

Innovations in HIV care delivery during the COVID-19 pandemic: Policies to strengthen the  
Ending the Epidemic Initiative – A Policy Paper of the Infectious Diseases Society of America  
and the HIV Medicine Association

Wendy S. Armstrong<sup>1,2</sup>, Allison L. Agwu<sup>3,4</sup>, Ernie-Paul Barrette<sup>5</sup>, Rachel Bender Ignacio<sup>6,7</sup>,  
Jennifer J. Chang<sup>8</sup>, Jonathan A. Colasanti<sup>1,2,9</sup>, Michelle Floris-Moore<sup>10</sup>, Marwan Haddad<sup>11</sup>,  
Lynsay MacLaren<sup>12</sup>, Andrea Weddle<sup>13</sup>

<sup>1</sup>Division of Infectious Diseases, Emory University School of Medicine, Atlanta, GA, USA;

<sup>2</sup>Grady Healthcare System, Infectious Diseases Program, Atlanta, GA, USA; <sup>3</sup> Division of  
Pediatric Infectious Diseases, Department of Pediatrics, <sup>4</sup>Division of Infectious Diseases,  
Department of Medicine, Johns Hopkins University School of Medicine; Baltimore, MD, USA;

<sup>5</sup>Division of Infectious Diseases, Washington University in St Louis, St Louis, MO, USA;

<sup>6</sup>Division of Allergy and Infectious Diseases, University of Washington, Seattle, WA, USA;

<sup>7</sup>Vaccine and Infectious Diseases Division, Fred Hutchinson Cancer Research Institute,  
Seattle, WA, USA; <sup>8</sup>Kaiser Permanente at Los Angeles Medical Center, Los Angeles CA, USA; <sup>9</sup>

Rollins School of Public Health, Emory University, Atlanta, GA, USA; <sup>10</sup>Division of Infectious  
Diseases, University of North Carolina School of Medicine, Chapel Hill, NC, USA; <sup>11</sup>Center for

Key Populations, Community Health Center, Inc. Middletown, CT, USA; <sup>12</sup>Whitman Walker

Health, Washington DC, USA; <sup>13</sup>HIV Medicine Association of the Infectious Diseases Society  
of America, Arlington, VA.

**Corresponding author:**

Wendy S. Armstrong, MD

Department of Medicine, Division of Infectious Diseases

Emory University School of Medicine

341 Ponce de Leon Ave, Atlanta, GA 30308

Telephone: 404-616-2493

Email: [wsarmst@emory.edu](mailto:wsarmst@emory.edu)

**Summary:** The COVID-19 pandemic has led to innovative changes in HIV health care delivery that have promoted patient-centered care and may enhance efforts to End the HIV Epidemic. Recommendations for permanent policy changes to maintain this progress are offered.

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**Abstract:**

The goal of the *Ending the HIV Epidemic Initiative* is to reduce new infections in the US by 90% by 2030. Success will require fundamentally changing HIV prevention and care delivery to engage more persons with HIV and at-risk of HIV in treatment. While the COVID-19 pandemic reduced in-person visits to care facilities and led to concern about interruptions in care, it also accelerated growth of alternative options, bolstered by additional funding support. These included the use of telehealth, medication delivery to the home and increased flexibility facilitating access to Ryan White HIV/AIDS Program services. While the outcomes of these programs must be studied, many have improved accessibility during the pandemic. As the pandemic wanes, long term policy changes are needed to preserve these options for those who benefit from them. These new care paradigms may provide a roadmap for progress for those with other chronic health issues as well.

**Keywords:** Telehealth, Antiretroviral therapy, Pre-exposure prophylaxis, HIV, Ryan White HIV/AIDS Program

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Healthcare systems have been deeply impacted by the COVID-19 pandemic. In some cases, hospitals have been overwhelmed and non-essential services, including many outpatient activities, were scaled back or suspended. Patients, concerned about the risk of SARS-CoV-2 acquisition, have forgone preventive services, emergency services and chronic disease care.<sup>1-3</sup> The impact of these changes on the Ending the HIV Epidemic (EHE) Initiative<sup>4</sup>, though not fully understood, is concerning. In July, 2020, the WHO released data showing the COVID-19 pandemic has severely impacted international progress toward HIV epidemic control, “blowing us completely off track.”<sup>5</sup> In the United States (US), disruptions in HIV testing programs and in provision of pre-exposure prophylaxis (PrEP) have occurred. At one large center, nearly 75% fewer persons initiated PrEP between January and April, 2020.<sup>6</sup> In the face of concern about losing ground in the fight to end the HIV epidemic, some programs have developed innovative solutions that not only help mitigate the effects of the COVID-19 pandemic, but could also lead to substantial progress in transforming HIV prevention and care to be more patient-centered, accessible, collaborative, and less bureaucratic.<sup>7</sup> In this paper, we describe critical areas where progress has been made, highlight remaining research questions, and discuss policies needed to maintain that progress (Table 1). While these examples are specific to the provision of HIV prevention and care and include the federally funded Ryan White HIV/AIDS Program (RWHAP) that provides care and treatment to more than half of the diagnosed persons with HIV (PWH) in the US, many of the innovations have been applied to the delivery of healthcare for other chronic diseases.<sup>8</sup>

## Telehealth for routine HIV care

The most widespread healthcare adaptation triggered by the COVID-19 pandemic has been the rapid expansion of telehealth services.<sup>9</sup> Traditionally, HIV care has been limited to in-person visits in “brick and mortar” clinics at prescribed intervals with little flexibility. Retention in care metrics and reimbursement payment models have reinforced these practices despite patients citing challenges with transportation, childcare, and clinic stigma as significant reasons for missed visits.<sup>10</sup> Prior to the COVID-19 pandemic, telehealth practices were sparse, regional, and had limited adoption by certain specialties like behavioral health. One highly successful asynchronous care model, Project ECHO, has utilized technology to connect specialists with primary care clinicians in rural and underserved urban areas. This work has been largely grant funded and reimbursement is not consistent across states.<sup>11-13</sup> Regulatory and fiduciary restrictions on telehealth have led to strict limitations on what constituted private, confidential platforms, and what would be considered reimbursable by third party payers. In part due to these regulatory hurdles, many health systems failed to invest in the information technology infrastructure to support telehealth at scale.

Following years of work to address the barriers to widespread deployment of telehealth solutions, in the face of shelter-in-place orders, direct provider-to-patient synchronous telemedicine was adopted across the nation with unprecedented speed in order to ensure continuity of care.<sup>14</sup> Through federal emergency authorization measures (HR6074)<sup>15</sup>, telephonic and video-based telemedicine visits have become a reimbursable model, including through Medicaid and Medicare. Physicians and providers now have the capability to meet patients “where they are,” eliminating some barriers that prevent regular

clinic attendance. Telehealth may reduce patient anxieties or stigma associated with seeking care at a clinic for HIV/AIDS, mental health or substance use disorders and is supported by the Infectious Diseases Society of America for HIV care.<sup>16</sup> Telehealth also offers opportunities to engage or reengage patients who have struggled with clinic visit adherence and provides greater flexibility for interim visits, including adherence and side effect check-ins. Many clinicians have anecdotally reported high uptake and satisfaction with telehealth by subsets of patients, in particular adolescents who are comfortable with technology.<sup>7</sup> One author's clinic (RBI) has estimated a drop in "no show" rates by 50% since rapid telehealth roll-out in April, 2020, compared to the previous year.

The advantages of telehealth have been clear for patients with access to technology, but, when the pandemic wanes, policy changes are needed to continue this practice. First, adequate and ongoing reimbursement from all third-party payers will be needed in order for patient care via telemedicine to be sustainable. Reimbursement must continue at rates similar to in-person visits for both video and telephonic visits to avoid disadvantaging those without adequate access to video technology, including older individuals, those with lower incomes, and those without adequate internet access. Second, appropriate infrastructure is required for both provider and patient. Healthcare systems must adopt approved platforms for telehealth visits and have adequate clinic personnel available to assist patients with use. Ryan White funding should be increased to support smartphones, tablets, and data plans for patients, and technology support for patients and staff. Third, telehealth must be allowed as a core RWHAP medical service equivalent to an in-person visit in retention measures. Fourth, policies which support maximizing the capacity of the limited HIV expert workforce are needed. In the South, 81% of counties lack an expert HIV provider.<sup>17</sup> Telehealth provides

opportunities to expand that reach if states allow physicians and advanced practice providers (APPs) to practice virtually across state borders and if advanced practice providers (APPs) can practice telehealth without additional licensing barriers. This flexibility would also offer opportunities to provide care to PWH who cannot find local specialists or have confidentiality concerns.

During this seismic paradigm shift, there has been little time to identify and adopt best practices for integrating telehealth into HIV care. As we move forward, the implementation and outcomes of telehealth must be evaluated to determine how to best benefit patients. Still unknown is the ideal frequency of in-person versus telehealth visits, the patient subgroups who most benefit from telehealth visits and those who do not, the role of in-person visits in establishing and maintaining a trusting and confidential provider-patient relationship, and the best way to incorporate team-based care, a cornerstone for many RW-funded clinics, into virtual care models. We must also prevent widening of already existing disparities among populations with more limited access to technology.

In sum, telehealth – and particularly synchronous telemedicine - provides an exciting new platform to provide patient-centered care. We now have the opportunity to study, inform and shape HIV care using telehealth, which in turn informs all types of chronic disease management.

## HIV Prescription Drug and PrEP Access

### *Access to Antiretroviral Therapy*

In order to optimize individual health outcomes and minimize risk of secondary HIV transmission, reliable access to antiretroviral therapy (ART) is required but is impacted by structural, environmental, psychosocial, and individual factors. Even prior to the COVID-19 pandemic, medication access for PWH was often challenging. Because antiretrovirals are categorized as specialty drugs, ART prescriptions often have higher copays and are generally limited to 30-day supplies, necessitating monthly pharmacy trips with associated barriers such as transportation, stigma, and competing family or work demands.<sup>18,19</sup> Support for medication cost is available through the state RWHAP AIDS Drug Assistance Programs (ADAP) for individuals with low income. However, qualifying income thresholds for ADAP support vary considerably, ranging from 550% of the federal poverty limit (FPL) in South Carolina to 200% FPL in Texas and Idaho.<sup>20</sup> Cost sharing remains a barrier for patients who do not qualify for assistance. Medication delivery has not been an option for many PWH due to coverage policies, privacy concerns, cost of delivery, and lack of a stable address. Others are required to fill prescriptions at pharmacies co-located in an HIV clinic, which can increase stigma and travel time. While local pharmacies may be more convenient, many do not keep antiretrovirals in stock and lack the expertise to navigate coverage schemes.

The COVID-19 pandemic risks treatment disruptions for PWH. While data are not yet available to assess the impact on medication access, by mid-March 2020, coverage restrictions were relaxed to help ensure uninterrupted treatment for some PWH. These changes allowed increased refill flexibility including provision of 60 to 90-day supplies by some ADAPs and insurance companies. Early refills have been implemented in at least 33



states.<sup>21</sup> Many insurance providers waived co-pays or suspended the requirement for prior authorizations for specialty medications.<sup>22</sup> Waiver of in-state licensing requirements and flexibility for prescription transfers between pharmacies in some states also facilitated access.<sup>23,24</sup>

Pharmacist-led adherence programs adopted telehealth technologies to support medication adherence in patients with access to the appropriate tools such as smartphones and tablets. Clinical staff with reduced on-site responsibilities had time to proactively reach out to patients, provide preemptive refills and facilitate medication delivery. The Coronavirus Aid, Relief and Economic Security (CARES) Act funding allowed programs to offer additional co-pay assistance and transportation coverage for PWH and also provided funding to offset the costs associated with medication delivery.<sup>25</sup>

These strategies implemented in response to COVID-19 have facilitated medication access. In two authors' clinic (WSA, JAC), despite a dramatic reduction in visits and laboratory draws, pharmacy refills remained unchanged due to medication delivery options, critical to maintaining virologic suppression. These valuable innovations should not end with the pandemic but will require permanent policy changes including allowing 60- to 90-day medication supplies, waiving some or all co-pays, and authorizing early refills. The augmented funding and loosened restrictions that have facilitated mail delivery should be continued when the CARES Act funding ends, and should be enhanced to support personnel costs, co-pay coverage, and mailing/delivery costs. Delivery options should eliminate signature requirements and allow medication delivery to a secure box or other location for those with unstable housing, inflexible work schedules, and privacy considerations.

### *Pre-Exposure Prophylaxis (PrEP)*

PrEP is highly effective in preventing HIV infection. While PrEP use has increased significantly since approval in 2012, uptake of PrEP, during the pre-COVID era, remained poor in certain high-risk populations, including young Black men who have sex with men, and in high HIV incidence regions like the Southern US. Several factors contribute to low PrEP use, including distance from prescribing clinics, stigma, and inadequate healthcare system capacity.<sup>26</sup> While strategies to address these barriers have been considered, the COVID-19 pandemic further exposed challenges to PrEP access and provided an opportunity to accelerate change.

PrEP is typically prescribed in the context of an in-person visit with a provider comfortable with PrEP and its associated laboratory testing. Receipt of PrEP often requires enrollment in industry patient assistance programs for uninsured patients. During the pandemic, some providers and programs adopted innovative PrEP service delivery strategies in order to minimize disruption in care. Similar to HIV treatment, these approaches included the use of telehealth visits, pharmacy delivery or curbside pick-up of PrEP, and reduction in barriers to insurance coverage of medications. Synchronous telemedicine offers an ideal platform for delivery of PrEP care, as the need for physical examination is limited, and counseling is a significant portion of the visit. Importantly, telemedicine also allows crucial access for patients without local PrEP providers, as is the case in many rural areas. During the COVID pandemic, many PrEP providers who shifted to virtual visits reported challenges in obtaining appropriate laboratory monitoring, including quarterly HIV and sexually transmitted infections (STI) studies, especially extra-genital testing. Subsequently, many PrEP providers reduced the frequency of testing at the risk of missing STIs or new drug-

resistant HIV infections acquired in the context of ongoing PrEP use. New approaches to testing are needed, including patient-obtained samples (swabs, dried blood spots) which can be mailed or brought to a commercial testing site for processing. Currently, many test sites do not accept self-swabs and mail-in test kits lead to costs related to mailing and staff tracking of kits. Streamlined protocols for laboratories to validate patient-obtained specimens would facilitate their ability to accept these specimens. In addition, adequate insurance coverage for home or facility-based testing is urgently needed.

Record levels of unemployment due to the COVID crisis have led to substantial losses of employer-based health insurance coverage. While the increase in patients who are uninsured has created HIV treatment access challenges, the impact on PrEP has likely been even greater because RWHAP assistance cannot be used for HIV prevention medications. In the few states with state-funded PrEP-Drug Assistance Programs (DAP), patients may qualify for co-pay or other assistance.<sup>27</sup> PrEP-DAP expansion in other states is greatly needed, particularly areas with the highest incidence of HIV infection. Allowing RWHAP program income to be used for selected prevention services if this does not compromise HIV treatment would help expand PrEP access. If these strategies can be adopted and reimbursement secured on an ongoing basis, tele-PrEP, self-testing or testing at laboratory facilities, and easier and more affordable access to medication could help expand the access and uptake of PrEP.

#### *Research Priorities*

The impact of these new innovations needs to be studied. Important research questions include: 1) evaluation of access and adherence to and persistence with HIV and PrEP treatment through telehealth versus facility-based care; 2) satisfaction with telehealth

for HIV prevention and treatment and the effect on stigma and other barriers; and 3) acceptability and accuracy of self-testing for HIV and STIs for PrEP.

### **The Ryan White HIV/AIDS Program**

The RWHAP serves as the payer of last resort for clinical care, support services and medications for un- and under-insured PWH but requires annual certification with self-attestation every six months to maintain eligibility. Patients must provide proof of HIV status, income, insurance status, and residence in order to receive services. These basic requirements are dictated by the Health Resources and Services Administration (HRSA), the granting agency, but local jurisdictions can add additional requirements and can dictate what constitutes “proof” for their grant recipients.<sup>28</sup> Some jurisdictions, for example, require in-person certification and paper signatures for RWHAP enrollment. Some have higher burdens of “proof” requiring wage statements issued by government agencies and obtained during in-person visits. Some states require current CD4 and HIV RNA values for certification. This latitude by individual jurisdictions can add additional layers of bureaucracy to an already challenging system for those without significant resources.

During the COVID-19 pandemic, as PWH without active health issues and with virologic suppression were advised to stay away from the clinic and forgo routine laboratory testing, HRSA encouraged states to be flexible in their certification and re-certification policies to support social distancing recommendations. Although the flexibility was allowed under existing policy, HRSA re-emphasized electronic certification and attestation and allowed e-mailed application forms, underscoring that these processes need not occur in person.<sup>29</sup> This explicitly-stated federal guidance encouraged local and state jurisdictions to relax many of their own added barriers. More states allowed flexibility in the timing of the

annual certification, authorized data-sharing agreements between agencies, and permitted case managers to work remotely and utilize telehealth communications. In some states, for PWH whose RWHAP and ADAP certifications were due to expire in the pandemic period, automatic extensions were granted, even without current laboratory tests.

While these measures were implemented to minimize the exposure of PWH to healthcare facilities, they also dramatically reduced barriers to care. Many RWHAP-funded clinics have been advocating for similar changes prior to the COVID-19 pandemic. These efforts have been particularly visible in the high-prevalence counties identified in the EHE Initiative where HIV care providers, the advocacy community, and PWH highlight restrictive RWHAP bureaucracy as a major barrier to care.

As we reconfigure care delivery models in RWHAP with enhanced use of telemedicine, medication delivery and other services that do not require frequent physical presence at the clinic, it is imperative that COVID-19 related advances are not lost. Clear federal guidance was transformative in states where excessive concerns about accountability during audits previously limited progress. While HRSA allows jurisdictional flexibility, this latitude must not allow more restrictive policies to augment the federal requirements. In recognition of the potential harms that service and treatment delays or disruptions can cause, allowing for a margin of error in certifying and recertifying patient eligibility for Ryan White services would allow jurisdictions to introduce more innovative and proactive programs. This would also facilitate rapid enrollment and initiation of ART. Required metrics for retention and other outcomes should be updated to reflect new care models as well.

### **Additional Innovations during COVID-19**

*Public health workforce*— An urgent need to enhance contact tracing, as a response to COVID-19, has triggered massive hiring of contact tracers in health departments across the country.<sup>30</sup> In the future, this public health workforce may be further deployed for COVID-19 vaccination campaigns. Contact tracers trained as community health workers could lay the groundwork for a much more robust public health workforce across the US and allow that workforce to be leveraged for other urgent public health needs like HIV, STI, chronic disease, and cancer screenings. Structural racism and social determinants of health drive healthcare disparities not only in COVID-19 but also in these other disease processes and prevention efforts. A culturally competent, well-trained, and well-financed public health workforce with robust outreach prevention services could help mitigate these disparities and reduce stigma with a focus on overall health. This opportunity should not be wasted.<sup>31</sup>

*Housing* – The COVID-19 pandemic has highlighted the link between health outcomes and housing.<sup>32</sup> Similarly, unstable housing is one of the greatest predictors of poor health outcomes and mortality for PWH.<sup>33</sup> While the Housing Opportunities for Persons with AIDS (HOPWA) Program was created in 1990, capacity is limited in many jurisdictions. During the current pandemic, many cities established temporary housing and shelters to facilitate quarantine for those with COVID-19 or to allow social distancing.<sup>34</sup> The creativity shown during COVID-19 to rapidly create housing opportunities needs to be applied after the pandemic for those with HIV and unstable housing.

The COVID-19 pandemic has disrupted life in the US in an unprecedented way. Rapid mitigation strategies have led to significant innovation that may lead us to a better “new normal” with less reliance on routine older practices and greater flexibility that ultimately could positively impact EHE efforts. To realize this promise, however, policies that permit ongoing flexibility will be necessary to sustain these changes. In addition, careful evaluation of practice changes is necessary to assess impact and improve outcomes.

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**Table 1 Summary of Policy Innovations and Future Recommendations**

<p><b>Telehealth</b></p> <ol style="list-style-type: none"><li>1. All third-party payers should provide adequate and ongoing reimbursement for telehealth conducted by video or telephone.</li><li>2. States should facilitate the ability of healthcare providers to conduct telehealth across state lines to improve access to expert HIV care providers.</li><li>3. States should allow advanced practice providers to deliver telehealth without additional licensing requirements.</li><li>4. Asynchronous telehealth services like Project ECHO which link primary care providers to specialists should be funded and services reimbursed.</li><li>5. Include telehealth visits in quality metrics measuring retention in care.</li><li>6. Increase Ryan White HIV/AIDS Program funding to support smart phones, smart tablets, data plans and airtime for patients and allow for telehealth expenses to be considered a core service.</li><li>7. Support clinical research to identify patients for whom telehealth works well, assess if it reduces barriers to care such as transportation and stigma and determine the right balance between in-person and telehealth visits.</li></ol>
<p><b>HIV Drug Access</b></p> <ol style="list-style-type: none"><li>8. Allow flexibility for medication refills including early refills and 60 to 90-day supplies to prevent treatment disruptions.</li><li>9. Waive, reduce or streamline prior authorization requirements for specialty medications.</li><li>10. Facilitate access to HIV treatment through mail-order by not requiring a signature and allowing delivery to a secure box or other location and through home delivery of medications.</li></ol>
<p><b>Pre-exposure Prophylaxis (PrEP)</b></p> <ol style="list-style-type: none"><li>11. Reduce physical barriers to PrEP access, by offering telehealth visits by telephone and video.</li><li>12. Provide coverage of home HIV and STI screening costs.</li><li>13. Streamlined protocols for laboratories to validate patient-obtained specimens</li><li>14. Modify policies and provide resources to support mail-order, home delivery or curbside pick-up of PrEP medications.</li><li>15. Allow for RWHAP program income to be used for select preventive services if HIV treatment access is not compromised as a result</li><li>16. Support clinical research to evaluate changes in PrEP uptake and adherence due to COVID-19 and the frequency of STI screening and test positivity rates, including HIV.</li></ol>
<p><b>Ryan White HIV/AIDS Program</b></p> <ol style="list-style-type: none"><li>17. Issue strong national guidance setting expectations for states to reduce barriers to services by streamlining Ryan White Program AIDS Drug Assistance Program certification and recertification processes through electronic submissions and eliminating in-person attestation requirement.</li><li>18. Encourage jurisdictions to introduce innovative programs to support rapid start ART treatment by allowing a margin of error for a small percentage of patients to receive services who it may be determined have other coverage sources or whose HIV test is negative.</li></ol>

19. Allow flexibility in the timing of the RWHAP and ADAP annual certification and automatic extension of eligibility for a limited period to prevent care and treatment disruptions.
20. Incentivize states to authorize data-sharing agreements between agencies and permit case managers to work remotely and utilize telehealth communications.

**Public Health Workforce**

21. Leverage the development of a more robust public health workforce for contact tracing for other urgent public health needs, including HIV, STI and chronic disease screening.

**Housing as Healthcare**

22. Recognize and support housing as a critical healthcare service to improve health outcomes for people with HIV and as a public health strategy to reduce COVID-19 risks.

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