LIMITATIONS TO TREATMENT SAFETY AND EFFICACY

Adherence to the Continuum of Care

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Key Considerations and Recommendations
• Linkage to HIV care and adherence to both antiretroviral therapy (ART) and clinic appointments should be regularly assessed. • An individual's barriers to ART and clinic appointment adherence should be assessed before or shortly after the initiation of ART and regularly thereafter. • Rapid access to ART is one of the pillars of the United States' plan to end the HIV epidemic; therefore, delays in access to ART should be addressed and treatment initiated as soon as possible. • People with HIV having ART adherence problems should be placed on regimens with high genetic barriers to resistance, such as dolutegravir, bictegravir, or boosted darunavir. Side effects, out-of-pocket costs, convenience, and individual preferences should also be considered. • People with HIV having difficulties with adherence to appointments or ART should be provided additional adherence support using a constructive, collaborative, nonjudgmental, and problem-solving approach. • The approach taken to improve adherence should be tailored to each person's needs and barriers to care. Approaches could include, but are not limited to— o Changing ART to simplify dosing or to reduce side effects o Allowing flexible appointment scheduling o Finding resources to assist with treatment costs to maintain uninterrupted access to both ART and appointments o Linkage to resources to assist with unmet social and economic needs, such as transportation, food, housing, and other support services o Linkage to services to overcome stigma, substance use, or mental illness • A multidisciplinary approach—including collaborations with nursing, pharmacy, social work, and case management (to the extent available—is often necessary to identify solutions to ART and appointment adherence. The clinician's role is to help people with HIV understand the importance of adherence to the continuum of care, identify the barriers to adherence and address those that are within their purview, and link them to resources to overcome other barriers. • Single-tablet ART regimens are generally recommended when clinically appropriate, but high-quality evidence to definitively recommend them is lacking and shared decision-making between clinicians and people with HIV is essential **(BIII).** • At this time, evidence does not support the use of financial incentives to engage people with HIV in ongoing routine care. • Methods to estimate adherence based on drug levels measured in plasma, dried blood spots, urine, and hair samples are available. Measuring adherence with these methods has not been shown in randomized studies to improve outcomes. However, these methods should be used in a collaborative manner to avoid an adversarial relationship between the provider and people with HIV.

- Because delayed administration of long-acting cabotegravir plus rilpivirine (LA CAB/RPV) may lead to the emergence of drug resistance, LA CAB/RPV is not generally recommended as a complete regimen in people with viremia due to suboptimal adherence to ART, or in people who have ongoing challenges with retention in HIV care. However, based on very limited data, the Panel for the Use of Antiretroviral Agents in Adults and Adolescents With HIV recommends the use of LA CAB/RPV on a case-by-case basis in select individuals with persistent virologic failure despite intensive adherence support on oral ART, and who have no evidence of resistance to rilpivirine RPV or CAB and, with shared decision-making between providers and people with HIV **(CIII).** See Virologic Failure for a more detailed discussion.
- A summary of best practice interventions to improve linkage, retention, and adherence can be found in the Centers for Disease Control and Prevention's Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention.

Rating of Recommendations: *A = Strong; B = Moderate; C = Weak*

Rating of Evidence: *I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion*

Introduction

HIV treatment adherence includes initiating care with an HIV provider (linkage to care), regularly engaging in appointments (retention in care), and adhering to antiretroviral therapy (ART). The concept of a "continuum of care" has been used to describe the process of HIV testing, linkage to HIV care, initiation of ART, adherence to ART, retention in care, and virologic suppression.[1-3] The Centers for Disease Control and Prevention (CDC) estimates that about 13% of people with HIV are undiagnosed in the United States.[4] Based on 2022 data, about 82% of individuals were linked to care within 30 days of receiving an HIV diagnosis.[5,6] However, only 54% of people with diagnosed HIV were retained in HIV care. It is estimated that only approximately 69% of people with complete data were virologically suppressed within 6 months of diagnosis. This low rate of viral suppression is primarily due to poor adherence to clinic appointments and ART.[5,7] Outcomes along the continuum of care also vary by geographic region and other population characteristics, such as sex, race and ethnicity, and HIV risk factors.[7] To achieve optimal clinical outcomes and to realize the potential public health benefit of treatment as prevention, adherence to each step in the continuum of care is critical.[8] It is important to note that retention and adherence may fluctuate as a result of life events, changes in insurance status, comorbid conditions, and health system changes, causing people with HIV to shift back and forth on the continuum. Knowledgeable providers and high-quality system processes are vital in promoting rapid linkage and sustained retention in care and adherence to ART. Finally, clinicians should recognize that adherence is a complex behavior requiring knowledge, motivation, memory, behavior change, external resources, and successful and persistent interaction with complex and, sometimes, challenging health care systems.[9-11] The patient–provider relationship is central to improving HIV care engagement and adherence to treatment. Providers must recognize that adherence is a collaborative effort between clinicians and people with HIV.

Addressing social determinants of health (SDOH) is critical to adherence along the HIV continuum of care. The CDC defines SDOH as "the conditions in which people are born, grow, work, live, and age" and "that influence health outcomes."[12] SDOH include access to education, income, nutritious food, transportation, stable housing, and health insurance coverage, as well as policies that may lead to structural racism, HIV criminalization, stigmatization, or immigration status. There are several commonly used screening tools for health-related social needs, including the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE),[13] the American Academy of Family Physicians Social Needs Screening Tool (long and short forms),[14,15] and the Centers for Medicare & Medicaid Services (CMS) Accountable Health Communities Health-Related Social Needs (AHC-HRSN) Screening Tool.[16] The CMS Accountable Health Communities Model conducted a randomized trial connecting beneficiaries to community resources for five core health-related social needs compared with a referral-only group. Individuals in the community resources

group received an in-depth assessment of social needs, planning, referral to community services, and follow-up until the needs were resolved or determined unresolvable. The beneficiaries who received community service navigation experienced reduced emergency department visits and a trend toward lower expenditures and improved hospital-based utilization outcomes compared with the referral-only group.[17] Any unmet social and economic needs identified via screening should be addressed, either through direct service provision or by community referrals.

This section provides guidance on linking people with HIV to care, assessing and improving retention in care, and assessing and improving adherence to ART. The CDC maintains a Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention to improve linkage, retention, and adherence, and the Health Resources and Services Administration (HRSA) has multiple tools to assist clinics housed in the Ryan White HIV/AIDS Program (RWHAP) Best Practices Compilation. In addition, a number of other groups and organizations have provided guidance for improving adherence to the steps in the care continuum.[8,18]

Linkage to Care

Receiving an HIV diagnosis can be traumatic, and linkage to care efforts must be delivered with compassion and persistence. The time from diagnosis to linkage to care can be affected by many factors, including insufficient socioeconomic resources, active substance use, mental health problems, stigma, and disease severity (symptomatic HIV is associated with more successful linkage).[19-23] In the United States, youth, people who use injection drugs, and Black/African American people have lower rates of linkage to care.[7] Some health system factors have also been associated with linkage success or failure. Co-location of testing and treatment services[22] and active linkage services (e.g., assistance in setting up HIV care appointments, maintaining an active relationship with individuals until linkage is completed, providing linkage case management services)[24-26] bolster linkage to care. Conversely, passive linkage (e.g., only providing names and contact information for treatment centers) is associated with lower linkage to care.

Monitoring Linkage to Care

Linking to HIV care after a new HIV diagnosis is defined as completing an outpatient appointment with a clinical provider who has the skills and ability to treat HIV, including prescribing ART. People with HIV should be linked to care as soon as possible after HIV diagnosis, preferably within 30 days. Monitoring linkage is critical to ensure that interventions can effectively reach people who are not linked to care. If the facilities that diagnose and treat an individual are the same or share the same electronic medical record system, it is relatively straightforward to monitor linkage to care. Monitoring linkage for people whose HIV is diagnosed outside the treatment provider's health care system is difficult and generally is the responsibility of the diagnosing provider or entity and the public health authority. However, once people with HIV make contact with the treating clinical system, they should be engaged in linkage efforts. The referring entity should monitor for successful linkage to and retention in HIV care.

Improving Linkage to Care

Strategies to improve linkage to care are summarized in Table 19 below. Linkage efforts should include immediate referral to care at diagnosis, appointment reminders, and outreach efforts if needed.[24] The only intervention shown to increase linkage to care in a randomized trial conducted in the United States is the Anti-Retroviral Treatment and Access to Services (ARTAS) intervention.[25] In this study, participants randomized to the control arm received information about HIV and care resources and a referral to a local HIV medical provider, whereas participants in the intervention arm worked with an ARTAS interventionist for five sessions, 90 days, or until linkage—whichever came first. The interventionist helped participants to identify and use their strengths, abilities, and skills to

link to HIV care; participants were also linked to community resources. Linkage to care, defined in this study as completing at least one visit with an HIV clinician within the first 6 months, was greater among the ARTAS participants than the control participants (78% vs. 60%, adjusted risk ratio = 1.36, $P < 0.001$). Furthermore, a greater percentage of ARTAS participants were retained in care, defined as visiting an HIV clinician at least once in each of the first two 6-month blocks after enrollment (64% vs. 49% for ARTAS and control participants, respectively; adjusted risk ratio = 1.41, $P = 0.006$). The results from the ARTAS intervention have been replicated in a community-based study.[26] The CDC supports free training in the ARTAS intervention. Other studies support the importance of post-test counseling to educate, motivate, and present positive messages about HIV,[27] peer support,[28] and engaging people with HIV at the clinic in advance of the visit with the provider.[29] Financial incentives did not increase linkage to care within 90 days in a large randomized trial.[30]

Retention in Care

Poor retention in HIV care is associated with a greater risk of death.[31,32] Poor retention is more common in people who use substances, have serious mental health problems, have unmet socioeconomic needs (e.g., housing, food, transportation), lack financial resources or health insurance, have schedules that complicate adherence, have been recently incarcerated, or face stigma.[33-36] At the provider and health system level, low trust in providers and a poor relationship between providers and people with HIV have been associated with lower retention, as has lower satisfaction with the clinic experience.[37-39] Availability of appointments and timeliness of appointments (i.e., long delay between the appointment request and the appointment date) and scheduling convenience are also factors.

Monitoring Retention in Care

Retention in care should be routinely monitored.[8] There are various ways to measure retention, including measures based on attended visits over a defined period of time (constancy measures) and measures based on missed visits.[40] Both approaches are valid and independently predict survival.[41] Missed visits and a prolonged time since the last visit are relatively easy to measure and should trigger efforts to retain or reengage a person in care. Constancy measures (e.g., at least two visits that are at least 90 days apart over 1 year, or at least one visit every 6 months over the last 2 years) can be used as clinic quality assurance measures.

Improving Retention in Care

Strategies to improve retention in care are summarized in Table 19 below. The Retention through Enhanced Personal Contact (REPC) intervention was tested in a randomized trial in six clinics in the United States. The study enrolled people with HIV who had a history of inconsistent clinic attendance. The intervention relied on personal contact and included a brief face-to-face meeting upon returning to care and at each subsequent clinic visit, plus three types of phone calls (check-ins between visits, to provide appointment reminders just before visits, and to attempt to reschedule missed visits). REPC resulted in small but significant improvements in retention in care, including in racial/ethnic minority populations and people with detectable plasma HIV RNA.[42] When necessary, in-clinic opioid replacement therapy helps opioid users remain in care.[43] An intervention using the electronic medical record to alert providers when people had suboptimal follow-up or high viral loads also improved retention in care.[44]

Telehealth has emerged as an important modality for retention in HIV care during the COVID-19 pandemic. A cluster-randomized study conducted in the U.S. Department of Veterans Affairs health facilities before the pandemic showed that the availability of telehealth resulted in improvements in viral suppression and the number of completed visits.[45] Reengaging and retaining people who are out of care remains particularly challenging.

Navigation services for out-of-care individuals with HIV in a New York City Medicaid health plan resulted in faster re-linkage to care but did not improve retention in care.[46] In two randomized trials involving out-of-care, hospitalized people with HIV, peer counselors and patient navigators did not improve re-linkage to care after hospital discharge.[47,48] Two randomized studies tested a Data to Care intervention, which uses clinic and public health data to reach and reengage out-of-care people with HIV.[49] One trial conducted in Seattle found that the intervention did not result in significantly faster time to re-linkage or viral suppression.[50] However, only people with unsuppressed viremia and CD4 T lymphocyte (CD4) cell counts <350 cells/mm^3 or people with no laboratory values in the preceding 12 months were included, reflecting the HIV treatment guidelines at the time. The Cooperative Re-Engagement Controlled Trial (CoRECT) was more recently conducted in the Northeast United States (Connecticut, Massachusetts, Philadelphia) and included people with HIV with no evidence of a clinic visit or laboratory measurement in the preceding 6 months, regardless of their most recent laboratory results. The proportion of people re-linked to care within 90 days and retained in care at 12 months was significantly higher in the intervention group, but no differences were observed in the proportion who achieved viral suppression in 12 months. Time to viral suppression among those who achieved viral suppression in 12 months was shorter for participants who were randomized to the Data to Care arm compared with the standard of care. Using the Data to Care approach requires substantial resources and notable privacy concerns; although short-term re-linkage may be improved, there is no evidence of an impact on long-term re-linkage or time to viral suppression.

Data from nonrandomized studies are less conclusive, but many interventions bear mentioning. Clinic-wide marketing (e.g., posters, brochures) and customer service training of staff to promote attending scheduled visits and provide people with a welcoming and courteous experience have improved retention.[51] People with HIV who rated their experience with their doctor more highly were more likely to stay in care.[52] Stepped-case management and social and outreach services,[53] including mobile health applications that enhance communication and provide support, are beneficial, although the applications that have been developed and studied are not available for widespread public use. Differentiated care approaches reduce the need for appointments and other expectations for people doing well and allow extra resources to be devoted to people not achieving optimal health outcomes. The evidence to support the use of differentiated care is strongest in low-resource settings, whereas in the United States, the evidence is limited to observational data, which suggests the approach has a beneficial impact.[54]

Overall, these data support the concept that all clinic personnel, from the facilities' staff to nurses to providers, play important roles in supporting retention in care by providing the optimal care experiences, constructively affirming attendance rather than criticizing non-attendance, and collaboratively solving problems with people to overcome barriers to care.[38,42,51] Flexible appointment schedules, expanded clinic hours, and copay or other financial or insurance assistance—such as that provided by the RWHAP—also facilitate uninterrupted access to clinical care. Navigation services, telehealth, and engaging with people through mobile health applications are likely to improve outcomes, although the evidence is not sufficient to support their use unequivocally.

The use of financial incentives or rewards to promote retention in care has been studied. A large study randomized clinic sites to financial incentives or standard of care. At baseline, 45% of the participants were retained in care in these clinics. The relative increase in the proportion of participants retained in care was 9% higher in clinics offering incentives than in standard-of-care clinics. Viral suppression also improved by 4% at financial incentive clinics, from a baseline of 62%.[30] Evidence from a *post hoc* analysis of a subset of the sites involved in that trial shows a reduced but persistent improvement in retention in care after the withdrawal of the incentives without a persistent effect on viral suppression.[55] In another large, randomized study of people who were out of care and hospitalized, financial incentives plus patient navigation did not lead to sustained

improvement in retention or viral load suppression compared to standard care.[47] At this time, financial incentives remain experimental in the context of improved retention due to a lack of data supporting their use in routine care.

Adherence to Antiretroviral Therapy

Adherence to ART can be influenced by several factors, including a person's social situation, clinical condition, the prescribed regimen, and the patient–provider relationship.[56] Poor adherence is often a consequence of one or more behavioral, structural, and psychosocial barriers (e.g., depression and other mental illnesses, neurocognitive impairment, low health literacy, low levels of social support, stressful life events, busy or unstructured daily routines, active substance use, homelessness, poverty, nondisclosure of HIV serostatus, denial, stigma, inconsistent access to medications due to financial and insurance status).[57-60]

Characteristics of one or more components of the prescribed regimen can affect adherence. Once-daily regimens,[61] including those with low pill burden (even if not one pill once daily), no food requirement, and few side effects or toxicities, are associated with higher levels of adherence.[62,63] Single-tablet regimens (STRs) that include all antiretroviral (ARV) drugs in one pill taken once daily are easier for people to use. However, data to support or refute the superiority of an STR versus a once-daily multi-tablet regimen (MTR), as might be required for the use of some generic-based ARV regimens, are limited. Comparisons of these regimens are hampered because not all drugs and classes are available as STRs. There are demonstrated beneficial effects on virologic suppression in a meta-analysis of MTRs versus STRs.[64,65] Whether an STR is beneficial in people with HIV who are ART-naive is not known, with observational cohort studies showing the benefit of a once-daily STR versus a once-daily MTR.[63,66-69] On the other hand, observational data from Spain showed that co-formulated dolutegravir (DTG)/abacavir (ABC)/lamivudine (3TC) resulted in similar viral suppression compared to DTG plus ABC/3TC when used both at treatment initiation and when people with viral suppression on STR were switched to the two-pill formulation as a cost-saving strategy.[70] Given these findings and their wide availability, STRs are generally recommended when clinically appropriate, but high-quality evidence to definitively recommend them is lacking, and shared decision-making is essential **(BIII).**

Characteristics of the clinical setting can also have important structural influences on the success or failure of medication adherence. Settings that provide comprehensive multidisciplinary care (e.g., by case managers, pharmacists, social workers, mental health and substance use providers) support the complex needs of individuals, including those related to medication adherence. Treatment programs for substance use may offer services that promote adherence, such as directly observed therapy (DOT) (see Substance Use Disorders and HIV).

Monitoring Adherence to Antiretroviral Therapy

Adherence to ART should be assessed and addressed in a constructive and nonjudgmental manner at every clinic visit. Given the potency of contemporary ART, a detectable viral load identified during chronic care for a person with stable access to ART is most likely the result of poor adherence. Self-report, the most frequently used method for evaluating medication adherence, remains a useful tool. Carefully assessed self-report of high-level adherence to ART has been associated with favorable viral load responses,[71-73] whereas admission of suboptimal adherence is highly correlated with poor therapeutic response. The reliability of self-reporting often depends on how the clinician elicits the information. It is most reliable when ascertained in a simple, nonjudgmental, routine, and structured format that normalizes less-than-perfect adherence and minimizes socially desirable responses. To allow people to disclose lapses in adherence, some experts suggest inquiring about the number of missed doses during a defined period. For example, for a person with a detectable viral load, a provider might state, "I know it is difficult to take medicine every day. Most people miss doses at

least sometimes. Thinking about the last 2 weeks, how many times have you missed doses? Please give me a rough estimate so I can help you take the best care of yourself." Other research supports simply asking people to rate their adherence during the last 4 weeks on a 5- or 6-point Likert scale[74,75] or using qualitative response categories.[73]

Other measures of adherence include pharmacy records and pill counts. Pharmacy records can be valuable when medications are obtained exclusively from a single source. Because pill counts can be altered, are labor intensive, and can be perceived as confrontational, they are generally not used in routine care. Electronic measurement devices are costly and are generally reserved for research settings. Finally, methods to estimate adherence based on drug levels measured in plasma, dried blood spots, urine, and hair samples are available.[76] Some of these are commercially available, but none have been shown in randomized studies to improve outcomes. However, if these methods are used, they should be implemented collaboratively between the provider and the person with HIV to avoid an adversarial relationship.

Improving Adherence to Antiretroviral Therapy

Strategies to improve adherence to ART are summarized in Table 19 below. Just as they support retention in care, all health care team members play integral roles in successful ART adherence programs.[72,77-79] An increasing number of interventions have proven effective in improving adherence to ART (for descriptions of the interventions, see the CDC's Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention). These interventions can be customized to suit a range of needs and settings. Many interventions that are efficacious in randomized trials require specialized training and resources before they can be implemented in routine care, and this has limited their impact. Nonetheless, these interventions have contributed to our knowledge in developing general principles of improving and maintaining adherence.

Every person with HIV must receive and understand basic information about HIV infection, including the goals of therapy (achieving and maintaining viral suppression, which will decrease HIV-associated complications and prevent transmission), the prescribed regimen (including dosing schedule and potential side effects), the importance of adherence to ART, and the potential for the development of drug resistance as a consequence of suboptimal adherence. People with HIV must also be positively motivated to initiate therapy, which can be assessed by simply asking people if they want to start treatment for HIV. Clinicians should assist people with HIV in identifying facilitating factors and potential barriers to adherence and develop multidisciplinary plans to attempt to overcome those barriers. Processes for obtaining medications and refills should be clearly described. Transportation to pharmacy and clinic visits should be assessed with linkage to appropriate services as needed. Plans to ensure uninterrupted access to ART via insurance, copay assistance, pharmaceutical company assistance programs, or AIDS Drug Assistance Programs (ADAP), for example, should be made and reviewed with each person with HIV. Much of this effort to inform, motivate, and reduce barriers can be achieved by nonphysician members of the multidisciplinary team and can be accomplished concomitantly with, or even after, starting therapy.[80-83]

While delaying the initiation of ART is rarely indicated, some people may not be comfortable starting treatment right away. People expressing reluctance to initiate ART should be engaged to understand and overcome barriers to ART initiation. Although homelessness, substance use, and mental health problems are associated with poorer adherence, they are not predictive enough at the individual level to warrant withholding or delaying therapy given the simplicity, potency, and tolerability of contemporary ART. Rapid ART initiation at the time of HIV diagnosis has been pursued as a strategy to increase viral load suppression and retention in care, but safety data, data on intermediate or long-term outcomes, and data from randomized controlled trials conducted in high-resource settings are currently lacking.[80-86] In low-resource settings, data from randomized trials

suggest that rapid ART probably increases ART use and viral suppression at 12 months, but data on other important outcomes—such as retention in care, regimen switching, and mortality—are not sufficient to draw conclusions.[87,88] Rapid access to ART has become a pillar of the United States' plan to end the HIV epidemic, and delays in access to ART should be addressed.[89] For more details, see Initiation of Antiretroviral Therapy.

Successful treatment requires a regimen that the individual can adhere to,[90,91] considering their daily schedule, tolerance of pills (number, size, and frequency), and any issues affecting absorption (e.g., use of acid-suppressing therapy, food requirements). As reviewed above, STRs have been associated with high rates of adherence. People with risk factors for poor adherence or a history of poor adherence should be offered regimens with high genetic barriers to resistance (e.g., a second-generation integrase strand transfer inhibitor [INSTI] or a boosted protease inhibitor), if clinically appropriate. Using shared decision-making, a medication choice and administration schedule should be tailored to each person's daily activities. Clinicians should explain to people that their first regimen is usually the best option for a simple regimen, which affords long-term treatment success. Establishing a trusting patient–provider relationship and maintaining good communication will help to improve adherence and long-term outcomes. Medication adherence can also be enhanced using medication reminder aids. The evidence is strongest for text messaging, although pillbox monitors, pill boxes, and alarms may also improve adherence.[92-96]

Positive reinforcement, such as informing people of their low or suppressed viral load and increased CD4 counts, can greatly help maintain high levels of adherence. Motivational interviewing has also been used with some success.[97-99] Other effective interventions include nurse home visits, a five-session group intervention, and couples- or family-based interventions. Interventions involving several approaches are generally more successful than single-strategy interventions, and interventions based on cognitive behavioral therapy and supporter interventions have been shown to improve viral suppression.[100] Problem-solving approaches that vary in intensity and culturally tailored approaches are also promising.[99,101,102] Providing additional therapy (e.g., for substance use or mental health) and social support may be important to maintain high levels of adherence. DOT has been effective in providing ART to people actively using drugs[103] but not to people in a general clinic population[104] or in home-based settings with partners responsible for DOT.[105,106] The use of incentives or rewards to promote adherence has been studied, demonstrating improved adherence in one study conducted by the HIV Prevention Trials Network (HPTN)[30] and reduce viral load in another study that required very frequent viral load measurement and incentives.[107] Although the durability and feasibility of financial incentives are limited, and behavior change is generally not sustained after the incentives are withdrawn, the HPTN study did find some evidence of sustained adherence after 9 months.[55] Data are too limited to support the use of financial rewards for adherence to routine care.[47,108,109]

Transitions of Care

Transitions of HIV care are critical periods during which people may be more likely to fall out of care. Some important examples of transitions of care are discussed in further detail below.

Transition From Pediatric to Adult HIV Care

The transition from pediatric to adult HIV care requires proactive attention to the medical and psychosocial needs of adolescents as they move from a child-focused to an adult-focused health care system, with the goal of preventing disruption in care and ensuring ART adherence.[110] Recommendations for transition planning from pediatric to adult HIV care can be found in the Adolescents and Young Adults With HIV section of these guidelines and the Pediatric Antiretroviral Guidelines.

Transition From Obstetric to Primary HIV Care Postpartum

Pregnancy and the postpartum period offer a unique opportunity to engage in HIV care, both for people newly diagnosed with HIV during pregnancy and for people with HIV prior to pregnancy. Childcare responsibilities and postpartum depression can contribute to decreased adherence to HIV care in the postpartum period, thus requiring additional support services. Guidance on postpartum follow-up for people with HIV can be found in the Perinatal Guidelines.

Transitions Between Health Care Providers or Settings

Transitions in health care providers or settings can occur between hospitals, primary HIV care practices, ambulatory specialty care practices, long-term care facilities, home health, and rehabilitation facilities.[111] Safe transitions in HIV care can be supported by coordinating with HIV care providers and educating people with HIV and their support systems. In the setting of a health care facility discharge, bedside medication delivery or "Meds to Beds" programs may enhance post-discharge medication adherence by eliminating the need to visit a pharmacy to fill post-discharge medications.[112,113] In the setting of a residential move from one geographic area to another, a new HIV care provider would ideally be identified ahead of the move so that communication and transfer of medical records occur in a timely manner. This is particularly important for people with HIV who are receiving RWHAP services because not all HIV care providers receive RWHAP funding. HRSA provides an online resource for identifying RWHAP providers nationally. Provision of at least a 30-day ART supply at the time of a residential move may mitigate gaps in adherence due to delays in health care access in a new geographic area.

Reengagement in HIV Care After Loss to Follow-up

Adherence along the HIV care continuum is fluid and can change depending on an individual's life circumstances. In general, guidance around reengagement in care is similar to the guidance for individuals who are newly diagnosed with HIV. However, specific attention should be paid to understanding the reasons for previous disengagement from care, and shared decision-making should be used to identify strategies to address these barriers using a multidisciplinary approach. Hospitalization can provide an important opportunity for reengagement when an acute illness may increase an individual's motivation for behavior change. As noted above, bedside medication delivery or "Meds to Beds" programs have the potential to enhance post-discharge medication adherence.[112,113]

Individuals in Custody Released From Jails and Prisons

HIV continues to disproportionately affect individuals who are incarcerated at a rate three times that of the general population. Approximately 1.1% of individuals in custody have HIV, compared with 0.4% of the general population.[114,115] Incarceration presents an opportunity to identify and treat previously undiagnosed people with HIV, reengage those who had fallen out of HIV care in the community before incarceration, and stabilize HIV treatment among those who struggled with adherence and retention in care in the community. HIV treatment inside carceral facilities should mirror treatment in the community with respect to ART selection. Treatment interruptions should be avoided when people enter and leave such facilities. HIV treatment outcomes can be improved by having HIV specialty care teams within carceral facilities to communicate and coordinate care with community-based providers. There are unique considerations when treating HIV inside prisons and jails, given a lack of individual privacy, restricted movement to the health care unit, HIV stigma, and solitary confinement—all of which can negatively impact ART adherence while in custody. Conversely, this setting can allow the individual in custody to focus on adherence and allow the health care team to assess the safety, tolerability, and effectiveness of an ART regimen.

Adherence challenges can increase exponentially upon release from custody and include lapses in medical and prescription benefits (including for mental health and substance use disorders), housing instability, lack of transportation, lack of identification and other important documents (e.g., birth certificate, social security card) needed to secure medical benefits, relapse to substance use, and risk of overdose. Interventions to reduce barriers to HIV treatment should be assessed during the prerelease discharge planning process when feasible and can be enhanced by accessing assistance through community-based organizations that provide post-release services.[116] Factors that promote treatment adherence post-release include registering for health insurance and completing an ADAP application prior to release,[117] coordinating follow-up HIV care with community providers, and providing a 30-day supply of ART at the time of release.[118] Various interventions to improve post-release treatment adherence have demonstrated the efficacy of an interdisciplinary medical team, including case management and patient navigation resources.[119-124]

Long-Acting Antiretroviral Therapy

An ART regimen of long-acting intramuscular cabotegravir and rilpivirine (LA CAB/RPV) given monthly or every 2 months has been studied and approved for use in populations with viral suppression. In addition, preliminary data from a randomized clinical trial suggest that LA CAB/RPV may be safe and effective among people without viral suppression despite intensive adherence support on oral ART; however, final data and long-term outcomes are not yet available.[125] The long pharmacologic tail of LA CAB/RPV after the last dose raises concerns about the emergence of drug-resistance mutations in people who discontinue therapy without rapidly transitioning to oral therapy. Further, efficacy data from randomized clinical trials do not always translate to effectiveness in real-world settings.

The use of the LA CAB/RPV as a complete regimen is generally not recommended in people with viremia due to suboptimal adherence to ART, or in people who have ongoing challenges with retention in HIV care. However, limited data from small observational studies found that LA CAB/RPV can lead to high levels of viral suppression in people who have struggled with adherence to oral ART and who are viremic at treatment initiation.[126-128] It should be noted that these studies were conducted in settings where LA CAB/RPV was available on Medicaid and ADAP formularies. Further, significant social and case management support, including full-time dedicated staff, was provided to ensure adherence to the regimen. This support was provided by multidisciplinary teams involving clinicians, pharmacists, and case managers and included appointment reminders, assistance with transportation, financial incentives, and assistance with rescheduling missed injection appointments. Additionally, injections were offered in people's homes, at harm-reduction sites, and via street medicine. It is unknown whether similar responses can be achieved in clinics without the resources to provide the level of adherence support seen in previous studies.

Based on these limited data, the Panel recommends the use of LA CAB/RPV on a case-by-case basis in select individuals with persistent virologic failure despite intensive adherence support on oral ART, who have no evidence of resistance to RPV or CAB, and with shared decision-making between providers and people with HIV **(CIII)**.

This approach may provide alternatives for individuals with viremia and difficulties with adherence to oral ART, especially for those at the highest risk for disease progression or death. If LA CAB/RPV is used, close monitoring is recommended, with drug-resistance testing performed if virologic response is inadequate. Importantly, conventional adherence support is likely inadequate, and expanded, intensive, multidisciplinary case management and outreach support are needed when using this strategy to assure adherence and adequate monitoring for people while on LA CAB/RPV. People with HIV and providers need to be aware of the significant risk of developing resistance to non-nucleoside reverse transcriptase inhibitors and particularly INSTIs if virologic failure occurs on LA CAB/RPV, which may limit future treatment options and may also lead to

transmission of HIV; these concerns should be balanced with the given individual's HIV-related risk for disease progression and death. See Virologic Failure for a more detailed discussion.

Conclusion

Clinicians should obtain accurate information about a person's adherence and barriers to ART and appointment adherence, followed by meaningful discussions on solutions, rather than simply instructing adherence and warning about potential consequences of poor adherence. The latter approach fails to acknowledge a person's barriers to adherence, fails to provide actionable information, erodes rather than builds the patient–provider relationship, and has been demonstrated to not improve adherence.[129,130] At the same time, however, many of the interventions shown to improve adherence are difficult to implement in routine care. Nonetheless, effective lessons from this body of research can be applied to routine care to improve linkage to care, adherence to ART, and adherence to appointments. These lessons include the following:

- Regularly assess adherence to ART and appointments.
- Engage people struggling with adherence at any step on the care continuum with a constructive, collaborative, nonjudgmental, and problem-solving approach rather than reprimanding them or lecturing them on the importance of adherence.
- Elicit an individual's barriers to adherence, which may include personal, behavioral, medical, or structural barriers (e.g., substance use, housing instability, stigma, lack of transportation), clinic barriers (e.g., limited clinic hours, processes that make it more difficult to obtain prescriptions or schedule appointments), and system barriers (e.g., copays, prior approvals, processes that complicate maintaining pharmacy benefits or obtaining refills).
- Tailor approaches to improve adherence to an individual's specific needs and barriers, for example, by changing ART to simplify dosing or reduce side effects, finding resources to assist with copays or other out-of-pocket costs (see Table 19 below), to maintain an uninterrupted supply of ART, and to assure access to clinicians, or linking people to counseling to overcome stigma, substance use, or mental illness.
- Utilize ART regimens with high genetic barriers to resistance—such as DTG, bictegravir, or boosted darunavir regimens—for people with adherence problems. When selecting the regimen, consider possible side effects, out-of-pocket costs, convenience, and individual preferences, because the only regimen that will work is the one that people can obtain and are willing and able to take.
- Recognize the need for multidisciplinary approaches to identify and address barriers. Clinicians should help people with HIV understand the importance of adherence to the continuum of care, identify and address immediate barriers, and link them to resources for overcoming other obstacles.

Table 19. Strategies to Improve Linkage to Care, Retention in Care, Adherence to Appointments, and Adherence to Antiretroviral Therapy

Strategies	Examples
Provide an accessible, trustworthy, nonjudgmental multidisciplinary health care team.	• Include care providers, nurses, social workers, case managers, pharmacists, medication managers, and administrative staff on the care team; train all members on providing compassionate and person-centered care.
Strengthen early linkage to care and retention in care.	• Encourage health care team participation in linkage to and retention in care. • Use ARTAS training (if available). • Actively support linkage to care with assistance in making appointments and linkage to services to overcome barriers to care. • Streamline Ryan White HIV/AIDS Program eligibility verification processes for uninsured and underinsured clients.
Evaluate an individual's knowledge about HIV, HIV prevention, and HIV treatment and provide information based on this assessment.	• Keeping the current knowledge base in mind, provide information about HIV, including the natural history of the disease, HIV viral load and CD4 count and expected clinical outcomes according to these parameters, therapeutic and prevention consequences of poor adherence, and the importance of staying in HIV care.
Identify facilitators, potential barriers to adherence, and necessary medication management skills both when starting ART and thereafter.	• Assess each individual's cognitive competence and impairment. • Assess behavioral and psychosocial challenges, including mental illnesses, trauma, social support levels, alcohol consumption, substance use, nondisclosure of HIV serostatus, and stigma. • Identify and address language and literacy barriers. • Assess beliefs, perceptions, and expectations about taking ART (e.g., impact on health, side effects, disclosure issues, consequences of poor adherence). • Ask about medication-taking skills and foreseeable challenges with adherence (e.g., past difficulty keeping appointments, adverse effects from previous medications, issues managing other chronic medications, need for medication reminders and organizers). • Assess structural issues, including unstable housing, lack of income, unpredictable daily schedule, lack of prescription drug coverage, lack of continuous access to medications, and transportation problems.
Provide needed resources.	• Provide or refer for mental health and/or substance use treatment. • Provide resources to obtain prescription drug coverage (e.g., AIDS Drug Assistance Programs, Pharmaceutical Company HIV Patient Assistance Programs and Cost-Sharing Assistance Programs). • Assist people during insurance enrollment periods to facilitate enrollment in plans that cover antiretrovirals. • Provide resources about stable housing, social support, transportation assistance, income, and food security.

Table 19. Strategies to Improve Linkage to Care, Retention in Care, Adherence to Appointments, and Adherence to Antiretroviral Therapy

Strategies	Examples
Involve people with HIV in ARV regimen selection.	• Review potential side effects, dosing frequency, pill burden, storage requirements, food requirements, and consequences of poor adherence. • Assess daily activities and tailor a regimen to predictable and routine daily events. • Consider preferential use of ART regimen with a high barrier to resistance, such as BIC-, DTG-, or boosted DRV-based ART if poor adherence is anticipated. • Consider the use of STR or fixed-dose-combination formulations to reduce pill burden and/or dosing frequency. • Consider the use of LA CAB/RPV if clinically appropriate (see the Long-Acting Antiretroviral Therapy section above for further discussion). • Assess if the cost or copayment for drugs will affect adherence and access to medications.
Assess adherence at every clinic visit.	• Monitor viral load as a strong biological measure of adherence. • Use a simple behavioral rating scale or self-reported assessment. • Employ a structured format that normalizes or assumes less-than-perfect adherence and minimizes socially desirable or "white-coat adherence" responses. • Ensure that other members of the health care team also assess and support adherence.
Use positive reinforcement to foster adherence success.	• Inform people of the benefits of low or nondetectable levels of HIV viral load (e.g., "Undetectable = Untransmittable") and increases in CD4 counts. • Thank people for attending their appointments.
Identify the type of and reasons for poor adherence and target ways to improve adherence.	Identify if any of the following have contributed to poor adherence: • Failure to understand dosing instructions. • Complexity of regimen (e.g., pill burden, size, dosing schedule, food requirements, polypharmacy). • Pill aversion or pill fatigue. • Adverse effects. • Inadequate understanding of drug resistance and its relationship to adherence. • Appointment reminders and incorporation of input from people with HIV in appointment scheduling. • Cost-related issues (e.g., copays for medications or visits, missed work time). • Mental illness, drug and alcohol use, homelessness, or poverty. • Stigma of taking pills or attending HIV-related appointments. • Nondisclosure of status or privacy concerns leading to missed doses, refills, or appointments.

Table 19. Strategies to Improve Linkage to Care, Retention in Care, Adherence to Appointments, and Adherence to Antiretroviral Therapy

Strategies	Examples
Select from among available effective adherence and retention interventions.	• See the CDC's Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention for a summary of best practice interventions to improve linkage, retention, and adherence. • Use adherence-related tools to complement education and counseling interventions (e.g., text messaging, pill box monitors, pill boxes, alarms). • Use community resources to support adherence (e.g., visiting nurses, community workers, family, peer advocates, transportation assistance, pharmacy delivery). • Use prescription assistance programs (see "Provide needed resources" above in this table). • Use motivational interviews. • Provide outreach for people who drop out of care. • Use peer or paraprofessional treatment navigators. • Recognize positive clinical outcomes resulting from better adherence. • Arrange for DOT for people in substance use treatment (if feasible). • Enhance clinic support and structures to promote linkage and retention (e.g., reminder calls, flexible scheduling, assessment of clinic service satisfaction). • Offer telehealth services for primary care, as well as supportive services when appropriate.
Systematically monitor retention in care.	• Record and follow up on missed visits.

Key: ART = antiretroviral therapy; ARTAS = Anti-Retroviral Treatment and Access to Services; ARV = antiretroviral; BIC = bictegravir; CD4 = CD4 T lymphocyte; CDC = Centers for Disease Control and Prevention; DOT = directly observed therapy; DRV = darunavir; DTG = dolutegravir; LA CAB/RPV = long-acting cabotegravir/rilpivirine; STR = single-tablet regimen

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