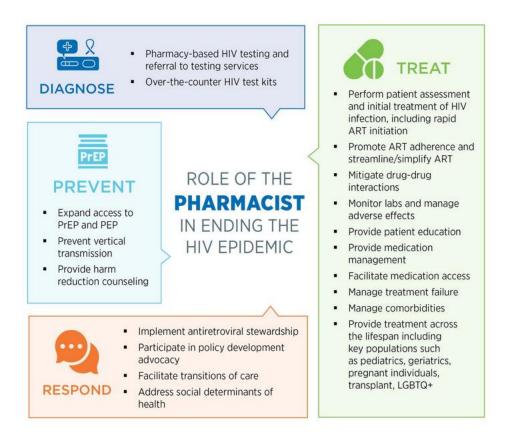
As therapies become more complex, pharmacists' expertise in pharmacotherapy will be crucial. The integration of digital health tools, such as point-of-care diagnostics, digital therapeutics, and health apps will become more common. Pharmacists can help patients set up and interpret data from these tools, enhancing personalized care. They will also play a larger role in population health management by using analytics to identify health improvement opportunities, developing clinical decision support algorithms, and designing programs to improve community health. The use of telehealth is expected to grow, allowing pharmacists to provide services remotely, which can improve access to care, especially in rural and underserved areas. Artificial intelligence (AI) and automation will streamline many pharmacy tasks, such as medication dispensing and inventory management, while identifying patients who need prescription refills. This will allow pharmacists to focus more on patient care. Additionally, pharmacists will be integral to the development and implementation of personalized medicine, tailoring treatments based on individual genetic profiles and other personal health data. These trends highlight the expanding role of pharmacists in healthcare and their potential to significantly impact patient outcomes and public health.

The role of pharmacists extends beyond individual patient interactions to encompass collaborative care with other healthcare providers. Pharmacists are recognized as important members of interprofessional team-based care for PWH. They work closely with physicians, case managers, and other specialists to ensure comprehensive and coordinated care for PWH. This interdisciplinary approach is vital for connecting or reconnecting patients to primary HIV care and other specialized services. Inpatient pharmacist models in HIV care vary across different healthcare settings. In some institutions, there are dedicated inpatient HIV pharmacists who are directly involved in antiretroviral stewardship programs (ARVSPs), inpatient HIV-focused consultation teams or services, and transitions of care processes. Inpatient ARVSPs and consultation can be fulfilled by various types of pharmacists, including clinical pharmacists, infectious diseases trained pharmacists, or ambulatory care HIV pharmacists within the same health system. The model, resources allocated, and percentage of time spent varies depending on the institution's specific needs, health-system size, volume of PWH, and other factors. Pharmacists' involvement in follow-up on clinical outcomes ensures that treatment plans are effective and adjusted as needed, fostering a comprehensive approach to patient care. <sup>16</sup>

In 2016, ASHP issued a statement detailing the pharmacist's role in caring for patients with HIV.<sup>16</sup> The current guidelines build upon that foundation, offering expanded guidance for pharmacists involved in HIV care. These guidelines aim to illustrate how pharmacists can effectively contribute to the care of PWH, particularly in their authority to furnish HIV pre-exposure prophylaxis (PrEP), simplify ART regimens, participate in ARVSPs and transitions of care, support the treatment and management of PWH across their lifespan, address the reimbursement landscape for pharmacy-driven clinical services, and identify areas for further research and expansion of pharmacy-based services in treatment and prevention. Furthermore, the current guidelines emphasize the critical importance of interdisciplinary collaboration to achieve optimal patient outcomes.<sup>16</sup>

These guidelines can be used to establish or enhance pharmacists' services in HIV care and can provide guidance for traditional pharmacist roles and identify new, emerging areas of pharmacy innovation to meet the evolving challenges of the HIV epidemic in the United States. Modeled after EHE's four key strategies, these guidelines expand on the pharmacist's role in HIV prevention, treatment, and management for PWH; advocate for both patients and the pharmacy profession; and highlight opportunities for pharmacist-led research (see Figure 1).

Figure 1. Pharmacist's Involvement in HIV Prevention and Management



## **Testing for HIV**

The need for expanded HIV testing in the United States is demonstrated by the fact that 13% of individuals with HIV in the country are unaware of their diagnosis and may, therefore, present an increased risk of transmission to others. Recommendations from both the Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF) stress the importance of routine "opt-out" HIV testing for adults in all healthcare settings, which recommends patients are informed about and undergo testing for HIV unless they specifically decline. Ubiquity, flexible hours, and a non-stigmatizing environment make pharmacies ideal locations for HIV testing. Pharmacists, as advocates for public health, are involved with HIV testing initiatives by recommending HIV testing, providing and/or counseling on HIV tests, and linking individuals to status neutral HIV treatment and prevention services. Status neutral

approaches incorporate both PWH and people at risk, using the same approach for care engagement, regardless of one's HIV status.<sup>20</sup>

HIV testing may not be easily within reach for people with limited access to healthcare. Ambulatory and community pharmacists address this issue and improve patient access to HIV testing by offering onsite rapid HIV testing and counseling services, thus increasing rates of HIV testing for populations most affected by HIV and for people who have not previously been tested for HIV.<sup>21-23</sup> These screening services are provided in both urban and rural settings, retail chain pharmacies, specialty pharmacies, independent community pharmacies, chain retail clinics, and ambulatory care clinics, and are often offered as walk-in services outside of traditional business hours—such as at night or on weekends. Pharmacists in community and outpatient settings perform point-of-care HIV tests, provide pretest and posttest patient counseling, counsel patients with a positive result about confirmatory testing, complete personalized risk mitigation counseling and education, and facilitate linkage to care. Some pharmacy-based HIV testing programs even combine point-of-care HIV testing with testing for hepatitis C virus (HCV) or with provision of HIV PrEP and post-exposure prophylaxis (PEP).<sup>24-26</sup> Successful pharmacist-led HIV testing initiatives foster collaborations with state and local departments of health, communitybased organizations, and local health clinics to ensure confirmatory bloodwork and subsequent treatment or assessment for PrEP, PEP, or substance use disorder.

Three basic models for HIV testing in pharmacies include a stand-alone pharmacy model where pharmacies develop and operate their own HIV testing programs; a collaborative model in which testing is conducted by pharmacists through partnerships with local or state health departments, community-based organizations, or clinics; and the pharmacy venue-based testing model where HIV testing is conducted by outside entities (e.g., health department or community-based organization staff) in a pharmacy setting. Testing alone does not improve outcomes unless individuals who obtain reactive (i.e., positive) results are linked with confirmatory testing and follow-up care. To prevent breaks in the HIV care continuum, referral procedures must be in place to link patients to HIV prevention, care, and treatment services depending on the test result. Pharmacies must have valid Clinical Laboratory Improvements Amendment (CLIA) Certificates of Waiver and adhere to CLIA regulations to serve as testing sites. Additional pharmacy considerations include infrastructure for private counseling and testing, appropriate pharmacy staff training, and adequate pharmacy staffing.

Expanding HIV testing to pharmacies serves to eliminate barriers and reduce stigma by providing convenient and widely available access to testing. Interest in pharmacy-based HIV testing initiatives has been documented from the perspectives of both pharmacy staff and patients.<sup>27-30</sup> The readiness of pharmacies to provide these services provides a benefit to both urban and rural communities and to hard-to-reach populations not integrated into the formal healthcare system.

HIV testing and early HIV diagnoses improve access to HIV treatment that prolongs life, preserves health, and prevents transmission to others. The CDC and Department of Human Health Services (HHS) maintain websites that list updated HIV testing recommendations, high risk behaviors, and

- common symptoms of early HIV infection (<a href="https://www.hiv.gov/">https://www.cdc.gov/hiv/</a>, respectively). CDC maintains a list of free HIV, STI, and viral hepatitis community testing sites (<a href="mailto:gettested.cdc.gov/">gettested.cdc.gov/</a> or 800-232-4636). Pharmacists in all settings can support routine HIV testing and identify sites for confirmatory testing and linkage to care.
- HIV testing in pharmacies has proven to be cost-effective. 30-31 Point-of-care HIV tests used in pharmacies are often less expensive than traditional laboratory tests, making them a more affordable option. Pharmacist-conducted testing also offers enhanced linkage to care when compared with over-the-counter self-tests. Testing in pharmacies can also lead to an earlier diagnosis, allowing for timely initiation of treatment and reducing the risk of further transmission. This early intervention can significantly lower long-term healthcare costs associated with HIV complications. Pharmacies offer a convenient and accessible location for individuals to get tested, potentially reducing healthcare costs associated with missed appointments or transportation in traditional clinic-based settings.
- Several pharmacy schools in the United States have recognized the role of the pharmacist in HIV testing and have incorporated HIV point-of-care counseling and testing training programs into their curricula.<sup>32-34</sup> These programs provide students with comprehensive training on performing HIV point-of-care testing, analyzing results, risk assessment and mitigation, and appropriate patient communication strategies. By integrating these trainings, pharmacy schools are preparing the next generation of pharmacists with the necessary skills and knowledge to provide HIV point-of-care testing.
  - Normalizing HIV testing through programs such as pharmacist-led testing may help expand access to the service and provide new opportunities to improve the health of the community. However, the current reimbursement structure for pharmacists does not support the time or financial incentives needed to launch widespread pharmacist-led HIV testing. Although pharmacy-based HIV testing removes many accessibility barriers, uncertainty around reimbursement needs to be addressed for this model to become an effective contributor to nationwide screening initiatives. One of the biggest challenges is the lack of framework for pharmacist reimbursement for HIV testing and counseling in an already time-limited practice setting. Regulatory inclusion of pharmacists as "health care providers" also varies from state-to-state and impacts potential compensation for health counseling and screening.

## **Prevention of HIV**

Among the four main strategies to end the HIV epidemic is a focus on preventing HIV transmission using evidence-based interventions including PrEP and PEP antiretrovirals. The landscape of HIV PrEP uptake in the United States has seen remarkable progress in recent years. As of 2022, approximately 36% of the 1.2 million people who could benefit from PrEP have been prescribed it. This marks a notable increase from 23% in 2019.<sup>35</sup>

- Despite this progress, disparities in PrEP uptake persist. For instance, while 64% of White individuals who could benefit from PrEP have been prescribed it, only 14% of Black and 18% of Hispanic/Latino individuals have received prescriptions. Additionally, 92% of males who could benefit from PrEP were prescribed it, compared to only 8% of females.<sup>35-37</sup> These disparities
- highlight the need for targeted efforts to ensure fair access to PrEP across all communities.<sup>37</sup>
- 176 Furthermore, PrEP uptake varies significantly across different regions and communities in the
- 177 United States. For example, urban areas tend to have higher uptake rates compared to rural
- 178 areas.<sup>36</sup>
- Low PrEP uptake is also observed among people who inject drugs. An analysis of commercial
- insurance claims from 2010 to 2019 indicated that among individuals likely engaged in injection
- drug use, fewer than 1 in 500 had pharmacy claims for PrEP.<sup>38</sup> It is important that PrEP be
- 182 consistently offered alongside treatment for substance use disorder, as well as other harm
- 183 reduction and HIV prevention services for this patient population. There are currently four
- antiretroviral medications approved for PrEP: two in pill form for daily use (i.e., tenofovir
- disoproxil fumarate/emtricitabine and tenofovir alafenamide/emtricitabine) and two as long-
- acting injections (LAI) administered bi-monthly and every six months (cabotegravir and
- lenacapavir, respectively).<sup>39</sup> Clinical trials are in progress to evaluate the efficacy of longer
- duration and exposure to LAI-PrEP medications to provide more options with the goal of
- increasing PrEP adoption and uptake among individuals at highest risk of acquiring HIV
- 190 infection.
- 191 The ongoing challenges in PrEP uptake underscore the need for targeted interventions that
- 192 improve access and use of PrEP as part of comprehensive HIV prevention strategies. To
- 193 effectively reduce new HIV diagnoses, programs must focus on enhancing PrEP uptake in highly
- 194 impacted communities with low use rates relative to their epidemic needs. For example, HIV
- diagnoses in the Southern regions account for approximately 53% of all diagnoses in the United
- 196 States.<sup>36, 40</sup>
- 197 Pharmacist-Initiated PrEP and PEP
- 198 The latest guidelines for HIV PrEP in the United States underscore a comprehensive approach to
- 199 HIV prevention. Pharmacists are pivotal in expanding access to HIV PrEP and PEP in their
- 200 communities. Community pharmacies serve as accessible points for PrEP and PEP services,
- 201 particularly for patients facing barriers to traditional healthcare settings. In fact, pharmacies are
- often more accessible than traditional healthcare settings, with many located within five miles of
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- 203 most Americans and offering extended hours, including evenings and weekends. This accessibility
- 204 makes it easier for individuals to obtain PrEP without the need for appointments or long wait
- 205 times, particularly benefiting those in rural or underserved areas. Moreover, pharmacies provide
- a non-stigmatizing environment for individuals seeking PrEP. This is particularly important for
- 207 populations that may face discrimination or stigma in other healthcare settings, such as men who
- 208 have sex with men (MSM), transgender individuals, and people who inject drugs.<sup>41</sup> Pharmacists

can offer a more discreet and comfortable setting for discussing and accessing HIV prevention services.

In some states, pharmacists have expanded prescriptive authority to initiate PrEP and PEP under various frameworks. These include standing orders issued by healthcare providers or public health authorities, statewide protocols allowing independent prescription, and direct statutory authority. Collaborative practice agreements (CPAs) further enable pharmacists to manage and initiate PrEP and PEP regimens in collaboration with other healthcare providers. They typically allow pharmacists to perform tasks such as therapy initiation, chronic care management, refill authorization, and formulary management. CPAs enhance patient access to HIV prevention, especially in underserved areas, by leveraging pharmacists' expertise in medication management. Pharmacist involvement can improve patient outcomes, increase cost-efficiency, and reduce the workload on other healthcare providers. These agreements delineate the scope of services pharmacists can provide, such as initiating, modifying, and discontinuing medication therapy. The services are provided to the scope of services agreements delineate the scope of services pharmacists can provide, such as initiating, modifying, and discontinuing medication therapy.

Various legislative frameworks allow pharmacists to have an active role in HIV prevention, from initial assessment and therapy initiation to ongoing monitoring and support. Several pharmacy programs across the United States have successfully expanded access to HIV PrEP and PEP.<sup>46</sup> Notable examples are discussed below:

- California's Senate Bill (SB) 159 marked a historic milestone as the first legislation in the United States to authorize licensed pharmacists to furnish PrEP and PEP without a prescription. This bill permits pharmacists to prescribe up to a 60-day supply of PrEP once every two years, provided certain criteria are met. Under California's Medicaid program, pharmacists must complete a California Board of Pharmacy-approved training program and register as providers. 50 Additionally, SB 159 prohibits insurance companies from imposing prior authorization requirements for individuals seeking to use their benefits to obtain PrEP or PEP. In 2024, California furthered its commitment with the passage of SB 339, which allows pharmacists to furnish up to 90 days of PrEP, contingent upon the pharmacist ensuring that the individual undergoes appropriate HIV testing and follow-up care in accordance with CDC guidelines. 43,51 Assembly Bill 317 (a.k.a., "Pharmacist Service" Coverage") legislation was passed in 2023, which addresses the reimbursement barriers experienced by pharmacists under SB 159 and 339. It mandates commercial health plans to reimburse pharmacists for providing clinical services within their scope of practice, including PrEP and PEP.<sup>52</sup> It aims to expand access to HIV prevention services by ensuring pharmacists are compensated for their work.
- Washington state's One-Step PrEP Program, is a pioneering effort to enhance HIV prevention by making PrEP more accessible in the pharmacy setting. The program offers both in-person and virtual services, known as One-Step PrEP® and One-Step TelePrEP, respectively. These services allow individuals to receive PrEP care with just one

- pharmacist visit every three months, either in-clinic or via a virtual appointment.

  Additionally, most patients incur no cost for the complete care provided. 53
  - In Colorado, HB20-1061 was passed in 2020 which created a statewide protocol for pharmacists to prescribe PrEP and PEP and required private insurers to reimburse pharmacists at the same rate as physicians for these services.<sup>54</sup>
  - Similarly, Oregon passed HB 2958 legislation in 2021 that authorizes pharmacists to prescribe, dispense, and administer PrEP (up to a 90-day supply) and PEP. Pharmacists are to be reimbursed in the "same manner as any other healthcare provider." 55
  - Iowa's TelePrEP Program is an innovative initiative designed to make PrEP more accessible, especially in rural areas. The program, a collaboration between the Iowa Department of Public Health and the University of Iowa, allows individuals to access pharmacist-prescribed PrEP, under a CPA, through secure telehealth services. Patients can consult with pharmacists via a private app on their smartphone, laptop, or tablet, and obtain necessary lab tests locally. Pharmacists can also arrange for PrEP medications to be delivered directly to patients' homes or make available for pickup at a pharmacy of their choice. This program ensures that PrEP is available to all Iowans, regardless of their location, making HIV prevention more convenient and accessible.
  - One study highlighted an initiative in New York City, where pharmacists were authorized to provide a 7-day supply of PEP under a CPA. This successful project used the extensive reach of community pharmacies to ensure timely access to PEP. Following New York's lead, eleven other states adopted similar measures—expanding the role of outpatient pharmacies in making PEP more readily available and ultimately contributing to broader efforts to curb HIV transmission.<sup>57</sup>
  - Philadelphia implemented a program to increase access to PEP through community pharmacies. This initiative involved training pharmacists to provide PEP and ensuring they were reimbursed for their services. The program successfully increased the availability of PEP, particularly in underserved areas, and improved patient outcomes.<sup>58</sup>
  - Illinois passed HB 4430 in 2022 which requires Medicaid and other payors to reimburse pharmacists for patient care services, including PrEP and PEP, at 85% of the rate reimbursed to physicians.<sup>59</sup>

Similar legislative efforts in states such as Maine, Nevada, Utah, and Virginia have granted pharmacists direct prescribing authority for PrEP under a statewide protocol, thereby increasing accessibility to preventive medications. Additional information about other states' legislation for pharmacist-initiated PrEP and PEP can be found via the NASTAD legislative tracker (Legislative Tracker: Pharmacist-Initiated PrEP and PEP | NASTAD). These measures are part of broader efforts to reduce barriers to HIV prevention and ensure timely access to care.

Two studies evaluated the implementation of California's SB 159 legislation in community pharmacies. An observational, cross-sectional survey of independent community and mail-order pharmacies was conducted to evaluate the implementation of California's SB 159 legislation in the San Francisco Bay Area. The study revealed that only 2.9% of pharmacies in the San Francisco

287 Bay Area were providing oral PrEP and PEP under SB 159, and less than 1% were doing so under 288 a CPA.<sup>61</sup> Another cross-sectional survey study evaluated the readiness of community pharmacists to provide long-acting injectable PrEP (LAI-PrEP).<sup>62</sup> The study's findings showed about 53% of 289 surveyed pharmacists indicated they would be willing to administer LAI-PrEP using gluteal 290 291 injections in their pharmacies. Willingness was higher among pharmacists working in pharmacies 292 that already provided vaccinations or other injections (56%) and those providing oral PrEP under 293 SB 159 (65%).<sup>62</sup> Of note, key barriers to LAI-PrEP provision included the need for increased 294 training and staffing, availability of a private room for injections, better medication access, and 295 payment for services.

Regardless of state policies, pharmacists can significantly enhance PrEP and PEP awareness in communities through a multifaceted approach. By educating and counseling patients during routine consultations, pharmacists can explain the benefits of PrEP and PEP and the importance of adherence. Engaging in community outreach through health events and workshops allows pharmacists to reach a broader audience. Collaborations with healthcare providers can ensure a coordinated approach to HIV prevention, while leveraging telehealth services and online platforms to extend their reach to remote areas. Implementing pharmacy-based PrEP and PEP programs reduces barriers to access, and targeted campaigns can address specific misconceptions within disproportionately affected populations. Providing informational resources in pharmacies and advocating for supportive policies could further bolster these efforts. Through these strategies, pharmacists play a crucial role in increasing PrEP and PEP awareness and uptake, ultimately contributing to the reduction of HIV incidence in their communities.

## Treatment of HIV

310 Initiating ART

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- 311 Patient Assessment and Laboratory Testing
- 312 Once the HIV diagnosis is confirmed, appropriate patient assessment and laboratory testing
- 313 should be performed, and pharmacists are commonly at the forefront of these baseline
- 314 evaluations to establish care. The initial patient assessment is important to select the most
- 315 appropriate ART regimen for the patient, as well as other considerations including but not limited
- 316 to opportunistic infection prophylaxis, sexually transmitted infection (STI) management, HIV-
- related complications, and other comorbidity management (e.g., diabetes mellitus, hypertension,
- 318 hyperlipidemia, etc.).
- 319 Patients should have a comprehensive medical and surgical history, physical examination, and
- 320 should be educated or counseled on the diagnosis of HIV and its implications.<sup>6</sup> Pharmacists are
- 321 also essential at performing a comprehensive medication review/reconciliation at baseline to
- 322 identify, assess, and manage potential drug interactions with antiretroviral initiation. 64-67 A
- 323 single-center, retrospective cohort study evaluated the number of antiretroviral-related and

clinically significant drug-drug interactions then identified significant reductions in drug-drug interaction occurrence following pharmacist involvement.<sup>67</sup>

It is important for pharmacists to have foundational knowledge and application of laboratory testing results since these can influence patient management. Table 1 describes the laboratory tests that should be performed initially. For example, pharmacists need to evaluate renal function to determine renal dosing of antiretrovirals, CD4+ T-lymphocyte counts to determine the need for opportunistic infection prophylaxis, hepatitis B co-infection to assess which antiretroviral regimens should be used, pharmacogenomic testing to evaluate if certain antiretrovirals can be used (e.g., abacavir and HLA-B\*5701), management of concurrent sexually transmitted infections, and immunization considerations.

Table 1. Recommendations and Considerations for Initial Laboratory Testing

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CD4+ T-lymphocyte count (and percentage if available)	Comprehensive metabolic panel
Plasma HIV 1/2 antigen/antibody and RNA (viral load)	Complete Blood Cell Count with Differential
Fasting lipid panel	Urinalysis
Genotypic drug-resistance testing	Serologies for hepatitis A, B, and C
Sexually transmitted infections	HLA-B*5701 (if considering abacavir)
Varicella IgG and cytomegalovirus IgG	Toxoplasma gondii IgG

Pharmacists are also commonly involved in efforts to improve adherence to care, initial patient assessment, and laboratory monitoring. One prospective randomized trial evaluated whether computer alerts were effective at increasing the percentage of patients with appropriate laboratory monitoring at initiation of ART.<sup>68</sup> Pharmacists were alerted to missing laboratory test results, had the capability of ordering missing tests, reminded patients to obtain tests, reviewed and evaluated test results, and managed laboratory tests that required interventions. The authors found significant improvement in the percentage of patients receiving laboratory monitoring at ART initiation following the pharmacist-driven intervention. Thus, pharmacist involvement in initial patient assessment and laboratory monitoring is essential and helps to maintain engagement for future patient assessment and laboratory monitoring through the continuum of care.

### Rapid Start

ART initiation on the day of an HIV diagnosis or as soon as possible following diagnosis (within days or weeks), also known as rapid ART or "test and treat," is a strategy to improve linkage to care, increase ART uptake, and reduce time to virologic suppression. However, while rapid ART is shown to improve clinical outcomes and is endorsed by national HIV guidelines, adoption of rapid ART is not widespread. Barriers to implementation of this service include the resource-intensive nature of the approach, the need to consolidate patient services into a single visit, and

provider availability.<sup>69</sup> Ambulatory care pharmacists often have flexible schedules that can accommodate same-day patient visits. In addition to their clinical expertise, pharmacists can navigate payer systems and funding mechanisms to ensure immediate access to ART.

One retrospective cohort study describes the successful implementation of a pharmacist-driven rapid ART program in an urban Ryan White HIV/AIDS Program (RWHAP)-funded clinic in Rhode Island. <sup>70</sup> In this model, two clinical pharmacists utilized a CPA to conduct patient visits, including the ordering of labs and prescribing of medications, for adults with a new diagnosis of HIV who were ART naïve. Clinical outcomes of the novel pharmacist-driven service were compared to those before its implementation. Time to virologic suppression was significantly shorter in the pharmacist-driven rapid ART group compared to the pre-implementation group. Expectedly, time to ART implementation was also significantly shorter in the rapid ART group compared to the pre-implementation group. There were no significant differences in rates of retention in care at one year, which remained high.

This study highlights pharmacist-driven rapid ART as a valuable strategy for expanding access to these critical services. Pharmacists' unique blend of clinical knowledge, widespread availability, and expertise in navigating ART access makes them uniquely poised in evaluating new patients for rapid ART initiation. However, of note, the pharmacists' encounters were non-billable at the time of the study, which underscores the importance of gaining universal provider status to ensure sustainability of these services.

# 375 Maintaining and Simplifying ART

 Maintaining ART Adherence

Modern antiretrovirals are potent, however, patients must still maintain high adherence to receive maximum immunologic and health benefits from their regimens. Prior literature suggested that adherence levels of 95% or higher were required for ART.<sup>71</sup> Subsequent studies indicate that lower adherence levels of 69-80% may still achieve viral suppression when using more modern regimens.<sup>72-73</sup> Maintaining adherence to any medication for chronic disease is a multifaceted challenge that can be framed within the context of the social determinants of health (SDoH). These determinants include economic stability, education access and quality, healthcare access and quality, neighborhoods and built environments, and the social and community context.<sup>74</sup> Income, education, insurance, stigma, health literacy, and other related factors can either positively or detrimentally impact a person's ability to adhere to or access ART in a timely fashion.<sup>75-76</sup> Comorbid conditions such as mental health, substance use, and polypharmacy may pose additional barriers. Lastly, specific regimen characteristics such as pill burden, regimen complexity, and associated side effects may result in lower adherence.

Pharmacist-led interventions to improve ART adherence have proven successful. A systematic review estimated that pharmacist care led to higher odds of achieving desired adherence outcomes in PWH when compared to usual care (OR: 2.70, 95%, CI 1.80-4.05).<sup>77</sup> Adherence programs where pharmacists play a central role have also demonstrated benefits beyond

improved adherence. In one pharmacist-led adherence program based at the University of New Mexico, 16 patients reduced their median viral load from 48,000 copies/mL to undetectable within a 6-month period; a cost-avoidance model estimated that \$2.96 would be saved on future medical expenses for every \$1 spent on the patient intervention.<sup>78</sup>

Pharmacists must take a patient-centered approach to support ART use. Each person's challenges are unique, and tailored strategies must be employed to optimize adherence.<sup>79</sup> Pharmacists should screen for adherence problems at pharmacy visits using self-report tools or by calculating prescription medication possession ratios.<sup>80</sup> For patients having medication access issues, pharmacists can leverage automatic refills, medication delivery services, and manufacturer patient assistance or copay programs. Pharmacists can review insurance formularies to identify covered antiretroviral medications and support completion of any necessary authorizations. Pharmacists who have training in motivational interviewing may use those skills to discern reasons behind missed doses and can offer tools such as reminder packaging and digital health apps to improve adherence. Pharmacists should work closely with the interdisciplinary team to adjust any ART regimens that hinder adherence due to side effects or complexity.

# Streamlining ART Regimens

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Streamlining an ART regimen can potentially decrease pill burden, reduce adverse effects, and improve adherence. Increased evidence supports switching regimens in patients who are virally suppressed. Switching may be performed for modernization purposes (substituting older antiretrovirals for newer ones with higher potency, lower toxicity, or fewer drug interactions) or simplification purposes (consolidating medications to increase convenience and reduce pill burden) or both.<sup>81</sup> One way to achieve this is to combine medications using single tablet regimens (STR) and fixed-dose combination (FDC) pills. Doing so may have the added benefit of decreasing medication copays if fewer pills are needed. 82 Use of STR and FDC may require switching between formulations or between similar medications such as substituting tenofovir alafenamide for tenofovir disoproxil fumarate, interchanging emtricitabine for lamivudine, or replacing ritonavir cobicistat as a pharmacokinetic enhancer. Two-drug regimens dolutegravir/rilpivirine, dolutegravir/lamivudine, or the long-acting injectable regimen cabotegravir with rilpivirine may also be appropriate options. 83-85

HIV pharmacists can review patient ART regimens to identify opportunities for simplification and modernization. Pharmacists should consider the patient's ART history, pattern of viral load measures, past adverse effects, all prior resistance tests, and history of adherence prior to recommending any switch. They should also evaluate concomitant medications to manage any drug-drug interactions that may ensue (or that may be undone) after changing medications. Pharmacists can follow up with patients after switching, to ensure the viral load remains suppressed and to assess any positive or negative changes in adverse effects and adherence.

Pharmacists currently play an important role in facilitating implementation of long-acting injectable antiretroviral therapy regimens (LAI-ART). These novel treatments can increase convenience and simplicity for patients by removing the requirement for daily oral therapy. They

433 also require close coordination between pharmacies, clinics, laboratories, and patients. 434 Pharmacists can support access to LAI-ART by facilitating procurement from pharmacies to clinics 435 for administration, or by helping clinics set up buy-and-bill processes. Pharmacists may screen 436 patients for eligibility for long-acting therapies and provide recommendations to the 437 interdisciplinary team on whether candidates may benefit from LAI-ART regimens. Pharmacists 438 should educate patients on the need for adherence to injection visits, on required laboratory 439 draws, and on the management of side effects. A pharmacist-led program in New York was 440 successful in initiating 43% of referred patients (n=73/171 referrals) onto LAI cabotegravir with rilpivirine and retaining 90% of the enrolled patients in care. 86 As new LAI agents emerge through 441 442 the antiretroviral pipeline, pharmacists will continue to be core team members for 443 implementation of these treatments.

# **Management of Virologic Failure**

- Pharmacists are commonly involved in the prevention, recognition, and management of HIV treatment failure. In collaboration with other members of the healthcare team, pharmacists routinely monitor trends and interpret CD4+ T-lymphocyte counts and HIV RNA viral loads. Pharmacists have a significant role in the prevention of treatment failure by improving adherence, mitigating potential drug interactions, managing pharmacokinetic issues, and providing education. Pharmacist involvement, particularly in integrated care models, has demonstrated reductions in virologic failure and preservation of the initial antiretroviral regimen.<sup>87</sup>
- Virologic failure is defined as the inability to achieve or maintain suppression of viral replication to HIV RNA level of <200 copies/mL.<sup>6</sup> Pharmacists should closely monitor trends in HIV RNA viral load to identify significant changes. If virologic failure occurs, pharmacists should work collaboratively with the treatment team to identify the most likely cause and implement strategies to mitigate their occurrence.
- 457 Pharmacists specialized in HIV are highly trained and qualified to perform drug-resistance testing 458 with respect to appropriate timing, interpretation of the test results with associated drug 459 resistance (if applicable), identification of potential treatment options available based on the HIV 460 resistance mutation patterns and associated antiretroviral medications, and development of a 461 new ART plan to optimize the chances of virologic suppression.
- 462 Pharmacists are also commonly sought after and involved in management of PWH who are 463 heavily treatment-experienced and/or have multidrug resistant HIV, particularly when novel 464 antiretrovirals need to be considered and used.<sup>88</sup> Depending on the scenario, limited fully active 465 options may be available in addition to optimized background therapy. It is crucial that 466 pharmacists are highly involved in providing continuous adherence support in these scenarios of 467 previous virologic failure with the goal of reestablishing virologic suppression and improving 468 CD4+ T-lymphocyte count to prevent HIV-related complications (e.g., opportunistic infections, 469 malignancies), reduce the risk of transmission, and improve the person's quality of life.

# **Antiretroviral Stewardship**

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PWH often require hospitalization for secondary conditions and may receive care from healthcare providers lacking specialized HIV training. This can increase the likelihood of inadvertently altering a patient's antiretroviral regimen upon transfer, thus resulting in downstream viral resistance and adverse effects. The frequency of inpatient antiretroviral errors has been reported as high as 86% and include antiretroviral or opportunistic infection medication omissions, incorrect dosing or scheduling of antiretrovirals, and drug interactions.<sup>89</sup> Antiretroviral stewardship programs (ARVSPs) offer a promising strategy to minimize these errors and maintain viral suppression. The Infectious Disease Society of America, HIV Medicine Association, and American Academy of HIV Medicine have called for implementation of ARVSPs into health systems to enhance patient safety.90 These programs require collaboration among interprofessional healthcare providers including physicians, advanced practice providers, and pharmacists. Antiretroviral stewardship is defined as "coordinated interventions designed to improve continuity of care for patients receiving antiretrovirals through the utilization of evidence-based antiretroviral practices including medication reconciliation, dosing, mitigation of drug interactions, and prevention of viral resistance."90 Notable ARVSP interventions include prospective review of electronic medical records, clinical checklists or protocols at care transitions, computerized physician order entry sets, and drug formulary management.

Pharmacists play an important role in optimizing ART and improving patient safety through ARVSPs. Numerous studies have explored the successful implementation and sustainability of interdisciplinary ARVSP teams. Notably, ARVSPs with pharmacist involvement have been shown to significantly reduce drug interactions, <sup>67,91</sup> mitigate medication errors, <sup>92-97</sup> and prevent prescribing errors. <sup>98</sup> Pharmacist-led ARVSPs have additionally demonstrated value in reducing hospital readmission rates and increasing linkage to outpatient HIV care. <sup>99-100</sup> In one study, the one-year cost savings for an inpatient ARVSP was estimated to be approximately \$263,000. <sup>101</sup> Because of the enormous benefits demonstrated by ARVSPs, programs have expanded in resource-limited countries as well. <sup>102</sup>

ARVSPs are not limited to only inpatient environments. Ambulatory care clinical pharmacists may be involved in ARVSPs in outpatient settings. One such study describes improved clinical outcomes with implementation of an ARVSP in an outpatient pediatric HIV clinic. 103 Pharmacists are essential contributors to ARVSPs, optimizing therapy, improving patient outcomes, and ensuring the long-term sustainability of these initiatives.

# **Transitions of Care**

Pharmacists play an indispensable role in the transitions of care for PWH, significantly impacting their health outcomes and overall quality of life. This role is multifaceted, encompassing medication management, patient education, adherence support, care coordination, and access facilitation. During transitions between different healthcare settings, pharmacists review and reconcile patients' ART and other medications. This process is critical for identifying and resolving discrepancies, ensuring that patients receive the correct medications and dosages. By preventing potential adverse effects and drug-drug interactions, pharmacists help ensure patient safety and the efficacy of HIV treatment regimens. <sup>16,99,104</sup>

Patient education is another critical area where pharmacists make a substantial impact. They provide comprehensive guidance on medication regimens to patients, explain how to take medications correctly, manage potential side effects, and emphasize the importance of adherence to ART. Education is vital for maintaining viral suppression and preventing the development of drug resistance. Pharmacists are also leaders in coordination during transitions of care to help create a seamless continuum of care for PWH. They work closely with a multidisciplinary team of healthcare providers, including physicians, nurses, and social workers, to ensure a cohesive and comprehensive approach to patient care that addresses the diverse and individualized needs of PWH. 105-106 By empowering patients with knowledge, pharmacists enable them to take an active role in managing their health.<sup>5,7,16</sup> Medications access is another critical aspect of the pharmacist's role. Pharmacists assist patients in navigating insurance and financial assistance programs, ensuring they have access to their medications. They manage medication refills and address any issues related to drug availability and formulary changes, thereby removing barriers to consistent treatment. By facilitating access to essential medications, pharmacists help ensure that PWH can maintain their treatment regimens without interruption.<sup>16</sup>

Two case studies have highlighted the significant role pharmacists play in the transitions of care for PWH. As integral members of a multidisciplinary healthcare team, pharmacists addressed comorbidities, optimized medication regimens, and ensured smooth transitions of care for PWH. The contributions pharmacists have made in this clinic have positively impacted the virologic outcomes and the overall health of PWH.<sup>5</sup> Another case study explored the impact of pharmacist-driven services and involved multiple aspects of HIV care, including medication reconciliation, communication with medical providers, and monitoring for adverse effects and drug interactions. Their involvement improved patient outcomes and enhanced the overall quality of care for PWH.<sup>104</sup>

Through pharmacists' expertise in medication management, patient education, adherence support, care coordination, and access facilitation, pharmacists play a vital role in enhancing the quality of care and improving health outcomes for PWH. By providing consistent and proactive care during the patient's transitions of care process, pharmacists help PWH achieve better health outcomes.<sup>77</sup> Their contributions are a testament to the critical role that dedicated healthcare professionals can play in the lives of those with HIV.

## Treatment and Prevention of HIV Across the Lifespan

Pharmacists hold unique expertise that can enhance treatment and prevention of HIV across various stages of an individual's life. This includes interventions in sexual and reproductive health, and the care of key populations including individuals identifying as lesbian, gay, bisexual, transgender, queer, and others (LGBTQ+), pregnant individuals, pediatric patients, geriatric patients, and transplant recipients.

# 550 Sexual and reproductive health

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Activities pharmacists may perform that support sexual and reproductive health range from screening for and administering routine immunizations such as human papilloma virus and mPOX vaccination, counseling on barrier methods such as condoms to prevent HIV and STIs and encouraging use of PrEP and PEP when appropriate. For PWH who are of childbearing age, all clinicians should be routinely assessing their desire for parenthood. Pharmacists in some states can furnish hormonal and emergency contraception for patients who do not desire pregnancy during certain timeframes of their lives. When recommending or dispensing contraception for PWH, pharmacists should carefully review drug-drug interactions between antiretrovirals and hormonal contraceptives.

# Pregnant people

In the United States, vertical HIV transmission occurs less than 1% of the time due to expanded HIV testing, maternal use of ART, increased uptake of PrEP for preconception, and technologies such as sperm washing. 110-111 If a pharmacist is the first healthcare provider a pregnant person encounters while purchasing an over-the-counter pregnancy test or obtaining a routine refill, they can assist with linkage to appropriate prenatal care. Pharmacists may also hold consultative roles on multidisciplinary teams. They should refer to the U.S. Perinatal HIV treatment guidelines for the most current evidence on HIV ART management during pregnancy. 110 There are multiple pharmacologic considerations: certain ART should be avoided during pregnancy due to concerns about efficacy or toxicity, some agents such as darunavir plus ritonavir must be dose-adjusted during the third trimester, and evidence is always evolving around the safety of newer ART agents and their impact on fetal development. 112 By remaining up to date, a pharmacist can ensure optimal selection of pharmacotherapy, support adherence, and facilitate access to medications. Some hospitals may not routinely stock the ART regimen a patient needs while hospitalized, such as intravenous zidovudine if the patient is not virally suppressed, or pediatric ART formulations required by the infant for prophylaxis or treatment. Pharmacists can educate patients on breastfeeding or chestfeeding in the setting of an undetectable viral load and can reinforce the need to maintain high ART adherence if the parent chooses this strategy for their infant. An example of the ways that pharmacists can improve the peri- and antenatal care of PWH is described by the Northern Alberta HIV Program, where a team of clinical pharmacists provides the services outlined above. 113

## 581 *Pediatric care*

Multiple pharmacologic considerations also exist for the treatment of pediatric patients, and pharmacists working closely with this population should familiarize themselves with national

guidelines that outline current standards of care.<sup>114</sup> Factors such as an infant's risk of acquiring HIV from vertical transmission, a child's age, laboratory values, ability to take pills, and comorbidities all guide the selection and timing of pediatric ART. However, as with most aspects of HIV, care standards evolve and change rapidly. Pharmacists can be a valuable resource to a team if they remain up to date around the safety and efficacy of different ART formulations as they are developed, adapted, and studied for use in children. Unlike for adults, where ART dosing is standardized, developmental differences in absorption, distribution, metabolism, and elimination influence ART dosing in children, which is based on weight, age, or body surface area.<sup>115</sup> Pharmacists are vital to ensure accurate ART dosing and formulations are provided, especially as children age and grow. Several pediatric ART formulations are not interchangeable on a milligram-per-milligram basis with adult tablets (e.g., raltegravir, dolutegravir, and rilpivirine-containing medications).

Supporting adherence can be complex when a caregiver is responsible for administering medications to a child. The dynamic shifts again over time as children and adolescents begin to hold responsibility for administering their own medications. Pharmacists must tailor educational strategies to fit the needs of both caregivers and children to promote adherence. Palatability can also be a barrier; pharmacists can advise on strategies to change or disguise the taste of certain antiretroviral medications. One retrospective review documented 8,893 patient care interventions performed by pediatric HIV clinical pharmacists at a healthcare center over a seven-year period; the study also observed an increase in proportion of pediatric patients with undetectable viral loads. 118

# Aging and HIV

Population models in the United States suggest that by the year 2030, the median age of a person using ART will be 52 years of age. 119 PWH may age more rapidly than those without HIV, and mechanisms for this (direct impact of virus versus virus as a risk factor that accelerates aging) remain unclear. With aging, many medication issues arise for pharmacists to be aware of. Older people are at higher risk of polypharmacy and drug-drug interactions due to accumulation of treatments for comorbidities. They may experience side effects from medications more frequently as drug metabolism changes with age. Use of medications that are not recommended for elderly people can result in increased frailty, falls, and cognitive impairment. Patients may need to add medications to stimulate bone health and reduce fracture risk, and pharmacists may need to review regimens to switch out any ART which could increase risk. Declining cognition may lead to lower ART adherence. Shifts in insurance coverage at later stages of life may also impact access to ART. Pharmacists can lead key initiatives to reduce polypharmacy, improve medication safety, and increase satisfaction for people aging with HIV and their providers. 120-121 A pharmacist-led program to reduce use of potentially inappropriate medications in older PWH found a large proportion of elderly clinic patients were prescribed medications that are not recommended by Beers (54%) or STOPP (63%) criteria. 122 The pharmacist in this program discontinued at least one medication for 69% of those individuals. Pharmacists working with older PWH should regularly assess medications for opportunities to deprescribe or substitute 624 potentially inappropriate therapies, to manage emerging adverse effects, and to manage drug-

drug interactions. Pharmacists can assist patients who may be changing insurance or shifting to

Medicare coverage to ensure their selected plan offers adequate, affordable coverage for ART

and other necessary medications.

## Treatment of HIV in Key/Special Populations

629 *LGBTQ+ Community* 

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630 Pharmacists play a vital role in providing inclusive healthcare services for sexual and gender

631 minorities, also referred to as LGBTQ+. They are actively involved in managing gender-affirming

hormone therapy (GAHT), ensuring that patients receive the correct dosages, monitor for any

side effects (e.g., changes in mood, weight, and cardiovascular health), and offer guidance on

634 medication adherence. Additionally, pharmacists are key players in HIV prevention and

treatment, offering PrEP and PEP to prevent HIV acquisition, as well as supporting PWH in

636 adhering to their ART regimens. 123-125

637 Beyond these specific services, pharmacists also assist in managing chronic conditions such as

diabetes, hypertension, and mental health issues, which can disproportionately affect sexual and

639 gender minorities. 126-127 Pharmacists work closely with endocrinologists and primary care teams

to ensure a coordinated approach to GAHT management. They strive to create a welcoming and

affirming environment by using inclusive language, understanding the unique health disparities

faced by these communities, and advocating for their needs within the healthcare system. 128-130

One descriptive, cross-sectional study delved into the pivotal role pharmacists play in supporting

sexual and gender minorities. 131 The authors explored the readiness of pharmacists to provide

pharmaceutical care to transgender patients from both pharmacists' and transgender individuals'

646 perspectives. The study concluded that addressing educational gaps (e.g., targeted educational

interventions to improve pharmacists' understanding and competence in providing care to

transgender patients) and barriers (e.g., lack of training, discomfort with the topic, and

insufficient resources) is crucial to enhance the quality of medication management provided to

650 transgender patients.

A survey study conducted by Jacobson and colleagues explored the campus climate regarding

LGBTQ+ care inclusion at colleges and schools of pharmacy. 132 They underscored the necessity

for pharmacists to be well-versed in the unique health needs and challenges faced by the LGBTQ+

654 community. They advocated for the integration of LGBTQ+ health topics into pharmacy education

and training, ensuring that future pharmacists are equipped with the knowledge and sensitivity

required to serve this population effectively. Another study discussed the discrepancies in care

for LGBTQ+ patients and how pharmacists can support more inclusive practices. These include

658 incorporating adequate education and training on LGBTQ+ health issues and fostering culturally

competent and equitable patient care in the pharmacy curricula. 133

There is a position statement that calls for pharmacists to adopt inclusive practices. This includes

using patients' preferred names and pronouns, fostering a welcoming environment, and being

cognizant of the specific health disparities that disproportionately affect LGBTQ+ individuals.<sup>134</sup>
Through these practices, pharmacists can create a more inclusive and supportive healthcare
experience for their sexual and gender diverse patients.<sup>135-136</sup>

One study demonstrates the pivotal role pharmacists can have in addressing the unique healthcare needs of the LGBTQ+ community. Conducted across three sites in California, Mississippi, and Florida, the study highlights the breadth of services provided by pharmacists, including GAHT management, antiretroviral adherence programs, primary care and chronic disease management, and mental health and substance use care. The findings underscore the potential of pharmacist-led services to significantly mitigate health disparities among sexual and gender minorities. By optimizing medication regimens, reducing adverse drug events, enhancing medication acquisition, and improving medication adherence, pharmacists can make a profound impact on the health outcomes of this community. Interestingly, there were several barriers and challenges to the implementation of these services that were identified. Stigma, discrimination, lack of provider knowledge, legislative and regulatory obstacles, along with variations in the scope of practice for pharmacists across different states, pose significant hurdles. These barriers highlight the need for policy changes to support the expansion of pharmacist-led services.

The critical role of pharmacists in providing inclusive and effective healthcare for the LGBTQ+ community deserves broader recognition. Through education, inclusive practices, advocacy, and efforts to overcome barriers to care, pharmacists could contribute to the creation of a more equitable, respectful, supportive, and high-quality healthcare system for all.<sup>138-139</sup>

682 People with HIV undergoing transplant

People with well-controlled HIV are candidates for solid organ and hematopoietic stem cell transplant (HSCT). Solid organ transplant outcomes for PWH have improved with more potent ART, greater use of integrase inhibitor-based ART versus protease inhibitor-based ART (which mitigates potential for drug-drug interactions), and the efficacy of direct-acting antiviral agents for HCV treatment. The HIV Organ Policy Equity (HOPE) Act allows PWH to serve as organ donors, and recent updates have further expanded opportunities for PWH to receive an organ at centers with expertise to perform such transplants. Outcomes for HSCT have not been demonstrated to differ between people with and without HIV and, in some rare cases, HSCT has provided a unique opportunity to try to cure HIV.

Pharmacists with expertise in transplant are typically included in multidisciplinary teams. <sup>143-144</sup> There are a host of pharmacologic issues that must be addressed along the continuum of the transplant process, and special considerations for HIV are addressed in national HIV treatment guidelines. <sup>6</sup> Pharmacists can assist in optimizing the ART regimen prior to transplant to avoid drug-drug interactions with immunosuppressants and other necessary supportive and prophylactic therapies. Maintaining viral suppression throughout the peri-transplantation process is critical, and pharmacists can support adherence to therapy through monitoring labs, education and counseling, and ensuring consistent access to medications. ART formulations may need to be adjusted due to fluctuations in kidney and liver function around the time of transplant;

STRs may need to be interchanged with individual components to adjust dosing, or liquid or crushed antiretrovirals may need to be substituted for administration via other routes. Patients may struggle with polypharmacy, especially given that comorbidities requiring treatment may emerge or worsen post-transplant. Pharmacists working with this population can provide immense support as patients navigate the lifelong journey of medications associated with receiving a transplant.

## **Pharmacist Care of Comorbid Conditions in People with HIV**

Compared to the general population, PWH may be more susceptible to chronic disease. ART allows people to live longer but when taken over the lifespan may also augment the development of disease or disease risk. Aging can compound inflammation caused by HIV, and the complete pathways by which HIV intersects with other chronic comorbidities are not well understood. Statistics predict that by the year 2030, 70% of people on ART will have more than one chronic condition that requires management, in addition to HIV.

Pharmacists hold an increasingly expanding role in the care and management of PWH with chronic comorbid conditions. There is a body of literature describing the impact of pharmacists on specific diseases and a smaller body of literature describing pharmacists' impact on the care of patients with comorbidities. These reports may describe specialty-trained pharmacists, often working in multidisciplinary teams, or pharmacists in the community. Some pharmacists may operate under CPAs to provide direct patient care; others may act through state authorities. Irrespective of the setting, pharmacist expertise can improve health holistically, for conditions that extend beyond HIV.

Pharmacists caring for PWH and comorbidities can encompass certain activities common to the care for any disease. For example, most common chronic conditions have treatment guidelines that pharmacists must familiarize themselves with; separate guidelines rarely exist that address management of a chronic condition in the setting of HIV. A useful tool that does address common primary care concerns in PWH is available from the HIVMA/IDSA. As comorbidities accumulate, medications accumulate. Estimates vary depending on the population studied, but non-ART related polypharmacy is generally very common in PWH. Pharmacists must regularly review medication lists to manage drug-drug interactions, support adherence through education and counseling, and facilitate access to medications, especially during transitions of care. The pharmacist must communicate closely with specialists, HIV primary care clinicians, and with other pharmacists to ensure everyone is informed of changes or discrepancies in patients' medication regimens. Pharmacists should be cognizant of the role that SDOH play in worsening chronic conditions and familiarize themselves with local resources to refer patients to. 152

It is beyond the scope of these guidelines to review the management of all common chronic conditions experienced by PWH or to review the entirety of evidence supporting pharmacist care of these conditions in people without HIV. The following sections will highlight select

738 pharmacologic issues unique to PWH that pharmacists should be aware of and examples of 739 pharmacist-based models of care for PWH and other comorbidities.

#### 740 Cardiometabolic diseases

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PWH have a higher likelihood of developing cardiometabolic disease due to a combination of traditional risk factors, untreated HIV, and potential direct impact of ART. 153 Pharmacists can 742 743 provide consultation on the selection or revision of ART regimens when components (e.g., boosted protease inhibitors or abacavir) may potentially influence cardiovascular risk. 745 Medication management can also successfully address modifiable cardiovascular risk factors. 746 One retrospective study found that patients cared for by an interdisciplinary team with a 747 pharmacist had a statistically significant improvement in lipids, smoking cessation, and 748 prescription of preventative aspirin when compared to those cared for by a single primary care provider. 154 Pharmacist care in this study was cost-effective, with an estimated savings of \$3000 749 per patient. Enhanced pharmacist care at a hypertension clinic in Nigeria resulted in higher antihypertensive adherence and a 3.2-fold higher odds of blood pressure control after 12 months 752 in people with hypertension and HIV.<sup>155</sup> Studies are currently evaluating the impact of 753 pharmacist-led interventions to reduce tobacco use in PWH. 156-157 The REPRIEVE trial has 754 expanded indications for statin therapy in PWH, yet statins often remain underprescribed, and pharmacists have an opportunity to improve uptake. 158-159 Multiple systematic reviews support 755 the efficacy and cost-effectiveness of pharmacist management of diabetes. <sup>160</sup> Clinical pharmacist 756 757 care improved diabetes at a Federally Qualified Health Center; PWH experienced similar 758 reductions in hemoglobin A1c (-1.7% vs -1.2%) as people without HIV.<sup>161</sup> There is increasing concern regarding obesity in the general population and in PWH. 162 Pharmacists can provide 760 expert consultation on weight loss pharmacotherapy options and may work closely with interdisciplinary team members to help patients achieve their goals.

#### 762 Chronic kidney disease

In addition to chronic kidney disease from other common causes, PWH are at risk for HIVassociated nephropathy (HIVAN), HIV-associated immune complex disease, and nephrotoxicity from ART.<sup>163</sup> Guidelines for the management of chronic kidney disease can be applied to populations with HIV. 164-165 Pharmacists should ensure regular monitoring of renal function to screen for kidney disease. For patients who have not yet started ART, pharmacists can encourage them to begin treatment given that ART is an important intervention for HIVAN and focal segmental glomerulosclerosis. Pharmacists can review ART regimens and labs to minimize the renal effects of ART, for example, determining whether it may be preferable to substitute tenofovir alafenamide for tenofovir disoproxil fumarate. They are also central to ensuring correct dosing for renally eliminated ART, such as the nucleoside reverse transcriptase inhibitors. Renal dosing may require fixed-dose combination tablets to be substituted with their individual components. Pharmacists may also facilitate adjustments of an ART regimen if patients with endstage renal disease are initiating hemodialysis.

## Viral hepatitis and other hepatic diseases

777 An estimated 5-15% of PWH in the United States are co-infected with hepatitis B virus (HBV), and 778 between 10-30% are coinfected with hepatitis C virus (HCV).<sup>6</sup> Pharmacists have been active in 779 the prevention and treatment efforts of these coinfections. In the United States, pharmacists can 780 immunize patients against HBV, however, the ability to administer specific vaccines depends on the state where the pharmacist is practicing. 166 They can ensure that PWH receive the most 781 782 effective HBV vaccine; currently HepB-CpG is preferred for adult PWH due to improved 783 response.<sup>64,167</sup> For people with HIV/HBV coinfection, pharmacists can recommend ART regimens 784 that are active against both viruses; and they should counsel patients with coinfection on the 785 dangers of acute liver inflammation if abruptly discontinuing ART with HBV activity.

786 Pharmacists have also significantly contributed to the care of people coinfected with and at risk 787 for HIV/HCV. Community pharmacies have demonstrated their ability to increase access to HIV 788 and HCV testing, while serving as sites for provision of clean syringes for people who use 789 injectable drugs. <sup>25-26</sup> Treatment of HCV infection often requires the expertise of specialty-trained 790 pharmacists to navigate complex health systems and insurance coverage for direct-acting 791 antivirals: one study found an average of 2.1 person-hours spent by pharmacy staff members on 792 each HCV antiviral prescription dispensed. 168 Pharmacists leading HCV/HIV coinfection treatment 793 programs perform many functions ranging from facilitating prior authorizations, to adherence counseling, to screening for drug-drug interactions, and more. 169-170 A pharmacist-led HCV 794 treatment program at a Federally Qualified Health Center achieved high rates of sustained viral 795 response (SVR = 76%) in people coinfected with HIV/HCV. 171 796

- PWH may also present with other liver issues such as metabolic dysfunction-associated steatotic liver disease (MASLD), metabolic dysfunction-associated steatohepatitis (MASH), or drug induced liver injury. The pharmacist can closely monitor medications to review for hepatotoxic drugs, assist in the management of metabolic-related conditions such as dyslipidemia, diabetes, hypertension, and obesity, and can recommend therapeutic lifestyle changes to support these conditions as well as liver health.
- 803 Neurologic conditions
- 804 There is a broad spectrum of neurologic conditions associated with HIV disease including 805 conditions such as HIV-associated neurocognitive disorders (HAND) and HIV-associated dementia 806 (HAD). Currently, there are no interventions strongly supported by evidence that improve these 807 types of cognitive impairment. Pharmacists working with PWH who have these conditions should 808 continue to encourage ART use and support high ART adherence. It is helpful for pharmacists to 809 understand basic principles of neurocognitive testing and to continually review medication lists to reduce use of medications that impair cognition. 172 PWH commonly experience neuropathic 810 pain associated with the virus or with the use of older ART medications. <sup>173</sup> Pharmacists can assist 811 812 in designing pharmacotherapy regimens that maximize multimodal treatment.
- 813 Mental health and substance use disorders
- Mental health conditions such as depression, anxiety, serious mental illness, and substance use are highly prevalent in PWH.<sup>174</sup> There is concern for decreased medication adherence and

decreased retention in care for these vulnerable populations; a model that integrated community pharmacists with an HIV medical home found improvements in viral suppression and retention in care for PWH and mental health conditions when compared to standard care models. 175 Pharmacist involvement can improve mental health treatment and HIV treatment. Phased involvement of a clinical pharmacist on an inpatient psychiatric ward significantly increased the proportion of patients with appropriate ART regimens and comprehensive HIV management over time.<sup>176</sup> An offsite, centralized team consisting of a pharmacist and a depression care manager supported PWH and depression at the Veterans Health Administration.<sup>177</sup> Both the HIV and mental health clinicians found pharmacist recommendations regarding antidepressant therapy selection and consultation on drug interactions to be very helpful. Pharmacist roles continue to expand for PWH and substance use. Similar to protocols exploring pharmacist interventions in people with tobacco use and HIV, the effectiveness of pharmacist management of alcohol use in PWH is currently being studied. There are future opportunities for increased pharmacist involvement in medication assisted treatment for opioid use disorder. <sup>178</sup> In addition to providing consultation on pharmacotherapy, pharmacists working with PWH who experience mental health conditions or substance use should use non-judgmental language and relationshipcentered communication strategies to reduce stigma associated with both conditions.

## Malignancy

PWH have an increased lifetime risk of developing AIDS-related and non-AIDS related cancers and have potentially lower survival rates. <sup>179</sup> Pharmacists interacting with PWH with cancer may be situated in a community or specialty pharmacy, in the primary care clinic, or with oncology specialists. Communication across all sectors of pharmacy is crucial for optimal care of PWH and cancer. The pharmacist can play an expanded role by educating PWH regarding recommended cancer screenings. A pharmacist should be included in the consultation prior to the patient undergoing chemotherapy as there may be drug-drug interactions between the proposed chemotherapy agents and the ART regimen, and alternative ART regimens may need to be considered. Pharmacists can facilitate patients' timely and affordable access to chemotherapy agents that are needed. Pharmacists may also support care by managing chemotherapy-associated side effects and adjusting regimens for nausea, mucositis, and other related complications.

Given the evolving nature of clinical guidance for HIV providers, staying current with the latest guidelines and tools is essential for practicing pharmacists (Table 2).

## **Table 2. Key HIV Resources for Pharmacists**

Diagnose		
CDC HIV testing and	services locator	https://locator.hiv.gov/
	CDC HIV testing	https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm
Clinical Practice Guidelines and Recommendations	USPSTF HIV screening	https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening#fullrecommendationstart
Treat		

Hotlines and Clinical Consultation services	National Clinician Consultation Center (ART, PrEP, PEP)	https://nccc.ucsf.edu/
Antiretroviral information (Drug Interactions, Crushing/Liquid	University of Liverpool Drug Interaction Database and Mobile Application	https://www.hiv-druginteractions.org/checker
Formulations)	Toronto General Hospital Immunodeficiency Clinic	https://hivclinic.ca/drug-information/additional-info/
HIV resistance	Stanford HIV drug resistance database	https://hivdb.stanford.edu/
testing and mutations	International Antiviral Society – USA drug resistance chart	https://www.iasusa.org/hiv-drug-resistance/hiv-drug-resistance-mutations/
	HIV-ASSIST  HHS antiretroviral guidelines for adult HIV, pediatric HIV, perinatal HIV, and opportunistic infections in adults and pediatrics	https://www.hivassist.com/ https://clinicalinfo.hiv.gov/en/guidelines
Clinical Practice Guidelines and Recommendations	HIVMA/IDSA primary care guidelines for PWH	https://academic.oup.com/cid/advance- article/doi/10.1093/cid/ciae479/7818967
	Long-acting antiretrovirals for HIV treatment and prevention	https://accpjournals.onlinelibrary.wiley.com/doi/10.1002/phar.2922
	CDC HIV Nexus Directory of AIDS Drug Assistance	https://www.cdc.gov/hivnexus/hcp/resources/index.html
Resources to	Programs	https://adap.directory/
Obtain Prescription Drug Coverage	Pharmaceutical Company HIV Patient Assistance Programs and Cost-Sharing Assistance Programs	https://nastad.org/resources/pharmaceutical-company-patient-assistance-programs-and-cost-sharing-assistance-programs
	out channey toolotained trograms	Prevent
APhA's Pharmacy-Bas Certificate Training Pr	sed HIV Prevention Services ogram	https://www.pharmacist.com/Education/Certificate-Training- Programs/Pharmacy-Based-HIV-Prevention-Services
American Academy of		https://aahivm.org/prep-your-clinic/
	CDC PrEP guidelines	https://stacks.cdc.gov/view/cdc/112360
Clinical Practice	CDC nPEP guidelines	https://stacks.cdc.gov/view/cdc/38856
Guidelines and Recommendations	CDC oPEP guidelines CDC immunization	https://stacks.cdc.gov/view/cdc/20711
nocommendations	recommendations	https://www.cdc.gov/acip/vaccine-recommendations/index.html
	,	Respond
Antiretroviral stewardship	Joint Policy Paper on Antiretroviral Stewardship in Inpatient Practice	https://pubmed.ncbi.nlm.nih.gov/32445480/
Advocacy	American Academy of HIV Medicine	https://aahivm.org/advocacy-and-policy/
	American Pharmacists Association	https://www.pharmacist.com/Advocacy/Issues
	American Society of Health- System Pharmacists	https://www.ashp.org/advocacy-and-issues
	IDSA/HIV Medicine Association	https://www.idsociety.org/policyadvocacy/member-advocacy- program/
Transitions of Care	HIV.gov	https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum  https://www.hiv.gov/hiv-basics/starting-hiv-care/find-a-provider/locate-a-hiv-care-provider#:~:text=Visit%20a%20health%20center%E2%80%94Health,follow%2Dup%20testing%20and%20care.
	HealthHIV.org	https://healthhiv.org/reinforce/#:~:text=The%20REINFORCE%20Center%20from%20HealthHIV.at%20HealthHIV.org/reinforce.

Social Determinants of Health	Center for Health Care Strategies	https://www.chcs.org/resource/screening-social-determinants-health-populations-complex-needs-implementation-considerations/
	HIV.gov	https://www.hiv.gov/topics/socialdeterminants
	Office of Infectious Diseases and HIV/AIDS, US Department of Human Health Services	https://www.hiv.gov/federal-response/ending-the-hiv- epidemic/overview
	World Health Organization	https://www.who.int/publications/i/item/9789241500852

# **Implementation of Pharmacist Services**

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- Addressing Social Determinants of Health (SDoH)
- Any pharmacy practice that serves PWH should consider how to address SDoH, which encompasses the conditions in which people live, learn, work, and play that can affect their health risks, and implement various services including HIV treatment and prevention. Pharmacist involvement is essential for improving health outcomes, particularly for vulnerable populations.
- 855 Through screenings, pharmacists can uncover barriers such as food insecurity, housing instability, lack of transportation, and social isolation. 180-181 By addressing these issues, they can improve 856 857 medication adherence and overall health. For instance, understanding a patient's transportation 858 challenges can lead to solutions like medication delivery services. Pharmacists also collaborate 859 with other healthcare providers to create comprehensive care plans that consider SDoH, ensuring 860 that all aspects of a patient's health are addressed. Additionally, they educate patients about the 861 impact of SDoH on their health and advocate for policies that address these determinants at both community and national levels. 74,177 862
- The multifaceted services provided by pharmacists are crucial in the ongoing effort to manage and prevent HIV transmission. By addressing SDoH and offering specialized HIV services, pharmacists significantly contribute to the health and well-being of individuals and communities. Their expertise, dedication, and patient-centered approach make them invaluable allies in the fight against HIV, fostering a more equitable and supportive healthcare system for everyone.
- 868 Reimbursement Landscape
- Economic evaluations consistently demonstrate the cost-effectiveness of clinical pharmacy services. A comprehensive review of studies from 2011 to 2017 highlighted the financial viability of clinical pharmacist services ranging from general pharmacotherapy to disease management, across various settings such as hospitals, ambulatory care clinics, and community pharmacies. Further analysis from 2016 to 2020 reinforced these findings, emphasizing the economic benefits of pharmacy services in diverse healthcare environments and improving patients' health outcomes. 183
  - Despite this, reimbursement by Medicaid or Medicare and commercial or private health plans for the clinical services pharmacists provide beyond medication dispensing and immunization administration remains complex and variable in each state. Reimbursement practices are often contingent upon the type of service and its setting. Surveys indicate that community and retail pharmacists frequently offer clinical services but encounter significant hurdles in securing sustainable reimbursement. While some services are compensated through traditional fee-for-

service models, others are aligned with value-based payment systems that prioritize outcomes and cost savings. Policy is needed for the sustainable reimbursement of pharmacy services, and literature advocates for standardized reimbursement models that duly recognize the clinical contributions of pharmacists. 185-186

On a national level, the Center for Medicare and Medicaid Services (CMS) has specific guidelines on billing for PrEP. Medicare covers FDA-approved PrEP medications, both oral and injectable, along with associated services such as counseling sessions and HIV screenings. This inclusive coverage ensures that older adults and individuals with disabilities have access to preventive HIV care, reflecting a commitment to protecting vulnerable populations. Pharmacies enrolled as Medicare Part B suppliers can bill for PrEP medications, including the administration fee for injectable PrEP. This not only enhances the accessibility of PrEP but also recognizes the critical role pharmacists play in the healthcare continuum. Unfortunately, CMS does not universally recognize pharmacists as providers, which limits reimbursement opportunities under other insurance plans.

The health insurance reimbursement landscape for pharmacy services in HIV prevention is marked by significant progress and challenges. Establishing CPAs can be challenging, limiting pharmacists' ability to prescribe PrEP and PEP independently. The lack of universal recognition of pharmacists as healthcare providers by CMS and other insurers continues to be a barrier to widespread reimbursement for their HIV prevention services. Legislative advancements in states such as California, Colorado, Illinois, and Oregon, among others, are paving the way for better reimbursement of pharmacy services in HIV prevention. These efforts are extremely important for expanding access to PrEP and PEP, ensuring pharmacists are adequately compensated to sustain their progress toward improving public health outcomes.

# **Advocacy and Professional Engagement**

Pharmacists must serve as strong advocates for both the profession of pharmacy and for populations of PWH to elevate services provided to PWH and other vulnerable populations. Beyond medication dispensing, pharmacists can provide a broad spectrum of support services that are essential for the overall well-being and health of PWH. Advocacy and professional engagement should be directed at the individual patient level, for populations, or aimed at broader systematic improvements that enhance the care ecosystem. Below are examples of multifaceted advocacy efforts to enhance patient medication access, clinical management, collaborative care, education, and public health initiatives.

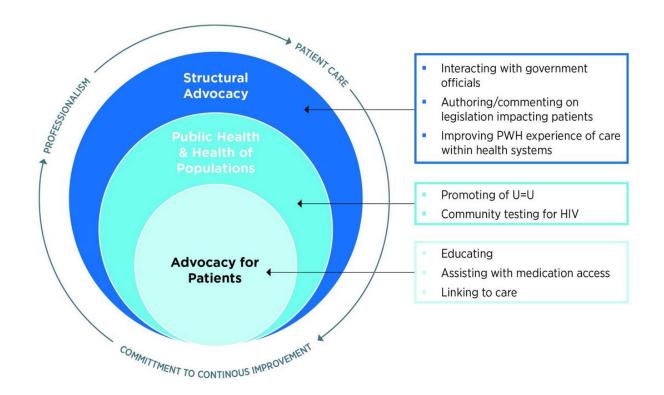
One of the primary challenges faced by PWH is accessing and affording medications. Pharmacists play a critical role in mitigating these challenges by facilitating enrollment in state-run AIDS drug assistance programs and manufacturer co-pay assistance programs.<sup>48-49</sup> These programs are vital to ensure patients can obtain their ART, PrEP, and PEP medications without excessive financial burden.<sup>49,57</sup> Pharmacists adeptly navigate the complex insurance prior authorization processes, dedicating significant time and effort securing approvals to ensure patients receive their

medications promptly, which is crucial for immune health and preventing HIV disease progression.

By providing individualized education, pharmacists empower patients to make informed decisions about their treatment. They educate patients on the importance of adhering to their ART regimens, which is essential for achieving and maintaining an undetectable viral load. This undetectable status is not only critical for the individual's health but also for preventing the transmission of HIV, as encapsulated in the "undetectable equals untransmittable" (U=U) concept. 189 Pharmacists can emphasize adherence during initial diagnosis counseling and routine consultations, addressing any concerns or barriers that patients may face. Their expertise in managing complex medication regimens ensures that patients understand their treatment plans and are aware of potential side effects, thereby enhancing adherence and clinical outcomes. 190

Pharmacists are also champions of public health initiatives, particularly in the realm of HIV prevention and education. In actively promoting the U=U concept, they reinforce scientific evidence that maintaining an undetectable viral load through effective ART prevents the transmission of HIV. This advocacy is crucial in reducing stigma and misinformation surrounding HIV. Pharmacists can participate in community outreach programs, offering HIV testing and counseling services, and raising awareness about HIV, its impact, and prevention strategies (see Figure 2).

Figure 2. The Role of Pharmacists as Advocates for Patients with HIV



941 Healthcare is a shifting landscape and there are many potential structural changes which can 942 improve care for PWH. In their day-to-day work, pharmacists see and hear about relevant issues 943 affecting individual patients. On a broader level pharmacists can also be cognizant of, advocate 944 for, and educate others on federal and state laws that may facilitate or hinder access to quality HIV care. Recognizing the impact of SDoH, this can extend to advocating for issues such as housing, socioeconomic status, and general access to healthcare. Pharmacists may achieve this 946 947 by interacting with local lawmakers, providing public comments on legislative bills and policies 948 when possible, and voting on issues affecting PWH.

Lastly, pharmacists must continue to advocate for themselves and their profession. By participating in HIV planning boards at the state and national levels, in professional pharmacy organizations, and in community-based organizations, pharmacists can advocate for expanded roles in HIV prevention and management. 42,63 Additionally, there is a pressing need for advocacy and policy initiatives to ensure that pharmacists receive appropriate compensation for expanding roles in patient care, mainly in providing PrEP and PEP. Several states have successfully passed legislation authorizing pharmacists to prescribe PrEP and PEP, under protocol or a CPA, and have added provisions for pharmacists to receive compensation for these HIV preventive services. Some states allow reimbursement for pharmacist services in furnishing PrEP/PEP, as mentioned in the PrEP and PEP section above. However, universal compensation for pharmacists' clinical services in this area remains a growing effort.

In summary, pharmacists can be indispensable advocates for PWH and the public health or policy initiatives that impact them. Through their dedication, expertise, and compassionate care, pharmacists play a significant role in ensuring that PWH receive the support and resources they need to manage their health effectively and live fulfilling lives.

## **Research Gaps and Opportunities**

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Many pharmacists would benefit from additional training and mentorship in research to systematically develop, enhance, implement, and promote new recommendations across the HIV care continuum. While the science surrounding HIV therapeutics and drug discovery is often robust, other pharmacy-based HIV and PrEP research have faced criticism for being of moderate quality and lacking strong evidence from randomized trials. <sup>4</sup> To address this, the profession must advocate for increased funding to support sustainable and high-quality pharmacist-led research. Additionally, finding efficiencies that enable more frontline pharmacists to engage in rigorous practice-based research is essential. 190-191 Research opportunities could focus on several areas:

- 1. Integration of innovative pharmacy services: Investigating the challenges and best practices for integrating HIV pharmacy services in various settings (e.g., implementation of LAI PrEP in community pharmacies and pharmacist-led ambulatory care clinics).
- 2. Reimbursement and impact of pharmacist-provided clinical services: Evaluating the cost-effectiveness and impact of the clinical services pharmacists provide in HIV

management and treatment versus the cost of PWH acquiring HIV and/or being hospitalized for an opportunistic infection associated with AIDS.

- 3. Addressing the impact of pharmacist provider status legislation on patient outcomes: Comparing the different legal definitions of pharmacists as healthcare providers in each state and their potential impact on compensation for health counseling and screening for PWH.
- 4. Training pharmacists and pharmacy staff: Expanding HIV clinical training program opportunities for pharmacists and developing effective training programs for pharmacy staff to enhance service delivery.
- 5. Addressing health disparities: Exploring ways pharmacists work to reduce health disparities in HIV and PrEP care through targeted interventions.

Increasing familiarity with diverse research methodologies, such as quasi-experimental studies and implementation science, can enhance the rigor and visibility of pharmacist-led HIV and PrEP research. Viewing pharmacy services or physical pharmacy spaces as "laboratories" for practicebased research can foster a culture of innovation and continuous improvement.<sup>63</sup>

Moreover, there is significant potential in analyzing big data and facilitating access to large pharmacy datasets. These resources can support early-career pharmacist-scientists and expand knowledge about pharmacist-provided HIV care and PrEP services. By leveraging this data, pharmacists can identify trends, measure outcomes, and develop evidence-based practices that improve patient care. To advance the field of pharmacy-based HIV and PrEP research, it is critical to invest in training, mentorship, and funding. Embracing diverse research methods and utilizing big data will enhance the quality and impact of pharmacist-led research, ultimately leading to better health outcomes for PWH and those at risk of acquiring HIV.

### Conclusion

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1003 Pharmacists are uniquely positioned to address the complex challenges and opportunities of HIV 1004 care, from expanding access to testing and prevention services to optimizing ART and managing 1005 comorbid conditions. Their expertise in pharmacotherapy, patient education, and care 1006 coordination is essential for improving health outcomes and enhancing the quality of life for PWH. 1007 The integration of pharmacists into HIV care teams, coupled with their expanded roles and 1008 responsibilities, is pivotal in achieving the ambitious targets of the EHE initiative. More 1009 importantly, pharmacists must continue to advocate for policy changes that support their expanding roles, including recognition of provider status and reimbursement for clinical services. Ongoing research and professional development and training of pharmacists in HIV practice are 1012 crucial for staying abreast of the latest advancements in HIV treatment and prevention. By 1013 fostering a culture of innovation and collaboration, pharmacists can drive significant progress in 1014 the fight against HIV and, ultimately, contribute to the goal of ending the HIV epidemic in the 1015 United States.

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## References

- 1. Centers for Disease Control and Prevention. Monitoring selected national HIV
  1029 prevention and care objectives by using HIV surveillance data United States and 6
  1030 territories and freely associated states, 2022. HIV Surveillance Supplemental Report
  1031 2024;29(No. 2). www.stacks.cdc.gov/view/cdc/156511. Published 2024. Accessed March
  1032 25, 2025.
- Samji H, Cescon A, Hogg RS, et al. Closing the gap: increases in life expectancy among treated HIV-positive individuals in the United States and Canada. *PLoS One*.
   2013;8(12):e81355.
- Davy-Mendez T, Napravnik S, Hogan BC, et al. Hospitalization Rates and Causes Among
   Persons with HIV in the United States and Canada, 2005–2015. *J Infect Dis.* 2021;223(12):2113-2123.
- 1039 4. Crawford ND, Myers S, Young H, et al. The Role of Pharmacies in the HIV Prevention and Care Continuums: A Systematic Review. *AIDS Behav*. 2021;25(6):1819-1828.
- Hill LA, Ballard C, Cachay ER. The Role of the Clinical Pharmacist in the Management of
   People Living with HIV in the Modern Antiretroviral Era. *AIDS Rev.* 2019;21(4):195-210.
- 6. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV. Department of Health and Human Services. www.clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed January 11, 2025.
- 7. Saberi P, Dong BJ, Johnson MO, et al. The impact of HIV clinical pharmacists on HIV treatment outcomes: a systematic review. *Patient Prefer Adherence*. 2012;6:297-322.
- McCree DH, Byrd KK, Johnston M, et al. Roles for Pharmacists in the "Ending the HIV Epidemic: A Plan for America" Initiative. *Public Health Rep.* 2020;135(5):547-554.
- 9. Fauci AS, Redfield RR, Sigounas G, et al. Ending the HIV Epidemic: A Plan for the United States. *JAMA*. 2019;321(9):844-845.
- 10. EHE overview. Health and Human Services Office of Infectious Disease and HIV/AIDS
   1054 Policy. www.hiv.gov/federal-response/ending-the-hiv-epidemic/key-strategies.
   1055 Accessed January 11, 2025.
- DiPiro JT, Hoffman JM, Tichy E, et al. ASHP and ASHP Foundation Pharmacy Forecast
   2025: Strategic Planning Guidance for Pharmacy Departments in Hospitals and Health
   Systems. Am J Health Syst Pharm. 2025;82(2):17-47.
- 1059 12. Dentzer S. Creating the future of artificial intelligence in health-system pharmacy. *Am J Health Syst Pharm.* 2019;76(24):1995-1996.
- 1061 13. Nelson SD. Artificial intelligence and the future of pharmacy. *Am J Health Syst Pharm.* 2024;81(4):83-84.
- 1063 14. Luzum JA, Petry N, Taylor AK, et al. Moving Pharmacogenetics Into Practice: It's All About the Evidence! *Clin Pharmacol Ther.* 2021;110(3):649-661.
- 15. Infectious Diseases Society of America. Position of the Infectious Diseases Society of
   America and the HIV Medicine Association on Team-based Infectious Diseases Care and

- the Roles of Advanced Practice Providers and Clinical Pharmacists. *Clin Infect Dis.* 2024;79(4):807-809.
- 1069 16. Schafer JJ, Gill TK, Sherman EM, et al. ASHP Guidelines on Pharmacist Involvement in HIV Care. *Am J Health Syst Pharm.* 2016;73(7):468-494.
- 1071 17. Centers for Disease Control and Prevention. U.S. Statistics. www.hiv.gov/hiv-1072 basics/overview/data-and-trends/statistics. Accessed March 25, 2025.
- 18. Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing
   of adults, adolescents, and pregnant women in health-care settings. MMWR Recomm
   Rep. 2006;55:1-17.
- 19. Moyer VA, on behalf of the U.S. Preventive Services Task Force. Screening for HIV: U.S.
   1077 Preventive Services Task Force recommendation statement. *Ann Intern Med.* 1078 2013;159:51-60.
- 1079 20. Myers JE, Braunstein SL, Xia Q, et al. Redefining Prevention and Care: A Status-Neutral Approach to HIV. *Open Forum Infect Dis.* 2018;5(6):ofy097.
- Sherman EM, Elrod S, Allen D, Eckardt P. Pharmacist testers in multidisciplinary health care team expand HIV point-of-care testing program. *J Pharm Pract.* 2014;27(6):578-581.
- Darin KM, Klepser ME, Klepser DE, et al. Pharmacist-provided rapid HIV testing in two community pharmacies. *J Am Pharm Assoc (2003)*. 2015;55(1):81-88.
- 1086 23. Collins B, Bronson H, Elamin F, et al. The "No Wrong Door" Approach to HIV Testing:
  1087 Results From a Statewide Retail Pharmacy-Based HIV Testing Program in Virginia, 20141088 2016. *Public Health Rep.* 2018;133:34S-42S.
- 1089 24. Kherghehpoush S, McKeirnan KC. Pharmacist-led HIV and hepatitis C point-of-care
   1090 testing and risk mitigation counseling in individuals experiencing homelessness. *Explor* 1091 *Res Clin Soc Pharm.* 2021;1:100007.
- 1092 25. Klepser DG, Klepser ME, Peters PJ, et al. Implementation and Evaluation of a
   1093 Collaborative, Pharmacy-Based Hepatitis C and HIV Screening Program. *Prev Chronic Dis.* 1094 2022;19:E83.
- 1095 26. Kherghehpoush S, McKeirnan KC. The role of community pharmacies in the HIV and HCV care continuum. *Explor Res Clin Soc Pharm.* 2023;9:100215.
- 1097 27. Deas C, McCree DH. Pharmacists and HIV/AIDS prevention: review of the literature. *J Am Pharm Assoc.* 2010;50(3):411-415.
- Lutnick A, Case P, Kral AH. Injection drug users' perspectives on placing HIV prevention
   and other clinical services in pharmacy settings. *J Urban Health*. 2012;89(2):354-64.
- Darin KM, Scarsi KK, Klepser DG, et al. Consumer interest in community pharmacy HIV screening services. *J Am Pharm Assoc* (2003). 2015;55(1):67-72.
- 1103 30. Lecher SL, Shrestha RK, Botts LW, et al. Cost analysis of a novel HIV testing strategy in community pharmacies and retail clinics. *J Am Pharm Assoc (2003)*. 2015;55(5):488-492.

- 1105 31. Mital S, Kelly D, Hughes C, et al. Estimated cost-effectiveness of point-of-care testing in community pharmacies vs. self-testing and standard laboratory testing for HIV. *AIDS*. 1107 2023;37(7):1125-1135.
- 1108 32. McKeirnan K, Czapinski J, Bertsch T, et al. Training Student Pharmacists to Perform 1109 Point-of-Care Testing. *Am J Pharm Educ.* 2019;83(7):7031.
- Staudt AM, Draime JA, Deitschmann N, et al. Training student pharmacists to facilitate
   human immunodeficiency virus point-of-care testing. *Curr Pharm Teach Learn*.
   2020;12(10):1245-1251.
- 1113 34. Diaz-Cruz ES, Thompson S, Hawkins M, et al. Leveraging Expertise from Community
  1114 Resources to Improve the Role of the Pharmacist in HIV Testing and Counseling. *Innov*1115 *Pharm.* 2021;12(4):10.24926/iip.v12i4.3918.
- 1116 35. Centers for Disease Control and Prevention. Expanding PrEP Coverage in the United 1117 States to Achieve EHE Goals. www.cdc.gov/nchhstp/director-letters/expanding-prep-1118 coverage.html. (accessed 12 Jan 2025).
- 1119 36. AIDSVu releases new PrEP data and launches PrEPVu.org, a new PrEP equity platform.

  1120 AIDSVu. June 25, 2024. www. aidsvu.org/news-updates/aidsvu-releases-new-prep-data1121 and-launches-prepvu-org-a-new-prep-equity-platform/ (accessed 12 Jan 2025).
- Townes A, Tanner MR, Yu L, et al; Targeted Highly Effective Interventions to Reverse the HIV Epidemic (THRIVE) Project Team\*. Inequities Along the Human Immunodeficiency Virus (HIV) Pre-exposure Prophylaxis Services Continuum for Black Women in the United States, 2015-2020. *Obstet Gynecol.* 2024;143(2):294-301.
- 38. Streed CG Jr, Morgan JR, Gai MJ, et al. Prevalence of HIV preexposure prophylaxis
   prescribing among persons with commercial insurance and likely injection drug use.
   JAMA Netw Open. 2022;5(7):e2221346.
- 39. Gandhi RT, Landovitz RJ, Sax PE, et al. Antiretroviral Drugs for Treatment and Prevention
   of HIV in Adults: 2024 Recommendations of the International Antiviral Society–USA
   Panel. JAMA. 2025;333(7):609–628.
- Sullivan PS, DuBose SN, Castel AD, et al. Equity of PrEP uptake by race, ethnicity, sex and region in the United States in the first decade of PrEP: a population-based analysis.
   Lancet Reg Health Am. 2024;33:100738.
- 41. American Pharmacists Association. Pharmacists expand access to PrEP in 17 states.
   1136 2023. www.pharmacist.com/CEO-Blog/pharmacists-expand-access-to-prep-in-17-states.
   1137 (accessed 12 Jan 2025).
- 1138 42. Cocohoba J, Tweedie L, Frank M, et al. Legislation expanding pharmacist scope of 1139 practice to furnish human immunodeficiency virus pre-exposure prophylaxis: a content 1140 analysis. *J Am Coll Clin Pharm.* 2023;7:25-30.
- 1141 43. Cocohoba J, Lam J, Lopez M, Dong BJ. A tale of two bills: Lessons learned in expanding pharmacist-led HIV pre-exposure and post-exposure prophylaxis. *J Am Coll Clin Pharm.* 2024;7:982-983.
- 1144 44. NASTAD. Pharmacist-Initiated PrEP and PEP. www.nastad.org/sites/default/files/2021-1145 11/PDF-Pharmacist-Initiated-PrEP-PEP.pdf (accessed 12 Jan 2025).

- 1146 45. NASTAD. Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative 1147 Practice Agreements. www.nastad.org/sites/default/files/2023-08/PDF-Pharmacist-1148 Authority-Initiate-PrEP-PEP.pdf (accessed 12 Jan 2025).
- 1149 46. NASTAD. Legislative Tracker: Pharmacist-Initiated PrEP and PEP.
   1150 www.nastad.org/resources/pharmacist-initiated-prep-and-pep-2024. (accessed 12 Jan 2025).
- Havens JP, Scarsi KK, Sayles H, et al. Acceptability and Feasibility of a Pharmacist-Led
   Human Immunodeficiency Virus Pre-Exposure Prophylaxis Program in the Midwestern
   United States. *Open Forum Infect Dis.* 2019;6(10):ofz365.
- Lopez MI, Grant RM, Dong BJ. Community pharmacy delivered PrEP to STOP HIV
   transmission: an opportunity NOT to miss! *J Am Pharm Assoc (2003).* 2020;60:e18-e24.
- Lopez MI, Cocohoba J, Cohen SE, et al. Implementation of pre-exposure prophylaxis at a
   community pharmacy through a collaborative practice agreement with San Francisco
   Department of Public Health. J Am Pharm Assoc (2003). 2020;60:138-144.
- SB 159, California Legislature, Senate. HIV: preexposure and postexposure prophylaxis.
   October 8, 2019. California Legislative Information.
- leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill\_id=201920200SB159 (accessed 2024 Feb 6).
- 51. SB 339, California Legislature, Senate. HIV Preexposure Prophylaxis and Postexposure Prophylaxis. https://legiscan.com/CA/text/SB339/id/2832417 (accessed 2024 Feb 6).
- 1166 52. AB 317, California Legislature, Assembly.
- https://legiscan.com/CA/text/AB317/id/2844438#:~:text=Existing%20law%20authorizes %20health%20care,Digest%20Key (accessed 2025 Jan 29).
- Tung EL, Thomas A, Eichner A, et al. Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care. *Sex Health.* 2018;15(6):556-561.
- 1172 54. HB20-1061, Colorado Legislature, House (2023). www.leg.colorado.gov/bills/hb20-1061 (accessed 12 Jan 2025).
- 1174 55. HB 2958, Oregon Legislature, House (2025). chrome-
- extension://efaidnbmnnnibpcajpcglclefindmkaj/https://olis.oregonlegislature.gov/liz/20 1176 21R1/Downloads/MeasureDocument/HB2958 (accessed 12 Jan 2025).
- Hoth AB, Shafer C, Dillon DB, et al. Iowa TelePrEP: A Public-Health-Partnered Telehealth
   Model for Human Immunodeficiency Virus Preexposure Prophylaxis Delivery in a Rural
   State. Sex Transm Dis. 2019;46(8):507-512.
- 1180 57. Scarnati K, Esser K, Sahloff EG, et al. The Role of Community Pharmacies in Providing Access to HIV Post-exposure Prophylaxis (PEP). *J Community Health*. 2024;49(2):222-1182 228.
- 1183 58. Centers for Disease Control and Prevention. Ending the HIV Epidemic in the US Success
  1184 Stories.www.cdc.gov/ehe/php/stories/index.html#:~:text=In%202022%2C%20the%20Ph
  1185 iladelphia%20Department,insurance%20coverage%20barriers%2C%20when%20needed
  1186 (accessed 12 Jan 2025).

- 1187 59. IL HB 4430, Illinois Legislature, House (2025) www.billtrack50.com/billdetail/
   1188 1414180/29918 (accessed 12 Jan 2025).
- 1189 60. National Alliance of State Pharmacy Associations. Pharmacist Prescribing: HIV PrEP and PEP. Published 2022. www.naspa.us/blog/resource/pharmacist-prescribing-hiv-prep-and-pep/. (accessed 12 Jan 2025).
- 1192 61. Bellman R, Mohebbi S, Nobahar N, et al. An observational survey assessing the extent of 1193 PrEP and PEP furnishing in San Francisco Bay area pharmacies. *JAPhA* (2003);62(1):370-1194 377.e3.
- 1195 62. Beltran RM, Hunter LA, Packel LJ, et al. A Mixed Methods Evaluation of Pharmacists'
  1196 Readiness to Provide Long-Acting Injectable HIV Pre-exposure Prophylaxis in California. *J*1197 *Acquir Immune Defic Syndr.* 2024;97(2):142-149.
- 1198 63. Lam J, Cocohoba J. At a crossroads: The crucial role of pharmacists in healthcare teams to end the HIV epidemic. *Am J Health Syst Pharm.* 2024:zxae261.
- 1200 64. Miller CD, El-Kholi R, Faragon JJ, et al. Prevalence and risk factors for clinically significant 1201 drug interactions with antiretroviral therapy. *Pharmacotherapy*. 2007;27(10):1379-1202 1386.
- de Maat MMR, de Boer A, Koks CHW, et al. Evaluation of clinical pharmacist
   interventions on drug interactions in outpatient pharmaceutical HIV-care. *J Clin Pharm Ther.* 2004;29(2):121-130.
- 1206 66. Evans-Jones JG, Cottle LE, Back DJ, et al. Recognition of risk for clinically significant drug interactions among HIV-infected patients receiving antiretroviral therapy. *Clin Infect Dis.* 2010;50(10):1419-1421.
- 1209 67. Billedo JAS, Berkowitz LB, Cha A. Evaluating the impact of a pharmacist-led antiretroviral stewardship program on reducing drug interactions in hiv-infected patients. *J Int Assoc* 1211 *Provid AIDS Care.* 2016;15(1):84-88.
- 1212 68. Raebel MA, Lyons EE, Chester EA, et al. Improving laboratory monitoring at initiation of drug therapy in ambulatory care: a randomized trial. *Arch Intern Med.*1214 2005;165(20):2395-2401.
- 1215 69. Koester KA, Moran L, LeTourneau N, et al. Essential elements of and challenges to rapid
  1216 ART implementation: a qualitative study of three programs in the United States. *BMC*1217 Infect Dis. 2022 Mar 31;22(1):316. doi: 10.1186/s12879-022-07297-3. PMID: 35361148;
  1218 PMCID: PMC8968260.
- 1219 70. Brotherton AL, Coroniti AM, Ayuninjam DK, et al. Pharmacist-Driven Rapid Initiation of 1220 Antiretroviral Therapy Decreases Time to Viral Suppression in People With HIV. *Open* 1221 *Forum Infect Dis.* 2024;11(5):ofae237.
- 71. Paterson DL, Swindells S, Mohr J, et al. Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. *Ann Intern Med.* 2000;133(1):21-30.
- Byrd KK, Hou JG, Hazen R, et al; Patient-Centered HIV Care Model Team. Antiretroviral
   Adherence Level Necessary for HIV Viral Suppression Using Real-World Data. *J Acquir Immune Defic Syndr.* 2019;82(3):245-251.

- 73. Stover S, Milloy MJ, Grant C, et al. Estimating the minimum antiretroviral adherence
   required for plasma HIV-1 RNA viral load suppression among people living with HIV who
   use unregulated drugs. AIDS. 2022;36(9):1233-1243.
- 74. Department of Health and Human Services Office of Disease Prevention and Health
   Promotion. (n.d.). Social Determinants of Health—Healthy People 2030. (accessed 26
   Jan 2025).
- 75. Carvalho PP, Barroso SM, Coelho HC, et al. Factors associated with antiretroviral therapy
   adherence in adults: an integrative review of literature. *Cien Saude Colet*.
   2019;24(7):2543-2555.
- Mgbako O, Conard R, Mellins CA, et al. A Systematic Review of Factors Critical for HIV
   Health Literacy, ART Adherence and Retention in Care in the U.S. for Racial and Ethnic
   Minorities. AIDS Behav. 2022;26(11):3480-3493.
- 77. Ahmed A, Abdulelah Dujaili J, Rehman IU, et al. Effect of pharmacist care on clinical outcomes among people living with HIV/AIDS: A systematic review and meta-analysis.
   Res Social Adm Pharm. 2022;18(6):2962-2980.
- 1242 78. Dilworth TJ, Klein PW, Mercier RC, et al. Clinical and Economic Effects of a Pharmacist-1243 Administered Antiretroviral Therapy Adherence Clinic for Patients Living with HIV. *J* 1244 *Manag Care Spec Pharm.* 2018;24(2):165-172.
- 1245 79. Iacob SA, Iacob DG, Jugulete G. Improving the Adherence to Antiretroviral Therapy, a
   1246 Difficult but Essential Task for a Successful HIV Treatment-Clinical Points of View and
   1247 Practical Considerations. Front Pharmacol. 2017;8:831.
- Amico KR, Zuniga JM, Wilson IB, et al. Provider guidance for linking patients to
   antiretroviral therapy adherence interventions: recommendations from an IAPAC
   advisory committee on adherence monitoring and support. *J Int Assoc Provid AIDS Care.* 2013;12(2):79-83.
- 1252 81. Altice F, Evuarherhe O, Shina S, et al. Adherence to HIV treatment regimens: systematic literature review and meta-analysis. *Patient Prefer Adherence*. 2019;13:475-490.
- 1254 82. Cohen J, Beaubrun A, Bashyal R, et al. Real-world adherence and persistence for newly-1255 prescribed HIV treatment: single versus multiple tablet regimen comparison among US 1256 medicaid beneficiaries. *AIDS Res Ther.* 2020;17(1):12.
- Aboud M, Orkin C, Podzamczer D, et al. Efficacy and safety of dolutegravir-rilpivirine for maintenance of virological suppression in adults with HIV-1: 100-week data from the randomised, open-label, phase 3 SWORD-1 and SWORD-2 studies. *Lancet HIV.* 2019;6(9):e576-e587.
- Orkin C, Oka S, Philibert P, et al. Long-acting cabotegravir plus rilpivirine for treatment in adults with HIV-1 infection: 96-week results of the randomised, open-label, phase 3 FLAIR study. *Lancet HIV.* 2021;8(4):e185-e196.
- van Wyk J, Ajana F, Bisshop F, et al. Efficacy and Safety of Switching to
   Dolutegravir/Lamivudine Fixed-Dose 2-Drug Regimen vs Continuing a Tenofovir
   Alafenamide-Based 3- or 4-Drug Regimen for Maintenance of Virologic Suppression in

- Adults Living With Human Immunodeficiency Virus Type 1: Phase 3, Randomized, Noninferiority TANGO Study. *Clin Infect Dis.* 2020;71(8):1920-1929.
- Nguyen NM, Kavanagh R, Gozar M, et al. Implementation of a Pharmacist-Led, Long Acting, Injectable Cabotegravir/Rilpivirine Program for HIV-1 at Health System-Based
   Clinics in the New York Metropolitan Area. AIDS Patient Care STDS. 2024;38(3):115-122.
- 1272 87. Byrd KK, Hou JG, Bush T, et al. Adherence and viral suppression among participants of the patient-centered Human Immunodeficiency Virus Care Model Project: a collaboration between community-based pharmacists and HIV clinical providers. *Clin Infect Dis.* 2020;70(5):789-797.
- 1276 88. Cluck DB, Chastain DB, Murray M, et al. Consensus recommendations for the use of 1277 novel antiretrovirals in persons with HIV who are heavily treatment-experienced and/or 1278 have multidrug-resistant HIV-1: Endorsed by the American Academy of HIV Medicine, 1279 American College of Clinical Pharmacy. *Pharmacotherapy*. 2024;44(5):360-382.
- 1280 89. Li EH, Foisy MM. Antiretroviral and Medication Errors in Hospitalized HIV-Positive Patients. *Ann Pharmacother.* 2014;48(8):998-1010.
- 90. Koren DE, Scarsi KK, Farmer EK, et al. A Call to Action: The Role of Antiretroviral
  Stewardship in Inpatient Practice, a Joint Policy Paper of the Infectious Diseases Society
  of America, HIV Medicine Association, and American Academy of HIV Medicine. *Clinical Infectious Diseases*. 2020;70(11):2241-2246. doi: 10.1093/cid/ciz792
- Bias TE, Venugopalan V, Berkowitz LB, et al. Incidence of Antiretroviral Drug Interactions
   During Hospital Course: The Role of a Pharmacist-Led Antiretroviral Stewardship
   Program. J Pharm Technol. 2014;30(2):48-53.
- 1289 92. Shea KM, Hobbs AL, Shumake JD, et al. Impact of an antiretroviral stewardship strategy on medication error rates. *Am J Health Syst Pharm.* 2018;75(12):876-885.
- 1291 93. Bernard GB, Montalvo S, Ivancic S, et al. Implementation of a pharmacist-led ARVSP in an academic hospital to reduce ART errors. *J Am Pharm Assoc (2003)*. 2022;62(1):264-1293 269.
- 1294 94. Nimarko K, Bandali A, Bias TE, et al. Impact of an Antimicrobial Stewardship Team on Reducing Antiretroviral Medication Errors. *Ann Pharmacother*. 2020;54(8):767-774.
- Sanders J, Pallotta A, Bauer S, et al. Antimicrobial stewardship program to reduce
   antiretroviral medication errors in hospitalized patients with human immunodeficiency
   virus infection. *Infect Control Hosp Epidemiol.* 2014;35(3):272-277.
- Jucker J, Mittal J, Jen SP, et al. Impact of Stewardship Interventions on Antiretroviral
   Medication Errors in an Urban Medical Center: A 3-Year, Multiphase Study.
   Pharmacotherapy. 2016;36(3):245-251.
- Pettit NN, Han Z, Choksi A, et al. Reducing medication errors involving antiretroviral therapy with targeted electronic medical record modifications. *AIDS Care*.
   2019;31(7):893-896.
- 1305 98. Guo Y, Chung P, Weiss C, et al. Customized order-entry sets can prevent antiretroviral
   1306 prescribing errors: a novel opportunity for antimicrobial stewardship. *P T.* 1307 2015;40(5):353-360.

- Brizzi M, Green SB. Rationale, evidence, and steps for implementation of medication for opioid use disorder treatment programs in HIV primary care settings. *AIDS Care*.
   2023;35(11):1760-1767.
- 1311 100. Roshdy D, McCarter M, Meredith J, et al. Implementation of a comprehensive intervention focused on hospitalized patients with HIV by an existing stewardship program: successes and lessons learned. *Ther Adv Infect Dis.*1314 2021;8:20499361211010590.
- 1315 101. DePuy AM, Samuel R, Mohrien KM, et al. Impact of an Antiretroviral Stewardship Team 1316 on the Care of Patients With Human Immunodeficiency Virus Infection Admitted to an 1317 Academic Medical Center. *Open Forum Infect Dis.* 2019;6(7):ofz290.
- 1318 102. Bronkhorst E, Hattingh S, Poka M. Antiretroviral stewardship in a tertiary academic hospital: The need for a clinical pharmacist. *Health SA*. 2023;28:2135.
- 1320 103. Hsu AJ, Neptune A, Adams C, et al. Antiretroviral Stewardship in a Pediatric HIV Clinic:
   1321 Development, Implementation and Improved Clinical Outcomes. *Pediatr Infect Dis J.* 1322 2016;35(6):642-648.
- 1323 104. Liedtke MD, Tomlin CR, Skrepnek GH, et al. HIV Pharmacist's Impact on Inpatient Antiretroviral Errors. *HIV Med.* 2016;17(10):717-723.
- 1325 105. Lelubre M, Clerc O, Grosjean M, et al. Implementation of an interprofessional medication adherence program for HIV patients: description of the process using the framework for the implementation of services in pharmacy. *BMC Health Serv Res.* 2018;18(1):698.
- 1329 106. Urano K, Ishibashi M, Matsumoto T, et al. Impact of physician-pharmacist collaborative 1330 protocol-based pharmacotherapy management for HIV outpatients: a retrospective 1331 cohort study. *J Pharm Health Care Sci.* 2020;6:9.
- 1332 107. Gonsalves L, Hindin MJ. Pharmacy provision of sexual and reproductive health commodities to young people: a systematic literature review and synthesis of the evidence. *Contraception.* 2017;95(4):339-363.
- 1335 108. Navarrete J, Yuksel N, Schindel TJ, et al. Sexual and reproductive health services provided by community pharmacists: a scoping review. *BMJ Open.* 2021;11(7):e047034.
- 1337 109. Tak CR, Kessler LT, Scott MA, et al. Pharmacist-prescribed hormonal contraception: A review of the current landscape. *J Am Pharm Assoc (2003).* 2019;59(5):633-641.
- 130 Department of Health and Human Services. Panel on Treatment of HIV During
  1340 Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of
  1341 Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV
  1342 Transmission in the United States. www.clinicalinfo.hiv.gov/en/guidelines/perinatal/
  1343 recommendations-arv-drugs-pregnancy-prevent-hiv-transmission-improve-health
  1344 (accessed 2025 Jan 16).
- 1345 111. Eke AC, Oragwu C. Sperm washing to prevent HIV transmission from HIV-infected men
   1346 but allowing conception in sero-discordant couples. *Cochrane Database Syst Rev.* 1347 2011;(1):CD008498.

- 1348 112. Neary M, Owen A, Olagunju A. Pharmacokinetics of HIV therapies in pregnant patients: an update. *Expert Opin Drug Metab Toxicol*. 2020;16(6):449-461.
- 1350 113. Foisy M, Hughes C. Role of the pharmacist in perinatal management of HIV disease. *Am J Health Syst Pharm.* 2011;68(22):2116, 2118, 2120-2122.
- 1352 114. Department of Health and Human Services. Panel on Antiretroviral Therapy and Medical
  1353 Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents
  1354 in Pediatric HIV Infection. www.clinicalinfo.hiv.gov/en/guidelines/pediatric-arv
  1355 (accessed 2025 Jan 16).
- 1356 115. Frange P, Bouazza N, Fassinou P, et al. Special considerations concerning the use of antiretroviral drugs in children. *Expert Rev Anti Infect Ther.* 2016;14(12):1155-1163.
- 1358 116. Horace AE, Akbarian-Tefagh J. Disguising the taste of antiretrovirals for pediatric patients infected with Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome: creative flavor compounding and techniques, part 1. *Int J Pharm Compd.* 2013;17(5):388-391.
- 1362 117. Horace AE, Akbarian-Tefagh J. Disguising the taste of antiretrovirals for pediatric patients infected with Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome: creative flavor compounding and techniques, part 2. *Int J Pharm Compd.* 2013;17(6):446-450.
- 1366 118. Morris JL, Briars LA, Kraus DM (2019). Characterization of clinical pharmacy services in a pediatric HIV clinic. *JACCP*. 2(5), 455–461.
- 1368 119. Althoff KN, Stewart CN, Humes E, et al. The shifting age distribution of people with HIV using antiretroviral therapy in the United States. *AIDS*. 2022;36(3):459-471.
- 120. Greene M, Myers J, Tan JY, et al. The Golden Compass Program: Overview of the Initial
   1371 Implementation of a Comprehensive Program for Older Adults Living with HIV. *J Int* 1372 Assoc Provid AIDS Care. 2020;19:2325958220935267.
- 1373 121. Tan JY, Greene M, Blat C, et al. Examining the Impact of the Golden Compass Clinical
   1374 Care Program for Older People with HIV: A Qualitative Study. *AIDS Behav*.
   1375 2022;26(5):1562-1571.
- 1376 122. McNicholl IR, Gandhi M, Hare CB, et al. A Pharmacist-Led Program to Evaluate and
  1377 Reduce Polypharmacy and Potentially Inappropriate Prescribing in Older HIV-Positive
  1378 Patients. *Pharmacotherapy*. 2017;37(12):1498-1506.
- 1379 123. Radix AE. Pharmacists' role in provision of transgender healthcare. *Am J Health-Syst* 1380 *Pharm.* 2017;74(3):103104.
- 1381 124. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, version 8. *Int J Transgend Health*. 2022;23(suppl 1):S1-S259.
- 1384 125. Gillis S, Wilby KJ, Walter R. Leveraging pharmacists' scope of practice to improve access to gender-affirming care: A scoping review. JACCP 2025;8(4):281-292. doi:10.1002/jac5.2064

- 1387 126. Macapagal K, Bhatia R, Greene GJ. Differences in healthcare access, use, and
  1388 experiences within a community sample of racially diverse lesbian, gay, bisexual,
  1389 transgender, and questioning emerging adults. *LGBT Health*. 2016;3(6):434-442.
- 1390 127. Ayhan CHB, Bilgin H, Uluman OT, et al. A systematic review of the discrimination against sexual and gender minority in health care settings. *Int J Health Serv.* 2020;50(1):44-61.
- 1392 128. Tran MT, Swank SD, Oliver AS, et al. Pharmacists perceptions and preparedness regarding gender-affirming hormone therapy. *J Am Pharm Assoc (2003)*.
  1394 2021;61(1):e30-e34. doi: 10.1016/j.japh.2020.08.039
- 1395 129. Chaudhary S, Ray R, Glass B. Pharmacists' role in transgender healthcare: a scoping review. *Res Social Admin Pharm.* 2021;17(9):1553-1561.
- 1397 130. Abrams LM, Look K, Imhoff L. The importance of providing gender-affirming care in
   1398 pharmacy practice. *Explor Res Clin Soc Pharm.* 2022;6:100135.
   1399 doi:10.1016/j.rcsop.2022.100135
- 131. Melin K, Hilera-Botet CR, Vega-Vélez D, et al. Readiness to provide pharmaceutical care to transgender patients: Perspectives from pharmacists and transgender individuals. *J Am Pharm Assoc (2003).* 2019;59(5):651-659. doi: 10.1016/j.japh.2019.04.018
- 1403 132. Jacobson AN, Matson KL, Mathews JL, et al. Lesbian, gay, bisexual, and transgender
   1404 inclusion: survey of campus climate in colleges and schools of pharmacy. *Curr Pharm* 1405 *Teach Learn*. 2017;9(1):60-65.
- 1406 133. Maxwell E, Salch S, Boliko M, et al. Discrepancies in lesbian, gay, bisexual, and
   1407 transgender patient care and how pharmacists can support an evolved practice. *Am J Pharm Educ.* 2017;81(7):6181.
- 134. Grundmann O, Segal R, Pullo J, et al. The pharmacist as an LGBTQ Ally. *Am J Pharm Educ.* 2020;84(7):ajpe7835.
- 1411 135. Newsome CC, Gilmer A. Strategies to bring transgender and non-binary health care into pharmacy education. *Am J Pharm Educ.* 2021;85(5):8283.
- 136. Courtney J, Aragon KG, Douglas M, et al. A Resource Compendium for Embedding
   1414 LGBTQIA+ Patient Care in the Professional Identity of Community Pharmacists. Am J
   1415 Pharm Educ. 2023;87(10):100127. doi: 10.1016/j.ajpe.2023.100127
- 1416 137. Phan T, Astle KN, Mills AR, et al. Implementation of pharmacist-led services for sexual
   1417 and gender minorities: A multisite descriptive report. Am J Health Syst Pharm.
   1418 2024;81(8):316-322.
- 1419 138. Redfern JS, Jann MW. The Evolving Role of Pharmacists in Transgender Health Care.
   1420 Transgend Health. 2019;4(1):118-130. doi: 10.1089/trgh.2018.0038
- 1421 139. Langdon E, Kavanagh P, Bushell M. Exploring pharmacists' understanding and
   1422 experience of providing LGBTI healthcare. *Explor Res Clin Soc Pharm.* 2022;6:100134.
   1423 doi: 10.1016/j.rcsop.2022.100134
- 1424 140. Werbel WA, Durand CM. Solid Organ Transplantation in HIV-Infected Recipients: History,
   1425 Progress, and Frontiers. *Curr HIV/AIDS Rep.* 2019;16(3):191-203.
- 1426 141. Department of Health and Human Services, Office of the Federal Register. Organ
   1427 Procurement and Transplantation: Implementation of the HIV Organ Policy Equity

- 1428 (HOPE) Act. Published 2024. www.federalregister.gov/documents/2024/11/27/2024-1429 27410/organ-procurement-and-transplantation-implementation-of-the-hiv-organ-1430 policy-equity-hope-act. (accessed 10 Jan 2025).
- 1431 142. Sáez-Cirión A, Mamez AC, Avettand-Fenoel V, et al. Sustained HIV remission after
   1432 allogeneic hematopoietic stem cell transplantation with wild-type CCR5 donor cells. *Nat* 1433 *Med.* 2024;30(12):3544-3554.
- 1434 143. Clemmons AB, Alexander M, DeGregory K, et al. The Hematopoietic Cell Transplant
   1435 Pharmacist: Roles, Responsibilities, and Recommendations from the ASBMT Pharmacy
   1436 Special Interest Group. *Biol Blood Marrow Transplant*. 2018;24(5):914-922.
- 1437 144. Sam S, Guérin A, Rieutord A, et al. Roles and Impacts of the Transplant Pharmacist: A
   1438 Systematic Review. *Can J Hosp Pharm.* 2018;71(5):324-337.
- 1439 145. Webel AR, Schexnayder J, Cioe PA, et al. A Review of Chronic Comorbidities in Adults
   1440 Living With HIV: State of the Science. *J Assoc Nurses AIDS Care*. 2021;32(3):322-346.
- 1441 146. Angibaud M, Jourdain M, Girard S, et al. Involving community pharmacists in
   1442 interprofessional collaboration in primary care: a systematic review. *BMC Prim Care*.
   1443 2024;25(1):103.
- 1444 147. Blood AJ, Saag H, Chesler A, et al. Integrating Ambulatory Care Pharmacists Into Value 1445 Based Primary Care: A Scalable Solution to Chronic Disease. *J Prim Care Community* 1446 *Health*. 2025;16:21501319241312041.
- 1447 148. Ruiz-Ramos J, Hernández MH, Juanes-Borrego AM, et al. The Impact of Pharmaceutical 1448 Care in Multidisciplinary Teams on Health Outcomes: Systematic Review and Meta-1449 Analysis. *J Am Med Dir Assoc.* 2021;22(12):2518-2526.
- 1450 149. Horberg M, Thompson M, Agwu A, et al. Primary Care Guidance for Providers of Care for
   1451 Persons With Human Immunodeficiency Virus: 2024 Update by the HIV Medicine
   1452 Association of the Infectious Diseases Society of America. Clin Infect Dis. 2024:ciae479.
- 1453 150. Edelman EJ, Rentsch CT, Justice AC. Polypharmacy in HIV: recent insights and future directions. *Curr Opin HIV AIDS*. 2020;15(2):126-133.
- 1455 151. Kara E, İnkaya AÇ, Aydın Haklı D, et al. Polypharmacy and drug-related problems among people living with HIV/AIDS: a single-center experience. *Turk J Med Sci.* 2019;49(1):222-1457 229.
- 152. Conley N. Social Determinants of Health, Chronic Disease Management, and the Role of the Primary Care Provider-to Include Cardiovascular Disease, Cancer, Diabetes, Major Causes of Morbidity and Mortality as Affected by Social Determinants of Health. *Prim Care.* 2023;50(4):671-678.
- 1462 153. Batterham RL, Bedimo RJ, Diaz RS, et al. Cardiometabolic health in people with HIV: expert consensus review. *J Antimicrob Chemother*. 2024;79(6):1218-1233.
- 1464 154. Cope R, Berkowitz L, Arcebido R, et al. Evaluating the Effects of an Interdisciplinary
  1465 Practice Model with Pharmacist Collaboration on HIV Patient Co-Morbidities. *AIDS*1466 Patient Care STDS. 2015;29(8):445-453.

- Jackson IL, Ukwe CV. Clinical outcomes of pharmaceutical care intervention in HIV
   positive patients with hypertension: A randomized controlled study. *J Clin Pharm Ther.* 2021;46(4):1083-1094.
- 1470 156. Edelman EJ, Dziura J, Deng Y, et al. A SMARTTT approach to Treating Tobacco use
   1471 disorder in persons with HIV (SMARTTT): Rationale and design for a hybrid type 1
   1472 effectiveness-implementation study. *Contemp Clin Trials*. 2021;110:106379.
- 1473 157. Foster MG, Toll BA, Ware E, et al. Optimizing the Implementation of Tobacco Treatment for People with HIV: A Pilot Study. *Int J Environ Res Public Health*. 2022;19(19):12896.
- 1475 158. Grinspoon SK, Fitch KV, Zanni MV, et al; REPRIEVE Investigators. Pitavastatin to Prevent Cardiovascular Disease in HIV Infection. *N Engl J Med.* 2023;389(8):687-699.
- 1477 159. Gallegos Aragon K, Ray G, Conklin J, et al. Underprescribing of statin therapy in people
   1478 with HIV at risk for atherosclerotic cardiovascular disease. *Am J Health Syst Pharm*.
   1479 2022;79(22):2026-2031.
- 1480 160. Abdulrhim S, Sankaralingam S, Ibrahim MIM, et al. The impact of pharmacist care on diabetes outcomes in primary care settings: An umbrella review of published systematic reviews. *Prim Care Diabetes*. 2020;14(5):393-400.
- 1483 161. Nelson NE, Wilson M, Fine J, et al. Pharmacist Intervention Lowers HgbA1c in Diabetic Patients Regardless of HIV Status. *J Pharm Pract Res.* 2021;51(4):307-313.
- 1485 162. Parra-Rodriguez L, O'Halloran JA. HIV and obesity: updates in management strategies. 1486 *Curr Opin HIV AIDS.* 2023;18(2):68-74.
- 1487 163. Lucas GM, Ross MJ, Stock PG, et al; HIV Medicine Association of the Infectious Diseases
  1488 Society of America. Clinical practice guideline for the management of chronic kidney
  1489 disease in patients infected with HIV: 2014 update by the HIV Medicine Association of
  1490 the Infectious Diseases Society of America. *Clin Infect Dis.* 2014;59(9):e96-138.
- 164. Kidney Disease Improving Global Outcomes. KDIGO 2024 Clinical Practice Guidelines for
   the Evaluation and Management of Chronic Kidney Disease. *Kidney International*.
   www.linkinghub.elsevier.com/retrieve/pii/S0085253824001108 (accessed 25 Jan 2025).
- 1494 165. Swanepoel CR, Atta MG, D'Agati VD, et al; Conference Participants. Kidney disease in the setting of HIV infection: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney Int.* 2018;93(3):545-559.
- 1497 166. Le LM, Veettil SK, Donaldson D, et al. The impact of pharmacist involvement on 1498 immunization uptake and other outcomes: An updated systematic review and meta-1499 analysis. *J Am Pharm Assoc* (2003). 2022;62(5):1499-1513.e16.
- 167. Marks KM, Kang M, Umbleja T, et al; ACTG 5379 (BEe-HIVe) Study Team. HepB-CpG vs
   1501 HepB-Alum Vaccine in People With HIV and Prior Vaccine Nonresponse: The BEe-HIVe
   1502 Randomized Clinical Trial. JAMA. 2025;333(4):295-306.
- 1503 168. McLaughlin M, Kalfayan N, Grant J, et al. Time Requirements for Acquisition of Hepatitis C Virus Therapy in HIV/HCV Coinfected Patients. *J Pharm Technol.* 2018;34(4):149-152.
- 1505 169. Olea A Jr, Grochowski J, Luetkemeyer AF, et al. Role of a clinical pharmacist as part of a multidisciplinary care team in the treatment of HCV in patients living with HIV/HCV coinfection. *Integr Pharm Res Pract*. 2018;7:105-111.

- 170. Ryan KL, Jakeman B, Conklin J, et al. Treatment of patients with HIV or hepatitis C by pharmacist clinicians in a patient-centered medical home. *Am J Health Syst Pharm.*2019;76(11):821-828.
- 1511 171. Lam JT, Xavioer S. Impact of a Pharmacist-Led HCV Treatment Program at a Federally Qualified Health Center. Pharmacy (Basel). 2024;12(4):115.
- 172. Radtke KK, Bacchetti P, Anastos K, et al. Use of Nonantiretroviral Medications That May
  1514 Impact Neurocognition: Patterns and Predictors in a Large, Long-Term HIV Cohort Study.
  1515 J Acquir Immune Defic Syndr. 2018;78(2):202-208.
- 1516 173. Lu HJ, Fu YY, Wei QQ, et al. Neuroinflammation in HIV-Related Neuropathic Pain. *Front Pharmacol.* 2021;12:653852.
- 1518 174. Lang R, Hogan B, Zhu J, et al; North American AIDS Cohort Collaboration on Research
  1519 and Design (NA-ACCORD) of the International Epidemiologic Databases to Evaluate AIDS
  1520 (IeDEA). The prevalence of mental health disorders in people with HIV and the effects
  1521 on the HIV care continuum. AIDS. 2023;37(2):259-269.
- 1522 175. Byrd KK, Hardnett F, Hou JG, et al. Patient-Centered HIV Care Model Team.
   1523 Improvements in Retention in Care and HIV Viral Suppression Among Persons with HIV
   1524 and Comorbid Mental Health Conditions: Patient-Centered HIV Care Model. AIDS Behav.
   1525 2020;24(12):3522-3532.
- 176. Margulis A, Uhlyar S, Chin-Beckford N, et al. Clinical pharmacist input on HIV
   1527 management may improve antiretroviral prescribing for psychiatric patients. *Am J Health Syst Pharm.* 2021;78(Suppl 1):S10-S15.
- 1529 177. Daly CJ, Costello J, Mak A, et al. Pharmacists' perceptions on patient care services and social determinants of health within independent community pharmacies in an enhanced services network. *J Am Coll Clin Pharm.* 2021;4:288-295.
- 178. Womack JA, Leblanc MM, Sager AS, et al. The Feasibility and Acceptability of a Clinical
   Pharmacist-delivered Intervention to Reduce Bothersome Health Symptoms from
   Polypharmacy and Alcohol Use and Communicate Risk among People with HIV: Pilot
   Study Protocol. AIDS Behav. 2025;29(2):482-496.
- 1536 179. Lurain K. Treating Cancer in People With HIV. J Clin Oncol. 2023;41(21):3682-3688.
- 180. Markus D, Dean S. Tackling Social Determinants of Health by Leveraging Community
   Pharmacies in a National, Scalable Model. Presented at: PQA 2020 Annual Meeting; May
   13-15, 2020.
- 181. Relf MV. The Social Determinants of Health Are the Key Drivers of HIV Prevention, Care, and Treatment Inequities. *J Assoc Nurses AIDS Care*. 2024;35(4):307-308.
- 1542 182. Talon B, Perez A, Yan CH, et al. Economic evaluations of clinical pharmacy services in the United States: 2011-2017. *J Am Coll Clin Pharm.* 2019;3:793-806.
- 1544 183. Phimarn W, Saramunee K, Leelathanalerk A, et al. Economic evaluation of pharmacy services: a systematic review of the literature (2016-2020). *Int J Clin Pharm.*1546 2023;45(6):1326-1348.
- 184. Nguyen E, Walker K, Adams JL, et al. Reimbursement for pharmacist-provided health care services: A multistate review. *J Am Pharm Assoc (2003).* 2021;61(1):27-32.

- 185. Manolakis PG, Skelton JB. Pharmacists' contributions to primary care in the United States collaborating to address unmet patient care needs: the emerging role for pharmacists to address the shortage of primary care providers. *Am J Pharm Educ*. 2010;74(10):S7.
- 1553 186. Dodd MA, Haines SL, Maack B, et al. ASHP Statement on the Role of Pharmacists in Primary Care. *Am J Health-Syst Pharm.* 2022;79:2070–2078.
- 187. Medicare.Gov. Pre-exposure prophylaxis (PrEP) for HIV prevention.
   1556 www.medicare.gov/coverage/pre-exposure-prophylaxis-prep-for-hiv-prevention
   1557 (accessed 12 Jan 2025).
- 1558 188. Center for Medicare and Medicaid Services. PrEP for HIV & Related Preventive Services.
  1559 www.cms.gov/medicare/coverage/prep (accessed 12 Jan 2025).
- 1560 189. Eisinger RW, Dieffenbach CW, Fauci AS. HIV Viral Load and Transmissibility of HIV 1561 Infection: Undetectable Equals Untransmittable. *JAMA*. 2019;321(5):451-452.
- 1562 190. Cocohoba J. 'The Pharmacist's Role in HIV Care', in W. David Hardy (ed.), *Fundamentals*1563 of HIV Medicine 2023. doi:10.1093/med/9780197679098.003.0015 (accessed 5 Feb.
  1564 2025).
- 1565 191. Ford N, Eshun-Wilson I, Ameyan W, et al. Future directions for HIV service delivery 1566 research: Research gaps identified through WHO guideline development. *PLoS Med.* 1567 2021;18(9):e1003812.