Perspectives

Rapid HIV Treatment Initiation in the Rural and Semi-rural U.S.: North Carolina Piloting a Model

Noah P. Manusco, B.S.[1], Christine A. Schalkoff, M.S.P.H.[1], Breana J. Uhrig Castonguay, M.P.H.[1,2], Candice J. McNeil, M.D., M.P.H.[3], Cynthia L. Gay, M.D., M.P.H.[2], Heidi Swygard, M.D., M.P.H.[2,4]

Ending the HIV epidemic in the United States has never been more possible than now. The 40,000 new infections each year are concentrated among communities of color and LGBTQ+ populations in the rural and semi-rural South and in urban centers of California and the Northeast.[1] The current administration has set forth Ending the HIV Epidemic: A Plan for America to address the public health crisis in these identified locations (Figure 1) by improving access to and retention in care in order to optimize individual health and eliminate the risk of sexual transmission.[2] To achieve the goal of a 90% reduction in new HIV infections by 2030, public health officials are encouraged to identify, learn from, and replicate successful international, state, and local interventions.[2]

An increasingly successful intervention to curb the HIV epidemic internationally is the rapid initiation of antiretroviral therapy (ART), referred to as "rapid-start" ART but with varying degrees of rapidity, for patients presenting with new HIV diagnoses. In low- and middle-income countries, evidence supports the benefits of these rapid treatment initiation (RTI) programs – which include medical, psychological, and social support – where HIV prevalence is high and access to care is limited.[3,4] RTI programs have recently been replicated in several large U.S. urban centers, too, producing high rates of viral suppression and increased retention in care compared to standard methods.[3,5,6] However, there is still a gap in the current research to support universal RTI program implementation in the U.S. because of limited evidence from rural and semi-rural settings. Further, the inconsistency on how to define "rapid-start," with definitions varying from "same day as diagnosis" to "within two weeks of diagnosis", makes proper evaluation difficult.[5,7] We believe "rapid-start" should be defined as ART initiated on the same day as HIV notification and will use this definition throughout.

Rural and semi-rural settings present different challenges for RTI compared to the RTI initiatives in urban centers. Rural-area patients have less access to public transportation, increased stigma and concerns with confidentiality, longer clinic wait times, minimal health insurance coverage, and overall lower socioeconomic status.[8-11] Addressing systematic barriers found in rural and semi-rural settings and providing more consistency to the definition of "rapid-start" ART are thus important for accurately measuring the impact of RTI. Since no model for these non-urban U.S. settings exists, we see a strong need to create and test new and innovative models specifically tailored to this setting's needs. Evidence-based results could then help pave the way for public health officials to coordinate national RTI expansion to efficiently reach the 2030 goal for HIV reduction.

[1]Department of Health Behavior, Gillings School of Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC

[2]Department of Medicine, Division of Infectious Disease, University of North Carolina at Chapel Hill, Chapel Hill, NC

[3]Department of Internal Medicine, Section on Infectious Disease, Wake Forest School of Medicine, Winston-Salem, NC

[4]North Carolina Department of Health and Human Services, Division of Public Health, Communicable Disease Branch, Raleigh, NC

Address Correspondence To:
Heidi Swygard M.D., M.P.H.
Department of Medicine
Division of Infectious Diseases
University of North Carolina at Chapel Hill
130 Mason Farm Road, CB 7030
Chapel Hill, NC 27599
heidi_swygard@med.unc..edu

If we look at North Carolina (Figure 2), 64 of the 100 counties are considered rural by the U.S. Census making it a great testing ground for new RTI models.[12] In terms of HIV diagnosis and care, Disease Intervention Specialists from the NC Department of Health and Human Services provide notification, intervention, and counseling services within 30 days of a chronic HIV diagnosis.[13] Patients then wait anywhere from four to ten weeks to receive their first dose of ART.[13,14] This is because referral appointments to initiate treatment can take up to four weeks due to transportation barriers for patients and availability of physicians. Pretreatment labs can take an additional one to two weeks, and then under- or uninsured patients must wait an additional three to four weeks for medication approval.[13,14] This large gap between HIV diagnosis and ART initiation is not unique to North Carolina. These delays are seen across the country. With current knowledge that an undetectable viral load lowers the risk of HIV transmission to zero, a four to ten week delay creates broad public health concern. It not only delays viral suppression but also increases both the chance of loss to follow up and the potential for new HIV transmission events.[15,16]

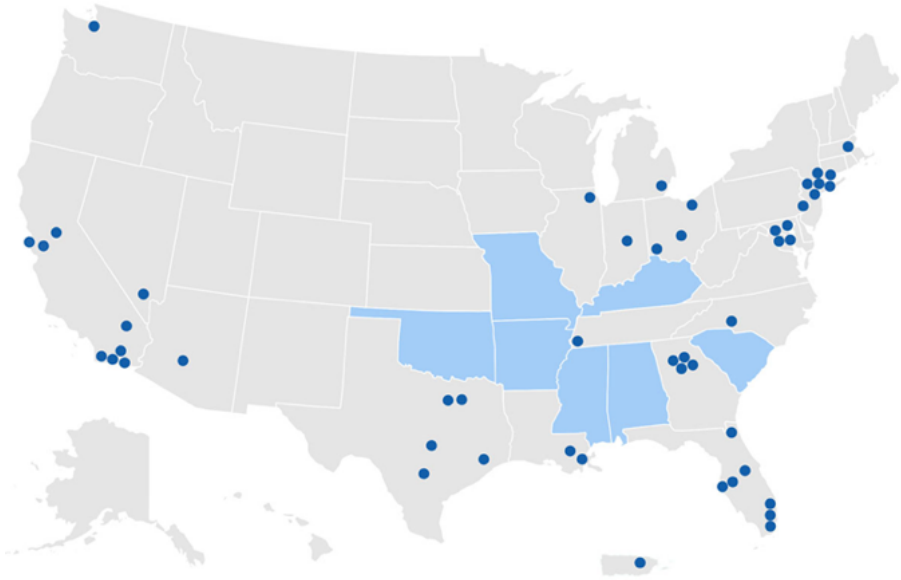

Figure 1. The 48 counties where more than 50% of new HIV diagnoses occurred in 2016 and 2017, along with seven states with a substantial HIV burden in rural areas, as reported by Ending the HIV Epidemic: A Plan for America[2]

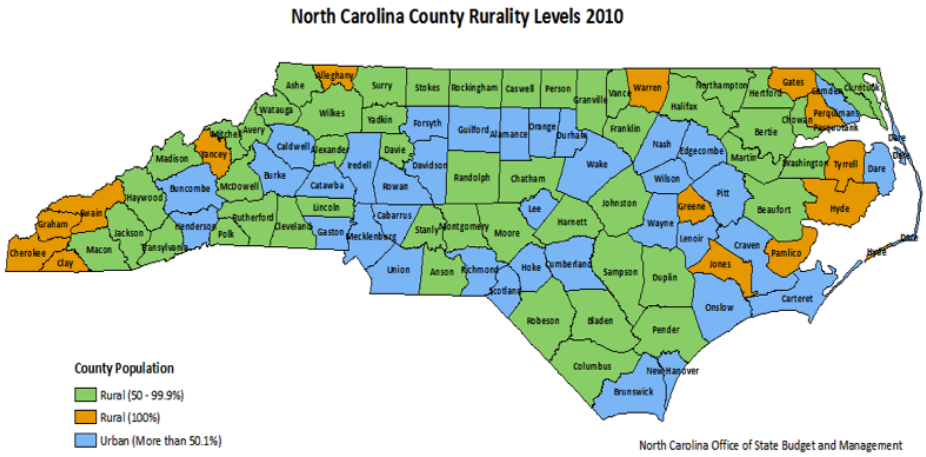

Figure 2. North Carolina Rurality Levels, 2010 Census Data[12]

To explore a potential RTI program suitable for the rural and semi-rural U.S., we will pilot the North Carolina Rapid ART Program for Individuals with an HIV Diagnosis (NC RAPID) starting in 2020. The NC RAPID program will offer newly diagnosed persons at the time of HIV notification immediate ART initiation (Biktarvy, Gilead Inc.) prior to presenting to clinic, combined with medication counseling and lab evaluation. On this same day, a clinic visit will be scheduled and a medication sustainability plan initiated to ensure continuous access to ART using existing medication assistance programs. This RTI model will be evaluated outside the metropolitan setting and is novel as it incorporates a pre-clinic definition of "rapid-start" while addressing several of the barriers to care mentioned earlier. Our outcomes of interest include time to viral suppression, linkage to care, retention in care at six and twelve months, and general acceptability of the program by both patients and local health care providers via in-depth interviews. For this pilot program, we will compare outcome data to a historical cohort in the same setting. These data will inform future implementation projects around RTI.

Health care providers and health officials are already slowly recognizing the potential of rapid HIV treatment in ending the HIV epidemic. Successful implementation and improved outcomes from NC RAPID could provide a new RTI model that specifically address the unique structural, financial, and social barriers to HIV care that exist in North Carolina and beyond. By providing evidence-based research in a non-urban setting of the U.S., supplementing the success of RTI implementation in large urban cities, North Carolina could help lay the groundwork for creating national RTI guidelines as an important tool to end the HIV epidemic in the U.S. – something never before imagined in our lifetime.

Disclosures

No financial support given. Authors report no conflicts of interest.

References

1. Center for Disease Control and Prevention. HIV in the United States by Region. (2019, September 26). Available at https://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html. Accessed October 27, 2019.
2. The White House, National Office of AIDS Policy. National HIV/AIDS strategy for the United States, updated to 2020. 2015. Available at: https://www.hiv.gov/sites/default/files/nhas-2020-action-plan.pdf. Accessed October 27, 2019.
3. Boyd MA, Boffito M, Castagma A, Estrada V. Rapid initiation of antiretroviral therapy at HIV diagnosis: definition, process, knowledge gaps. HIV Med 2019; 20(Suppl. 1): 3-11.
4. Rosen S, Maskew M, Fox MP et al. Initiating Antiretroviral Therapy for HIV at a Patient's First Clinic Visit: The RapIT Randomized Control Trial. PLoS Med 2016; 13(5).
5. Pilcher C, 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. JAIDS 2017; 74: 44-51.
6. Halperin J, Butler I, Katherine C et al. Linkage and Antiretroviral Therapy Within 72 Hours at a Federally Qualified Health Center in New Orleans. AIDS Patient Care ST 2018; 32: 39-41.
7. Ford N, Migone C, Calmy A et al. Benefits and Risks of Rapid Initiation of Antiretroviral Therapy. AIDS2018; 32: 17-23.
8. Brewer RA, Chrestman S, Mukherjee S, et al. Exploring the Correlates of Linkage to HIV Medical Care Among Persons Living with HIV Infection (PLWH) in the Deep South: Results and Lessons Learned from the Louisiana Positive Charge Initiative AIDS Behav. 2018; 22: 2615.
9. Reschovsky, J, Staiti A. Access and quality: does rural America lag behind? Health Affairs. 2005; 24(4): 1128-1139.
10. Parker, K, Horowitz, JM, Brown, A, Fry, R, Cohn, D, and Igielnik, R. Views of Problems Facing Urban, Suburban and Rural Communities. Pew Research Center. 2018. Available at https://www.pewsocialtrends.org/2018/05/22/views-of-problems-facing-urban-suburban-and-rural-communities/. Accessed October 25, 2019.
11. Douthit N, Kiv S, Dwolatzky T, and Biswas S. Exposing some important barriers to health care access in the rural USA. Public health. 2015; 129(6): 611-620.
12. The US Census Bureau. The Urban and Rural Faces of North Carolina. Available at https://files.nc.gov/ncosbm/documents/files/2018ACSNC.pdf. Accessed January 15, 2020.
13. Mobley, V. Personal Communication. 2019.
14. Sena A, Donovan J, Swygard H, et al. The North Carolina HIV Bridge Counselor Program: Outcomes from a Statewide Level Intervention to Link and Reengage HIV-Infected Persons in Care in the South. J AIDS. 2017; 76(1).
15. Mateo- Urdiales A, Johnson S, Nachega JB, Eshun- Wilson I. Rapid initiation of antiretroviral therapy for people living with HIV. Cochrane Database of Syst Rev. 2019; 2.
16. Rodger AJ, Cambiano V, Bruun T, et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet 2019; 393(10189).