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BIG IDEAS

MAXIMIZING THE IMPACT OF THE RYAN WHITE HIV/AIDS PROGRAM

LEVERAGING THE RYAN WHITE PROGRAM TO MAKE RAPID START OF HIV THERAPY STANDARD PRACTICE

LEADING VOICES are increasingly talking about how we end the HIV epidemic in the United States and states and local governments are beginning to develop concrete plans to do so. Achieving this vision often involves changing how services are delivered to provide more timely medical care to newly diagnosed individuals and to better support retention in care. One of the most significant elements of some of these emerging plans is to treat HIV earlier by offering rapid start of antiretroviral therapy (ART), i.e. within days of individuals receiving an HIV diagnosis or re-engaging in HIV care.[1] At present, the US health system is far from making this the standard of practice. The Ryan White HIV/AIDS Program is uniquely poised to lead the way, both in changing how its recipients operate and in demonstrating to Medicaid, Medicare, and private insurers how to make rapid start of ART a reality.

RAPID START GETS PEOPLE LIVING WITH HIV VIRALLY SUPPRESSED FASTER

Since the advent of effective HIV treatments in the mid-1990s, treatment guidelines have seesawed. Early on, the phrase, "hit hard, hit early" represented a prevailing view that it is best to start ART right away. This gave way to the idea that drug resistance was an inevitable problem, and thus treatment should be delayed as long as possible to preserve the beneficial effects of ART. A study of people living with HIV in care from 2004-2009 estimated that the median time from diagnosis to ART initiation was 10 months.[2] When the National HIV/AIDS Strategy was released in 2010, federal treatment guidelines did not recommend offering treatment to all newly diagnosed

THE RYAN WHITE HIV/AIDS PROGRAM LEADING THE WAY

Starting people with HIV on antiretroviral therapy (ART) on the same day that they are diagnosed has been shown to decrease the time to viral suppression and may also improve retention in care. Numerous financial and other challenges mean that most US clinics, health systems, and insurance programs do not currently have the capacity to offer rapid start to all newly diagnosed people or to all people who are being re-engaged in HIV care.

Making rapid start of ART the expectation for HIV health care systems is an urgent priority.

The Ryan White Program is a federal program that provides a comprehensive system of care for people living with HIV and is uniquely situated to work with clinicians, health departments, and community stakeholders to overcome barriers to widespread adoption of rapid start of ART. Moreover, the Congress can work with the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau to ensure that they have the resources and the tools to make rapid start of ART (within 7 days of diagnosis) a reality.

people until they met certain markers of immune decline. In 2012, the guidelines were updated to recommend offering ART immediately on diagnosis, and several randomized trials have validated this recommendation.[3,4,5]

Some have suggested that rapid start of ART could be an effective strategy for treating HIV earlier in the course of illness. Research studies in the US and abroad show that rapid start is safe and shortens the time to viral suppression.[6,7,8,9,10] It has been suggested that it also may improve long-term clinical outcomes. Current clinical guidelines also emphasize the importance of rapid initiation of ART.[11] How do we translate this research success into standard practice?

COMPONENTS OF RAPID START

While details of programs may vary, these elements of rapid start of ART are used by the RAPID Care protocol at San Francisco General Hospital:

1. **SAME DAY ACCESS TO AN HIV PROVIDER —** Appointment with an on-call HIV physician or nurse practitioner; taxi voucher from testing site to the clinic
2. **SAME DAY MEDICAL VISIT —** 2-3 hour visit to provide education on HIV infection, risk reduction, sexual health and benefits of ART, assess ART contraindications, permit the individual to accept or decline treatment, and conduct baseline laboratory testing
3. **ACCELERATED INSURANCE APPROVAL —** Activate mechanisms to provide for emergency drug assistance and follow-up to ensure that pending applications are prioritized
4. **PRE-APPROVED ART REGIMENS —** Regimens that can be used without genotype or lab testing were pre-approved by a local committee
5. **5-DAY STARTER PACK OF MEDICATIONS —** The ART prescription is sent to the pharmacy and starter packs are made available, as needed
6. **OBSERVED ADMINISTRATION OF THE FIRST DOSE —** Individuals accepting ART are offered the first dose in the clinic with the provider in the room for support
7. **TELEPHONE FOLLOW-UP —** Nurses contact patients no later than 7 days later to review lab results, ask about adherence, address pharmacy or side effect issues and efforts are made to get the individual back into the clinic within 1-2 weeks

Pilcher CD, Ospina-Norvell C, Dasgupta A, et al. The effect of same-day observed initiation of antiretroviral therapy on HIV viral load and treatment outcomes in a US public health setting. J Acquir Immune Defic Syndr. 2017;74(1):44-51, as updated by RAPID Program staff at San Francisco General Hospital in November 2018.

COMMON BARRIERS TO GETTING TO SCALE

Treating HIV is relatively easy compared to some other health conditions, yet treating right away is standard practice for many other conditions. The challenge in adopting rapid start of ART is developing workable models of care that can be implemented across our diverse national health care landscape. This is made more difficult by differences in health system capacity and in insurance coverage with some states having expanded Medicaid and others having not yet done so. Moreover, HIV testing is performed in a variety of settings and linking diagnosed individuals into a clinic can be a challenge. Barriers to systemwide adoption of rapid start include:

Clinician Acceptance: When a newly diagnosed individual enters into HIV care, providers follow well established practices that are intended to counsel patients, assess their knowledge of HIV infection and readiness for treatment, and providers perform a number of laboratory tests to test for co-occurring conditions and drug resistance that will guide the selection of an initial ART regimen. A key hurdle is assuring that providers are comfortable with upending many of these practices, and in particular, with starting ART without first having laboratory data, which demands using ART regimens that do not require baseline laboratory testing.

OFFERING A LIFELINE: A San Francisco Rapid Program provider said many clinicians were initially reluctant to offer rapid start. But it just takes one or two patients — on one of the worst days in our patients' lives we are offering a lifeline to a future of LIVING with HIV.

Patient Readiness: Telling a person that they are living with HIV is a critical milestone that requires counseling and education, as well as a discussion with providers about treatment options, which has

FROM PILOT TO PROGRAM: New York State used its ADAP system to conduct a rapid access treatment pilot that was successful at linking people to care and treating quickly. This led to the RapidTx Initiative being expanded to more provider sites across the state. The program provides a one-month supply of ART while ongoing heath care coverage is secured and reimburses for the initial consultation and a comprehensive HIV evaluation including laboratory tests.

RYAN WHITE PROGRAM SOLUTIONS FOR RAPID START

Federal policy cannot overcome every challenge, but federal leadership is essential. While the HRSA HIV/AIDS Bureau is already supporting efforts to adopt rapid start, further potential activities include:

PROVIDE CRITICAL LEADERSHIP

- **Make rapid start of ART a priority:** HRSA sets the agenda and could tell recipients and planning bodies that developing models for rapid start of ART in tandem with retention in care is a national priority and could create opportunities for shared learning among recipients.
- **Measure 'time to ART' and 'time to viral suppression':** HRSA needs to collect data and work with recipients to monitor both the time to start of ART and time to viral suppression along with existing metrics on retention in care and durability of viral suppression while working with recipients and providers to pare back other measures that are less relevant today.
- **Prioritize competitive funding for rapid start of ART:** HRSA awards competitive funds to address priority unmet needs. They can prioritize funding through the ADAP supplemental grant programs (and potentially Parts A and B supplemental programs) to help jurisdictions achieve rapid start. Further, they can revise guidance for the Part C program to promote the development of rapid start initiatives.

EXPEDITE ADAP ELIGIBILITY AND PROCURE STARTER COURSES OF DRUGS

- **Show states how to streamline ADAP eligibility:** HRSA can identify best practices and counsel states on how to make provisional same-day eligibility determinations and permit retroactive coverage for services provided prior to ADAP enrollment and also streamline the recertification process.
- **Facilitate purchase of ART starter packs:** HRSA can establish mechanisms for ADAP programs to purchase starter packs of ART (up to a month's supply) for any newly diagnosed or out-of-care person. The Ryan White Program should offer a safe harbor against violations of payer of last resort requirements if ADAP programs make a good faith effort to determine financial eligibility or in cases where ART was started for persons with a false positive test result

SUPPORT PRACTICE TRANSFORMATION

- **SPNS:** HRSA can use the Special Projects of National Significance (SPNS) program to develop models for offering rapid start of ART, dealing with issues such as on-call capacity. SPNS also could develop demonstration programs with Medicaid to move rapid start from a single clinic to widespread adoption.
- **AETC:** HRSA can highlight and bolster its work through the AIDS Education and Training Centers (AETC) program to disseminate rapid start protocols and develop curricula to address provider concerns and share provider and systems level best practices.

been made easier by newer medications with less likelihood of toxicity and fewer resistance concerns. This also requires determining whether individuals can safely process this information and make an informed decision about starting treatment. Many providers experienced with rapid start report that people with HIV eagerly want treatment.

GETTING TO SCALE: New York City launched their JumpstART program for rapid start in sexual health clinics. Already, more than half of newly diagnosed people in the city are enrolled in this program.

Insurance and ADAP Eligibility: Frequently, individuals receiving an HIV diagnosis or re-engaging in care do not have insurance. Because the Ryan White AIDS Drug Assistance Program (ADAP) must serve as the payer of last resort and each state ADAP has its own income eligibility standards and procedures, states vary dramatically in how quickly ADAP applications are processed or how readily eligibility determinations can be expedited.

Drug Procurement: Programs would like to be permitted to use ADAP to procure a one-time short-term supply (up to a month) of ART medications while ADAP eligibility can be established. Under current HRSA policy, however, this is not permitted.

Whereas New York City's JumpstART Program has used city appropriated funding, this is not an option in most places. Other programs have relied on donations from manufacturers or pharmacies, but these raise their own ethical and sustainability concerns and may create human resource burdens with assisting patients to access specific programs.

BUILDING PROVIDER CAPACITY: The Grady Health System in Atlanta proved the effectiveness of a rapid start program, but once they moved beyond the pilot, they were overwhelmed with potential enrollees. Ryan White Part A funding has enabled them to add a dedicated physician, but this is still insufficient and puts pressure on other over-extended clinicians.

THE TIME IS NOW

These preceding issues highlight some of the complexities of adopting rapid start. In addition to financing medications, the logistics hurdles involved with maintaining adequate provider capacity to see unscheduled patients (for hours at a time) on an on-call basis, as well as mobilizing the divergent components of the care system (from laboratories to insurance billing staff to patient navigators), are huge.

In many cases, there simply is not sufficient capacity to achieve rapid start with current resources. When the Congress next enacts a reauthorization to the Ryan White HIV/AIDS Program, they may consider a range of changes to improve outcomes and better support retention in care and adherence to treatment, including giving HRSA new tools to promote presumptive eligibility for ADAP and ensure that Medicaid, Medicare, and the marketplaces have the pharmacy benefits structures and staff capacity to operationalize rapid start of ART.

Making rapid start of ART standard practice for HIV clinical care is hard. But, many aspects of fighting HIV are hard. The science showing the benefits of rapid start is compelling; health departments, clinics, and people living with HIV support this approach. Now is the time to ask the Ryan White HIV/AIDS Program to help move this idea from leading clinics to standard practice across the health system.

ENDNOTES

1 For simplicity, we use rapid start as synonymous with same-day start of ART, meaning that individuals are given ART medication at the same time as being given an HIV diagnosis. The World Health Organization (WHO) defines "rapid" as being within 7 days from the date of diagnosis. See *Guidelines for Managing Advanced HIV Disease and Rapid Initiation of Antiretroviral Therapy, July 2017*. Geneva: World Health Organization; 2017:19-24. Available at https://www.ncbi.nlm.nih.gov/books/NBK475972/.

2 Adedinsewo DA, Wei SC, Robertson M, et al. Timing of antiretroviral therapy initiation in a national representative sample of HIV-infected adults receiving medical care in the United States. *AIDS Patient Care STDs*. 2014;28(12):613-621.

3 The Strategies for Management of Antiretroviral Therapy (SMART). Study Group. CD4+ count-guided interruption of antiretroviral treatment. *N Engl J Med.* 2006;355(22):2283-2296.

4 The INSIGHT START Study Group. Initiation of antiretroviral therapy in early asymptomatic HIV infection. *N Engl J Med.* 2015;373(9):795-807.

5 Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med.* 2011;365(6):493-505.

6 Rosen S, Maskew M, Fox MP, et al. Initiating antiretroviral therapy for HIV at a patient's first clinic visit: The RapIT randomized controlled trial. PLoS Med. 2016;13(5):e1002015.

7 Koenig SP, Dorvil N, Dévieux JG, et al. Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial. *PLoS Med.* 2017;14(7):e1002357.

8 Pilcher CD, Ospina-Norvell C, Dasgupta A, et al. The effect of same-day observed initiation of antiretroviral therapy on HIV viral load and treatment outcomes in a US public health setting. *J Acquir Immune Defic Syndr.* 2017;74(1):44-51.

9 Scheer S, Hsu L, Schwarcz S, et al. Trends in the San Francisco Human Immunodeficiency Virus Epidemic in the "Getting to Zero" Era. *Clin Infect Dis.* 2018;66(7):1027-1034.

10 Colasanti J, Sumitani J, Mehta CC, et al. Implementation of a rapid entry program decreases time to viral suppression among vulnerable persons living with HIV in the southern United States [published online ahead of print June 28, 2018]. *Open Forum Infect Dis.* doi. org/10.1093/ofid/ofy104.

11 Saag MS, Benson CA, Gandhi RT, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults: 2018 recommendations of the International Antiviral Society–USA Panel. *JAMA*. 2018; 320(4):379-396.

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