HIV TESTING and RAPID START

INITIATING EARLY TREATMENT IN NEWLY DIAGNOSED PATIENTS

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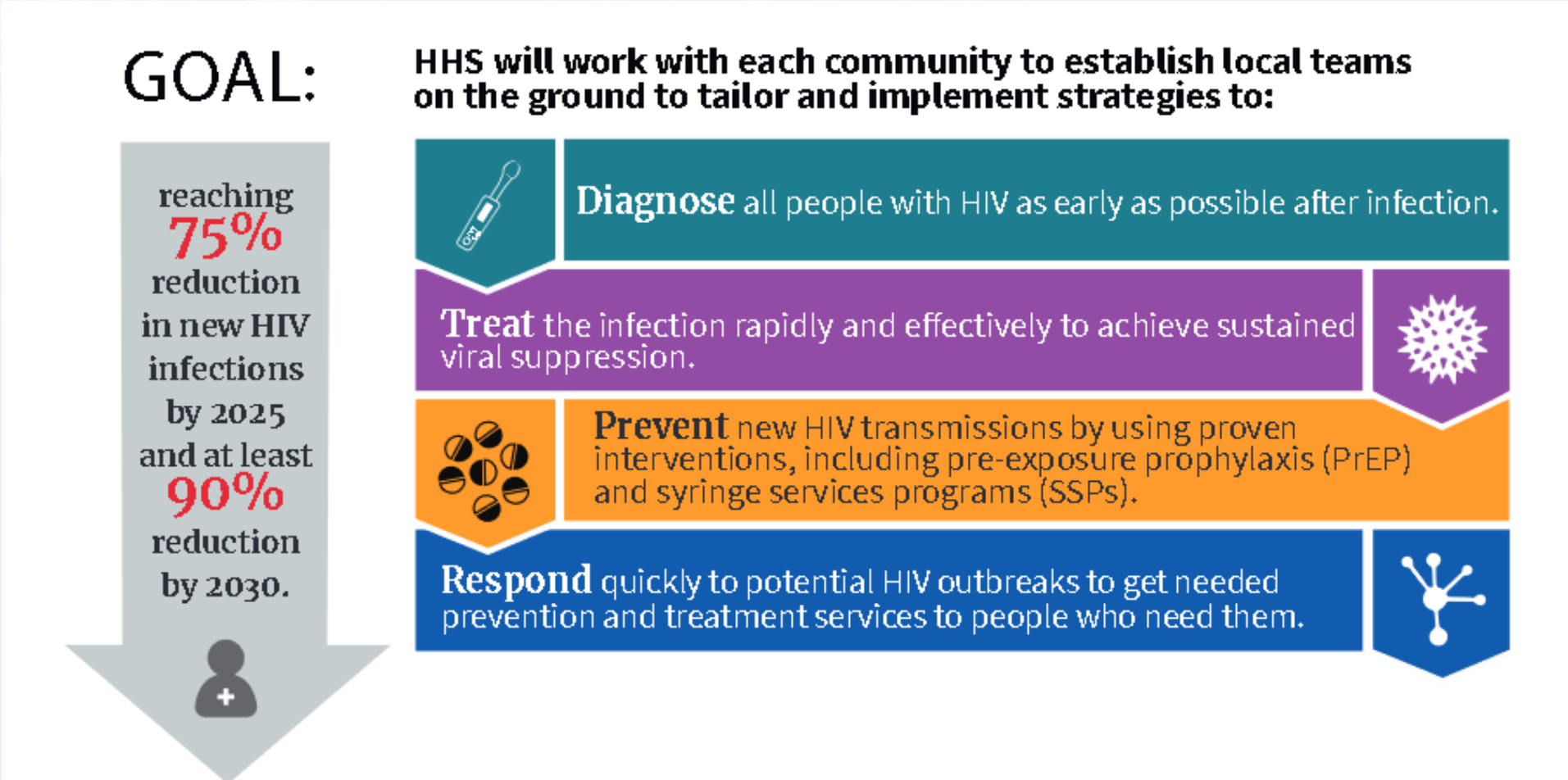
Disclosures

- Gilead & Janssen Speakers Bureau

Objectives

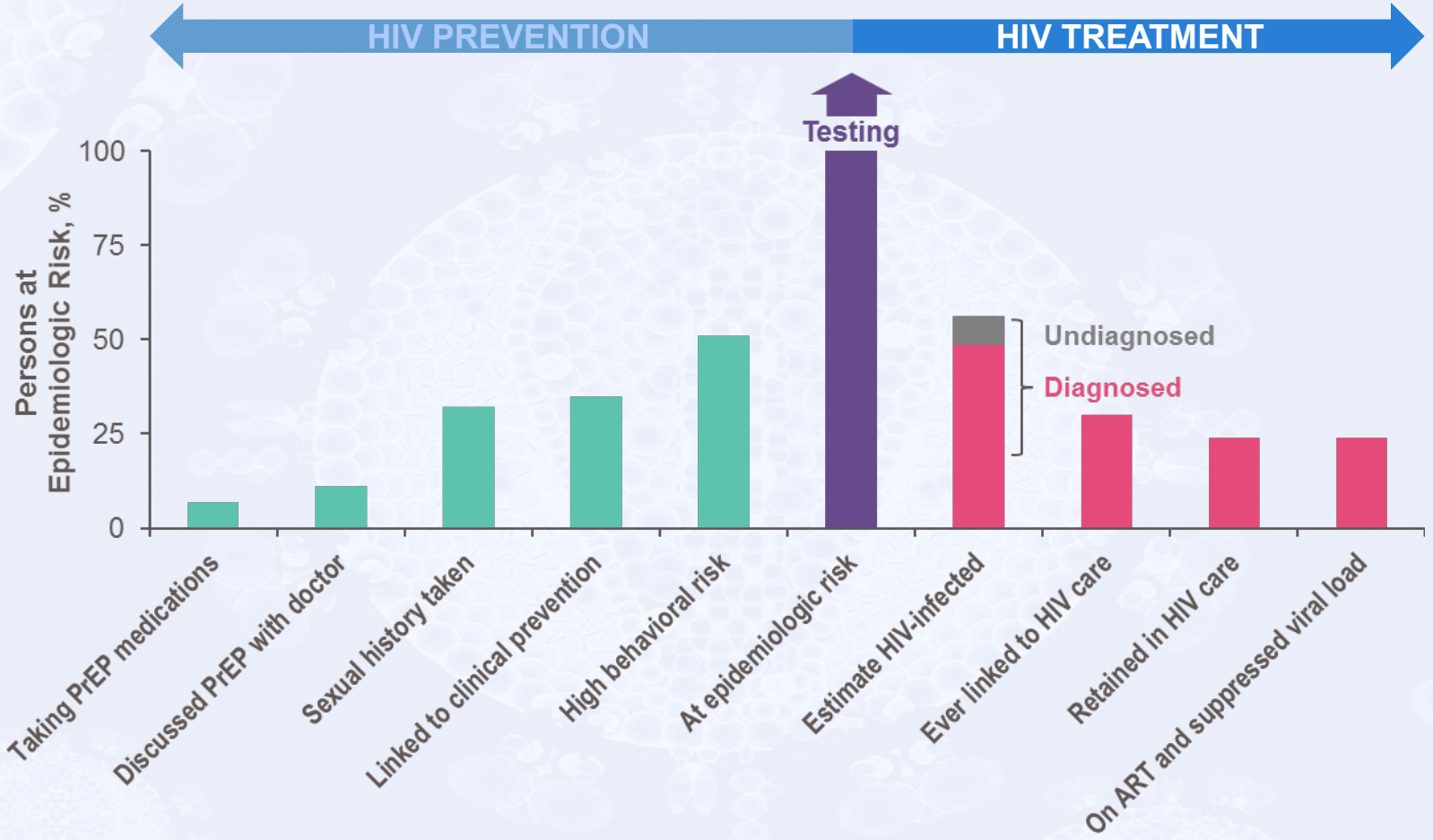
- Discuss Rapid ART therapy as a part of the status neutral approach
- Discuss how treatment decisions at the time of diagnosis may impact outcomes
- Examine approaches within pilot programs in New Orleans, Atlanta, and New York City
- Review and discuss cases of newly diagnosed patients
- Address ways to overcome challenges and implement early treatment initiation more broadly in your practice
- Introduce SPNS project for rapid start

EHE Goals



https://www.cdc.gov/endhiv/index.html

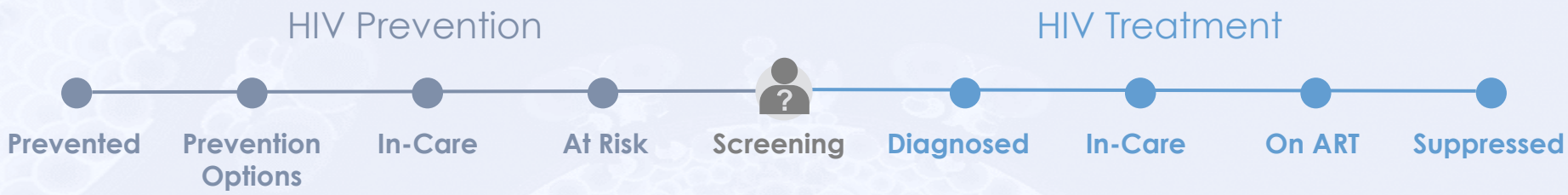
Testing, Prevention, and Treatment Could Change the HIV Epidemic[a]



- Proactive integration and optimization of treatment in HIV-positive individuals and prevention in HIV-negative individuals will improve our ability to control the HIV epidemic

a. Theoretical model.
Adapted from: Daskalakis D, et al. National HIV Prevention Conference 2015. Atlanta, GA. #1419; and Centers for Disease Control and Prevention. Understanding the HIV Care Continuum [fact sheet] 2017. https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf. Accessed August 2017.

Prevention Options Span Both Sides of the HIV Continuum



PrEP

- For people who are HIV negative and at risk for HIV[1]
- Taken before HIV exposure[1]
- Studies have successfully trialed same-day PrEP in sexual health clinics[2,3]

A multifaceted approach is needed to END the HIV Epidemic

Rapid Start

- The immediate treatment response to a HIV diagnosis
- Initiating ART immediately or as soon as possible after diagnosis to increase the uptake of ART and linkage to care, decrease the time of to viral suppression and improve the rate of suppression

TasP

- Getting to and keeping an undetectable viral load is the best thing people with HIV can do to stay healthy[8]
- Maintaining an undetectable viral load helps prevent sexual transmission, helping to lower new infections at the population level[9,10]
- The sooner viral suppression is achieved, the shorter the potential transmission period[10]

PEP = post-exposure prophylaxis, PLWH = people living with HIV, PrEP = pre-exposure prophylaxis, TasP = treatment as prevention.

References: 1. CDC. https://www.cdc.gov/hiv/basics/prep.html. Accessed June 28, 2019. **2.** Kamis K et al. *Open Forum Infect Dis.* 2018;5(Suppl 1):S20. **3.** NYC Health. https://www1.nyc.gov/site/doh/about/press/pr2017/pr003-17.page. Accessed July 8, 2018. **4.** CDC/HHS. https://www.cdc.gov/condomeffectiveness/docs/Condoms_and_STDS.pdf. Accessed June 28, 2019. **5.** CDC. https://www.cdc.gov/hiv/risk/analsex.html. Accessed June 28, 2019. **6.** CDC. https://www.cdc.gov/hiv/risk/vaginalsex.html. Accessed June 28, 2019. **7.** CDC. https://www.cdc.gov/hiv/basics/pep.html. Accessed July 19, 2019. **8.** CDC. https://www.cdc.gov/hiv/risk/art/index.html. Accessed January 22, 2020. **9.** Granich RM et al. *Lancet.* 2009;373(9657):48-57. **10.** DHHS. https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed February 18, 2020.

U=U Decisions made in one patient's journey can affect an entire community

CDC: People with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative sexual partners (1)

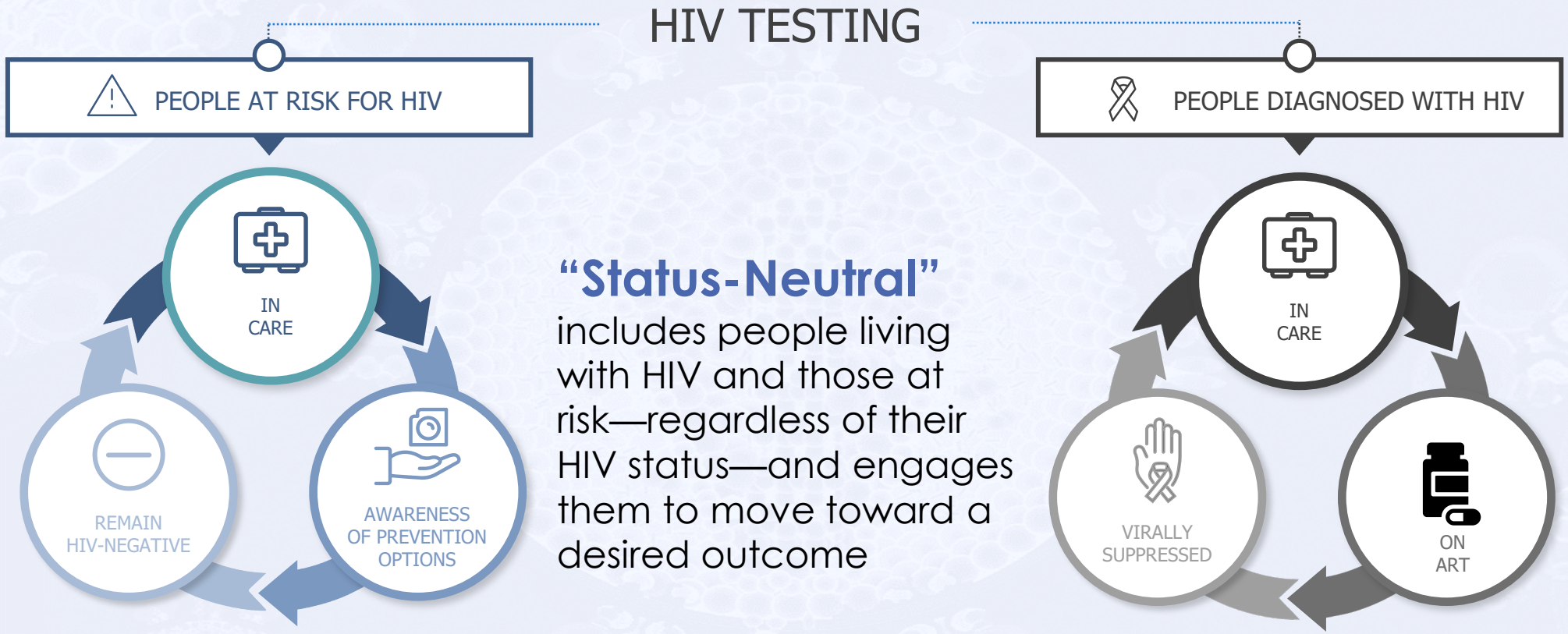
UNAIDS: There is strong scientific consensus that people living with HIV who are taking effective antiretroviral therapy and whose level of HIV is suppressed to undetectable levels will not transmit HIV sexually(2)

NIAID: "People living with HIV whose virus is completely, durably suppressed by treatment will not sexually transmit the virus to an HIV-negative partner"(3) –NIAID Director, Anthony Fauci, M.D.

Undetectable = Untransmittable (U=U): According to research, people with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative sexual partners (1-3)

CDC, Centers for Diseases Control and Prevention; UNAIDS, Joint United Nations Programme on HIV and AIDS; NIAID, National Institute of Allergy and Infectious Diseases. 1. Centers for Disease Control and Prevention. Evidence of HIV treatment and viral suppression in preventing the sexual transmission of HIV. https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf. Published October 2018. 2. UNAIDS. UNDETECTABLE = UNTRANSMITTABLE: public health and HIV viral load suppression. http://www.unaids.org/sites/default/files/media_asset/undetectable-untransmittable_en.pdf. Published July 20, 2018. 3. National Institute of Allergy and Infectious Diseases. Science validates undetectable = untransmittable HIV prevention message. https://www.niaid.nih.gov/news-events/undetectable-equals-untransmittable. Published July 18,2018

A multifaceted approach is needed to END the HIV Epidemic



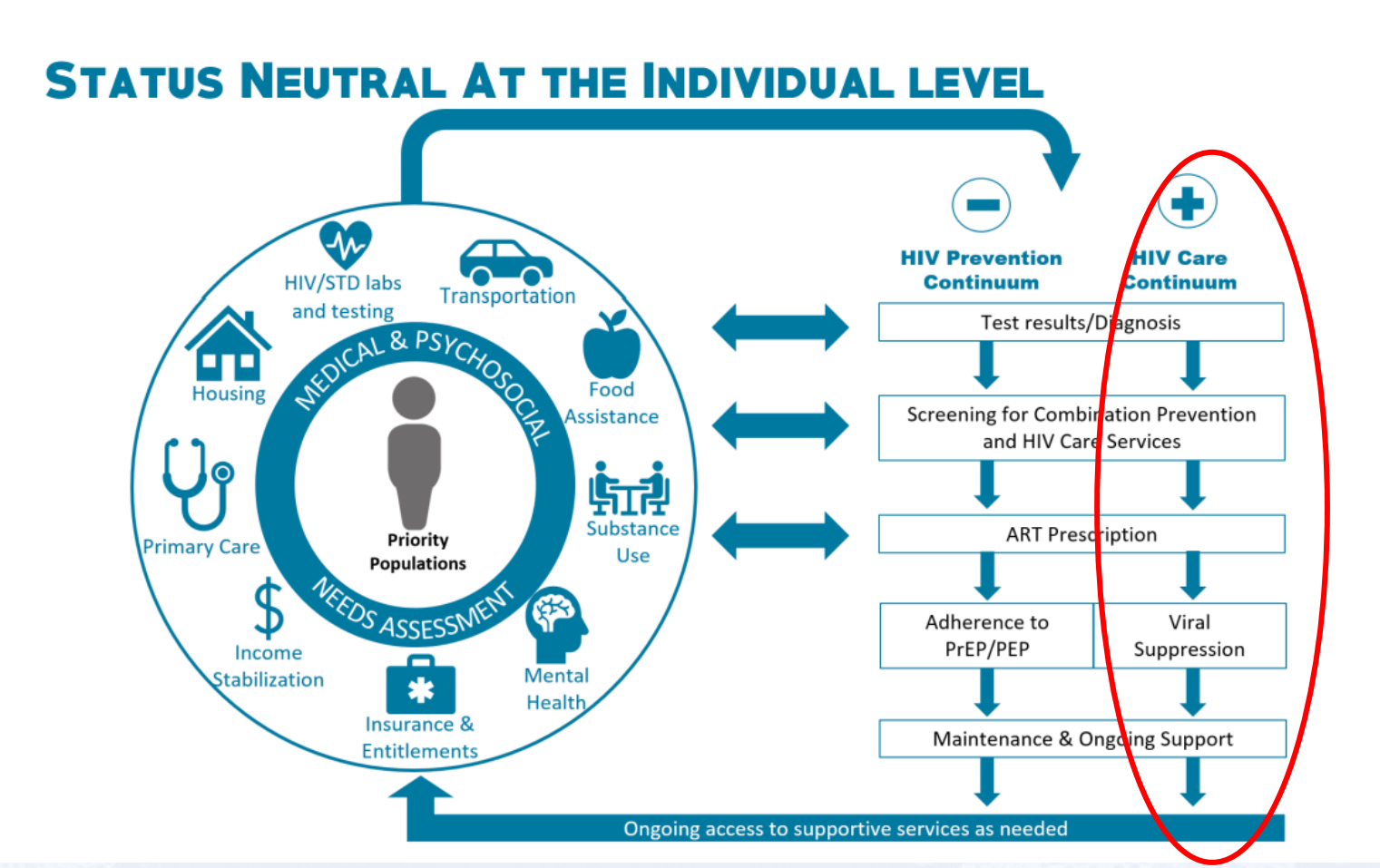
"Status-Neutral" includes people living with HIV and those at risk—regardless of their HIV status—and engages them to move toward a desired outcome

Supporting people at risk for HIV and people with HIV to move from testing through the other steps of the continuum can help them stay informed about their status

Working together to help stop the virus.

References: 1. CDC/Act Against AIDS. https://www.cdc.gov/hiv/pdf/library/infographics/cdchiv-infographic-continuum.pdf. Accessed July 22, 2019. **2.** Myers JE et al. *Open Forum Infect Dis.* 2018;5(6):ofy097.

HIV Status Neutral (Individual)



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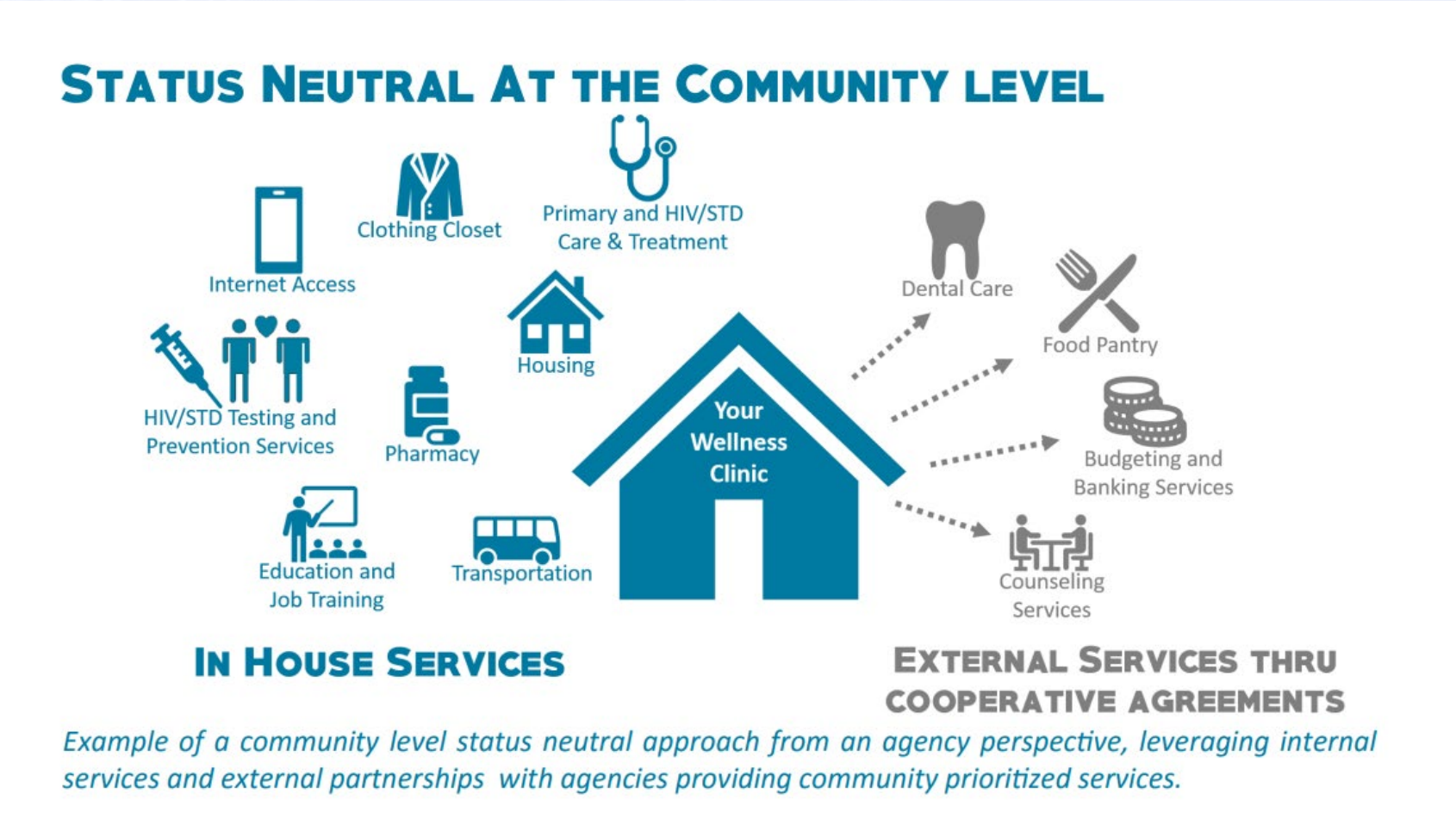
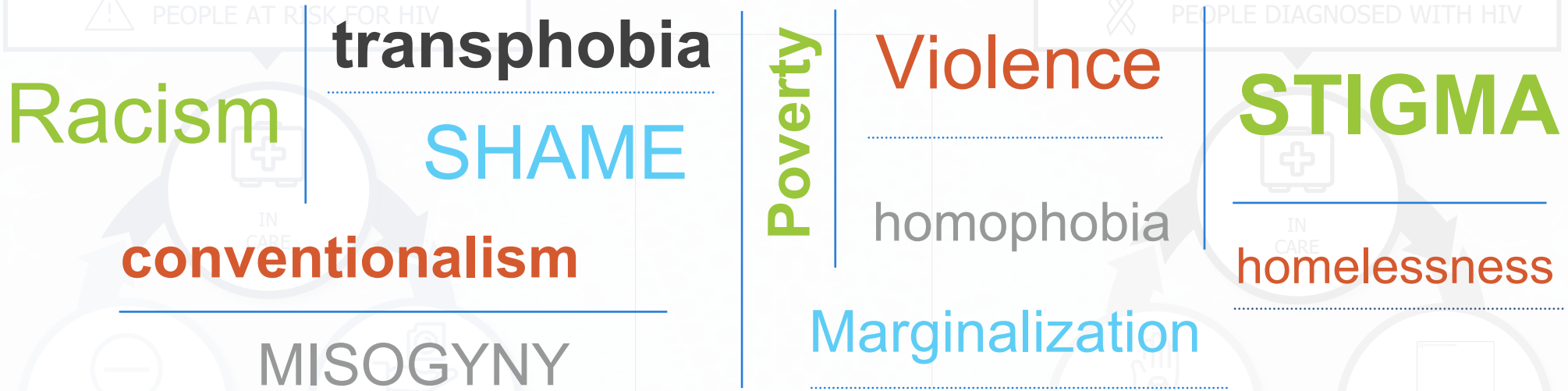
HIV Status Neutral (Community)



Example of a community level status neutral approach from an agency perspective, leveraging internal services and external partnerships with agencies providing community prioritized services.

Retrieved from www.StatusNeutralWhitePaper (2).pdf

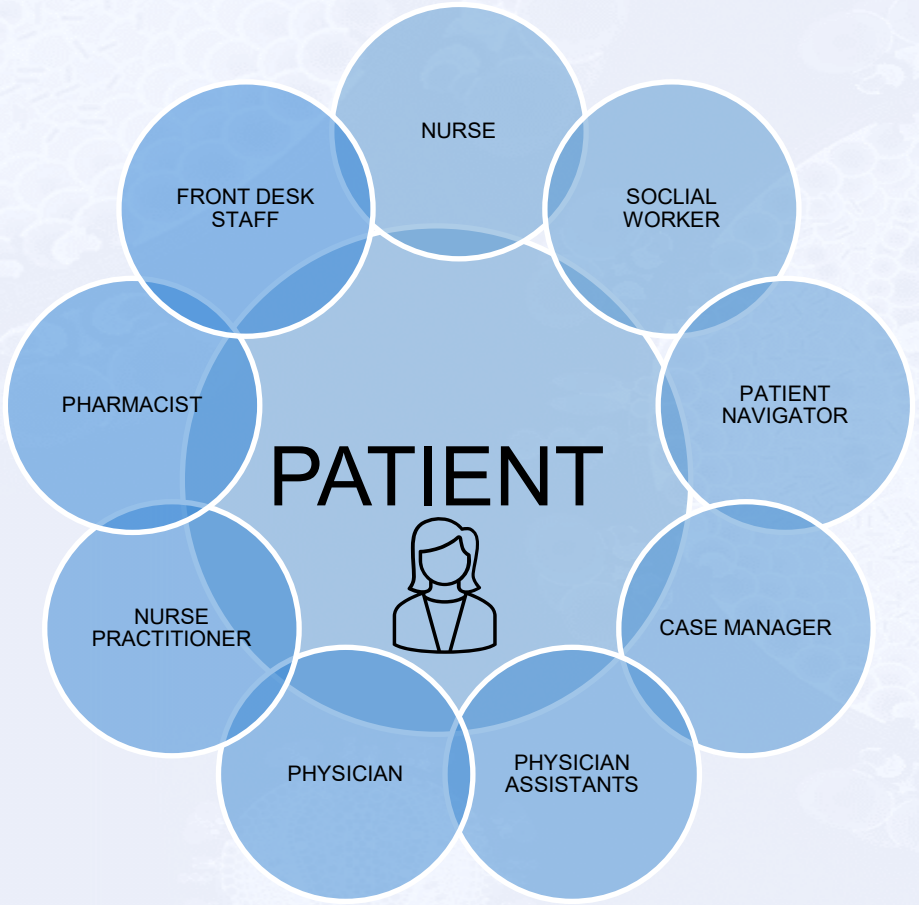
TESTING IS THE ENTRY POINT TO THE STATUS-NEUTRAL HIV CARE CONTINUUM[1]



Stigma and other social determinants can influence the HIV care continuum before an HIV diagnosis is even made[2]

STOP THE VIRUS.
Working together to help stop the virus.

RAPID START IS AN INTERPROFESSIONAL TEAM APPROACH



Every team member can play a role in supporting the goal of early treatment initiation.

Rapid Start or Early treatment initiation is recommended by the:

1. Department of Health and Human Services (DHHS) Guidelines(1)
2. International Antiviral Society (IAS)–USA Recommendations(2)
3. World Health Organization (WHO) Guidelines(3)

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. Department of Health and Human Services. http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Updated October 25, 2018. 2.
Saag MS, et al. JAMA. 2018;320(4):379-396. 3. World Health Organization. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. http://www.who.into/hiv/pub/guidelines/advanced-HIV-disease/en. Published July 2017.

YOUR IMMEDIATE CAN HAVE A LASTING IMPACT

Decisions made early can affect the entire patient experience

Early initiation of antiretroviral therapy (ART)[1-3]:

- ✓ Shortens the time between diagnosis and viral suppression
- ✓ Improves retention in care

Starting ART and achieving viral suppression earlier in the course of the disease may also:

- Reduce inflammation and immune activation [4]
- Help restore and preserve normal immune function [4,5]
  - (Immune system damage may occur early)
- Decrease future risk of AIDS events and non-AIDS health complications [4]

1. Pilcher CD, et al. J Acquir Immune Defic Syndr. 2017;74(1):44-51. 2. Rosen S, et al. PLoS Med. 2016;13(5):e1002015. doi:10.1371/journal.pmed.1002015. 3. Hoenigl M, et al. Sci Rep. 2016;6:32947. doi:10.1038/srep32947. 4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. Department of Health and Human Services. http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Updated October 25, 2018. 5. Sereti I, et al. Clin Infect Dis. 2017;64(2):124-131

What could rapid start look like at your site

The CrescentCare Start Initiative[1]

- FQHC in New Orleans, Louisiana
- Retrospective evaluation of early treatment initiation cohort (n=71) compared to a historical control (n=29); program occurred from December 2016 to October 2017
- Treatment-naïve HIV-infected adults to start ART within 72 hours of diagnosis

Rapid Entry and ART Clinic for HIV (REACH)[2,3]

- Large Ryan White-funded HIV clinic in Atlanta, Georgia
- Single-center, retrospective cohort study with 6-month follow-up; enrollment between January 2016 and July 2016
- Patients included pre-REACH historical controls (n=117) and newly enrolled* HIV-infected post-REACH patients (≥16 years old; n=90)
- Post-REACH patients to have first appointment and ART offered within 72 hours of first presenting to clinic

JumpstART Program[4]

- Sexual Health Clinics in New York City, New York
- Analysis of JumpstART intervention from November 2016 to July 2017
- Newly diagnosed, treatment-naïve HIV-infected adults (N=149) to be initiated on same-day treatment and provided with 30-day supply of ARVs on site

In these pilot programs, treatment was initiated within 24 to 72 hours[1-4]

*Either new diagnoses or re-entering care.

ARVs, antiretrovirals; FQHC, Federally Qualified Health Center.

1. Halperin J, et al. AIDS Patient Care STDS. 2018;32(2):39-41. 2. Colasanti J, et al. Open Forum Infect Dis. 2018;5(6):1-8. 3. Colasanti J, et al. Poster #1109 presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, MA. 4. Blank S, et al. Poster #1108 presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, MA

Rapid Start was initiated in a range of patients

Unstable Housing

7% of early treatment initiation patients at CrescentCare reported homelessness[1]

57% of post-REACH patients reported unstable housing[2*]

Substance Use

23% of CrescentCare patients reported drug use (not including THC)[1]

4% of CrescentCare patients reported injecting drugs[1]

46% of post-REACH patients reported active substance use[2†]

Mental Health Diagnoses

27% of post-REACH patients reported a mental health diagnosis[2‡]

1) Answering “non-permanently housed” to “Do you have a fixed, regular, adequate nighttime residence?” or 2) Reporting homelessness in the initial intake. †Alcohol, marijuana, cocaine, amphetamine use within last 3 months. ‡ Includes anxiety, depression, bipolar, and schizo-spectrum. THC, tetrahydrocannabinol. 1. Halperin J, et al. AIDS Patient Care STDS. 2018;32(2):39-41. 2. Colasanti J, et al. Open Forum Infect Dis. 2018;5(6):1-8.

Outcomes and Benefits Demonstrated

Time to Viral Suppression (VS)*

- **CrescentCare:** Median time to VS significantly decreased: 68 days in historical cohort vs 30 days in early ART initiation patients (*P*<0.0001)[1]
- **REACH:** Median time to VS from enrollment significantly decreased: 77 days in pre-REACH patients vs 57 days in early ART initiation patients (*P*=0.0022)[2]
- **JumpstART:** Time to VS was ≤45 days in 87% (45/52) of patients[3]

Time to Linkage to Care

- **CrescentCare:** The mean time to linkage to care significantly decreased: 30 days in control patients vs 1.3 days in early ART initiation patients (*P*<0.0001)[1]
- **REACH:** Median days to first attended provider visit significantly decreased: 17 days in pre-REACH patients vs 5 days in early ART initiation patients (*P*<0.0001)[2]
- **JumpstART:** 83% (81/98) of newly diagnosed patients had first primary care HIV visit within 30 days[3]

Engagement in Care

- **CrescentCare:** 92% (71/77) were linked, saw a treating provider, and started ART within 72 hours of diagnosis[1]
- **REACH:** 81% of early ART initiation patients attended first scheduled appointment vs 73% of pre-REACH patients (*P*=0.1557)[2]
- **JumpstART:** 73% (78/107) of newly diagnosed patients initiated the JumpstART program[3]

. Halperin J, et al. AIDS Patient Care STDS. 2018;32(2):39-41. 2. Colasanti J, et al. Open Forum Infect Dis. 2018;5(6):1-8.
3. Blank S, et al. Poster #1108 presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, MA.

Checklist for rapid ART at your site

- Following the science
- Being driven by champions
- Responding to patient interests and demand
- Implementing plans that prioritize rapid ART
- Acting upon community feedback

Begin with an assessment of your site

Tip: Set goals/metrics for your rapid ART program using local HIV data.

Components of Rapid Start Model

Testing and Linkage	Rapid Champion/Dedicated Rapid Team	Workflows	Protocols	Staff Buy-In and Training
Insurance and Medication Access	Support for Patients	Retention in Care	Data to Support Patients & Track Outcomes	Quality Improvement

Steps to Success

Know everyone's availability and roles

- ✓Activation of rapid team/process
- ✓Steps may include eligibility/benefits worker, social worker and/or case manager, nurse, laboratory staff, clinician, pharmacist, navigator

Minimize the number of people interacting with new patient

Use warm handoffs

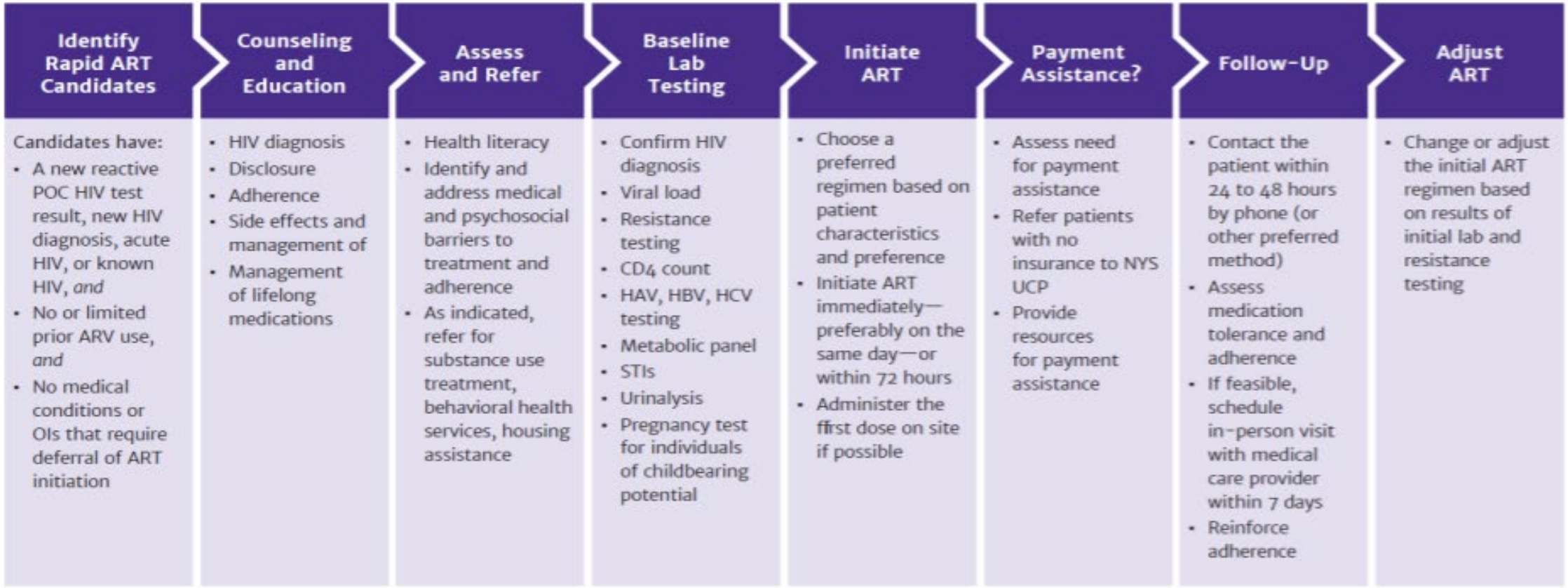
Case 1

Jorge, 29
Hispanic MSM

HIV-positive diagnosis	Established yesterday at a sexual health clinic
Labs	• **Viral load (copies/mL):** 94,000 • **CD4+ cell count (cells/μL):** 470 • **CrCl (mL/min):** 107
Medical history	Alcoholism (active); STIs
Before his exam	Jorge tells the nurse this is his first visit with a health provider in over 2 years.
Patient response to being offered treatment	Jorge told the nurse he's open to it, but she pulls you aside and expresses concern about Jorge's ability to adhere.

Rapid Start Guidelines

Figure 1: Protocol for Rapid ART Initiation



NYSDOH AI Clinical Guidelines Program www.hivguidelines.org

Rapid Start Protocol

Identify Rapid ART Candidates	Counseling and Education	Assess and Refer	Baseline Lab Testing	Initiate ART	Payment Assistance?	Follow-Up	Adjust ART
Candidates have: ▪ A new reactive POC HIV test result, new HIV diagnosis, acute HIV, or known HIV, *and* ▪ No or limited prior ARV use, *and* ▪ No medical conditions or OIs that require deferral of ART initiation	▪ HIV diagnosis ▪ Disclosure ▪ Adherence ▪ Side effects and management of ▪ Management of lifelong medications	▪ Health literacy ▪ Identify and address medical and psychosocial barriers to treatment and adherence ▪ As indicated, refer for substance use treatment, behavioral health services, housing assistance	▪ Confirm HIV diagnosis ▪ Viral load ▪ Resistance testing ▪ CD4 count ▪ HAV, HBV, HCV testing ▪ Metabolic panel ▪ STIs ▪ Urinalysis ▪ Pregnancy test for individuals of childbearing potential	▪ Choose a preferred regimen based on patient characteristics and preference ▪ Initiate ART immediately—preferably on the same day—or within 72 hours ▪ Administer the ffirst dose on site if possible	▪ Assess need for payment assistance ▪ Refer patients with no insurance to NYS UCP ▪ Provide resources for payment assistance	▪ Contact the patient within 24 to 48 hours by phone (or other preferred method) ▪ Assess medication tolerance and adherence ▪ If feasible, schedule in-person visit with medical care provider within 7 days ▪ Reinforce adherence	▪ Change or adjust the initial ART regimen based on results of initial lab and resistance testing

Medical History Checklist

- Date and result of last HIV test
- Serostatus of sex partners and their ART regimens if known
- Previous use of antiretroviral medications, including as PrEP or PEP, with dates of use
- Comorbidities, including a history of renal or liver disease, particularly hepatitis B infection
- Prescribed and over-the-counter medications
- Drug allergies
- Substance use
- Symptoms, to assess for active cryptococcal and TB meningitis Psychiatric history, particularly depressive or psychotic symptoms or any history of suicidality
- Possible pregnancy and childbearing plans in individuals of childbearing potential

Baseline labs

- HIV-1/2 antigen/antibody assay
- HIV quantitative viral load
- Baseline HIV genotypic resistance profile
- Baseline CD4 cell count
- Testing for hepatitis A, B, and C viruses
- Comprehensive metabolic panel (creatinine clearance, hepatic profile)

Choosing an ART Regimen

Clinicians should involve their patients when deciding which antiretroviral therapy (ART) regimen is most likely to result in adherence. (A3)

Before initiating ART, clinicians should:

1. Assess the patient's prior use of antiretroviral medications, including pre-exposure prophylaxis (PrEP), which may increase the risk for baseline resistance. (A2)

2. Assess for any comorbidities and chronic co-administered medications that may affect the choice of regimen for initial ART. (A2)

Choosing an ART Regimen(2)

At the time of HIV diagnosis, obtain genotypic resistance testing for the protease (A2), reverse transcriptase (A2), and integrase (B2) genes.

Ask individuals of childbearing potential about the possibility of pregnancy, their reproductive plans, and their use of contraception. (A3)

For ART-naive patients, clinicians should select an initial ART regimen that is preferred; see Table 1: Preferred and Alternative Regimens for Rapid ART Initiation in Nonpregnant Adults. (A1)

Clinicians should reinforce medication adherence regularly. (A3)

Clinicians should obtain a viral load test 4 weeks after ART initiation to assess the response to therapy. (A3)

See the NYSDOH AI guideline Virologic and Immunologic Monitoring for more information.

Case 2

Angela, 25
African American heterosexual female

HIV-positive diagnosis	Established yesterday at Planned Parenthood
Labs	• **Viral load (copies/mL):** 78,000 • **CD4+ cell count (cells/µL):** 350 • **CrCl (mL/min):** 111
Medical history	N/A
Before her exam	Angela is reading through a waiting-room brochure about resources for patients living with HIV.
Patient response to being offered treatment	"I have a lot going on right now. I'm in between jobs, I can't afford to feel sick. Can I think about it?"

Case 3

Vincent, 29
Biracial MSM

HIV-positive diagnosis	Established yesterday at a sexual health clinic
Labs	• **Viral load (copies/mL):** 96,000 • **CD4+ cell count (cells/μL):** 296 • **CrCl (mL/min):** 105
Medical history	N/A
Before his exam	In filling out his intake form, Vincent asked your receptionist if it was okay to provide his friend's mailing address as his own.
Patient response to being offered treatment	Vincent tells you, "Will it make me feel sick? I really can't afford to deal with side effects right now. Plus, I don't know how I can start treatment when I don't even have a place to live. Can I think about it?"


Building Your Protocol

Protocol Specifics

- Develop Protocols Tailored to Your Specific Circumstances
- Roles of Staff Members
- Steps in the Initial Rapid Visit: Insurance/benefits enrollment/optimization
- Patient screening, including medical history and physical exam - Laboratory work -
- Support/education
- Prescription Pre-selected ART Regimens - Prescription, +/- starter pack
- Plan for Patient Follow-up - Frequency
- Expert Consultation (e.g., for interpretation of confusing test results, medical/psychiatric comorbidities, individualized ART selection

Important Note: Medications

Need Access to ARVs on Day 1

Streamlined application process for rapid access to ADAP, emergency Medicaid

Ryan White vouchers (uninsured)

Starter Packs, "sample" packs (purchased by clinic or donated by pharmaceuticals)

Challenges

- ✓Prohibitions on Pharma donations
- ✓Over-reliance on starter packs
- ✓Covering costs not covered by ADAP/insurance

Rapid Start Challenges

- Funding for and access to medications for uninsured and underinsured (e.g., no pharmacy on site, prohibitions on use of starter packs)
- Buy-in from providers (rapid ART may ask providers to add to their schedules)
- Finding time to spend with patients
- Addressing immediate needs of patients
- Retention of patients lost to follow-up
- Staff turnover: ongoing training and buy-in
- Necessary expertise is not always available

Selected Rapid Start Benefits

For the Clinic

- Better patient outcomes, more empowered patients and staff
- Potential efficiency of clinic operations (e.g., making use of no-show slots)
- Potential cost-effectiveness
- Clinic staff enjoy adding a new service to their skill set
- Fewer visits to initiate someone on ART

For the EHE Jurisdiction

- Helps meet the Pillar 2 goal of promptly linking individuals newly diagnosed with HIV to care and treatment.
- Proactively addresses health disparities

Follow Up

Follow up by telephone or in-person within 48 hours after a person initiates ART. Once laboratory test results are available, ART should be discontinued if an HIV diagnosis is not confirmed

Assess for adverse effects, answer questions, and encourage adherence

Consider an in-person follow-up visit with a medical care provider within 7 days of ART initiation (assess and refer for PrEP)

If HIV diagnosis is confirmed, the ART regimen may be adjusted if necessary (e.g., if there is significant renal disease). Further adjustments may be required if major resistance mutations are found that will compromise the effectiveness of the initial regimen. Arrangements should be made for a viral load test 4 weeks after ART initiation to assess adherence and troubleshoot any problems with maintaining treatment.

https://targethiv.org/sites/default/files/media/documents/2021-10/Rapid%20ART%20-%20FINAL%20for%20TargetHIV%20Upload.pdf

Preferred and Alternative Regimens

AI

- Tenofovir alafenamide/ emtricitabine/bictegravir (TAF 25 mg/FTC/BIC; Biktarvy
- Tenofovir alafenamide/ emtricitabine and dolutegravir [a] (TAF 25 mg/FTC and DTG; Descovy and Tivicay)

A2

- Tenofovir alafenamide/ emtricitabine/darunavir/cobicistat (TAF 10 mg/FTC/DRV/COBI; Symtuza)

A3

- Dolutegravir and darunavir/cobicistat/ tenofovir alafenamide/emtricitabine [a] (DTG/DRV/COBI/TAF/FTC 10 mg/FTC; Tivicay and Symtuza) * Regimen for Patients With Exposure to TDF/FTC as PrEP since their last negative HIV test

https://targethiv.org/sites/default/files/media/documents/2021-10/Rapid%20ART%20-%20FINAL%20for%20TargetHIV%20Upload.pdf

Preferred and Alternative Regimens

Medication to Avoid

- Abacavir (ABC)
- Rilpivirine (RPV)
- Efavirenz (EFV

See Guidelines for pregnant women

Checklist Rapid ART Testing

Checklist Rapid ART Testing

Rapid ART Component	In Place	Somewhat in Place	Need to Develop	Need TA, Training, or Other Support (describe)
In-house HIV testing				
Linkage to HIV testing sites				
Providers are interested in providing rapid ART				
Providers trained to provide rapid ART				
Access to ART medications (same-day)				
Workflow and protocols support rapid ART provision				

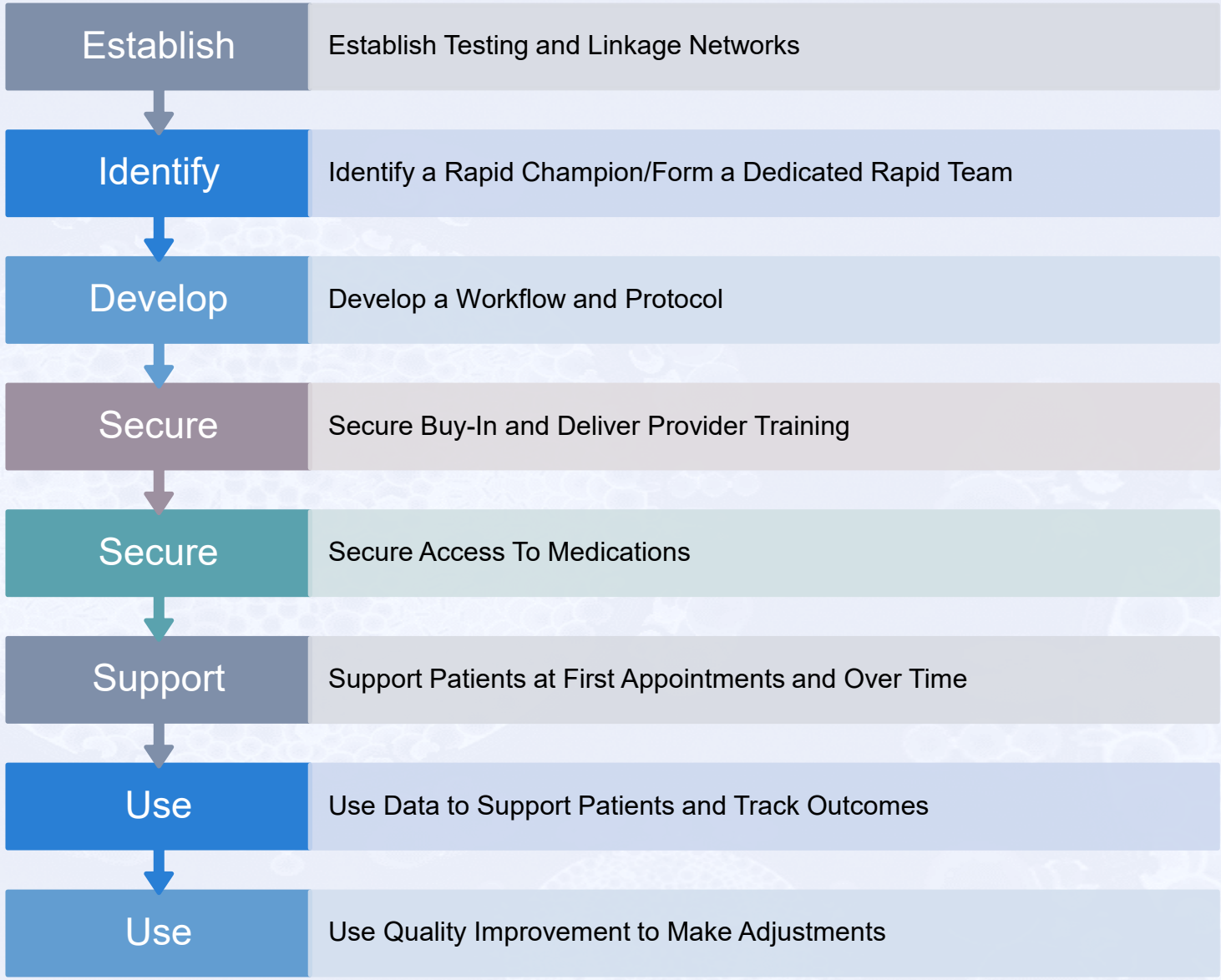
https://targethiv.org/sites/default/files/media/documents/2021-10/Rapid%20ART%20-%20FINAL%20for%20TargetHIV%20Upload.pdf

Checklist Rapid ART Testing Continuation

Rapid ART Component	In Place	Somewhat in Place	Need to Develop	Need TA, Training, or Other Support (describe)
Systems in place to provide follow-up and supportive services to promote retention (e.g., housing, community health workers (CHW), transportation)				
Other facilitators (e.g., patient education materials, EHR standing orders)				

https://targethiv.org/sites/default/files/media/documents/2021-10/Rapid%20ART%20-%20FINAL%20for%20TargetHIV%20Upload.pdf

SPNS Project/Toolkit Guidance



Link to Rapid ART Play book

- https://targethiv.org/sites/default/files/media/documents/2021-10/Rapid%20ART%20-%20FINAL%20for%20TargetHIV%20Upload.pdf

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