

# Rapid ART:

## Immediate ART initiation upon HIV diagnosis

### Immediate ART initiation:<sup>1,2</sup>

➤ Gets more people on treatment, and sooner, than waiting to start ART.



➤ Decreases the median time to virologic suppression by removing obstacles to care.



### San Francisco citywide RAPID initiative (2013-2017):<sup>1</sup>

- Faster time from HIV diagnosis to first HIV care visit, to ART initiation, and to virologic suppression.
- Faster ART initiation and viral suppression regardless of race/ethnicity, sex/gender, age, and housing status.

#### TIME TO HIV CARE, ART START, AND HIV SUPPRESSION

| Median Days                             | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|------|------|------|------|------|
| Diagnosis to 1 <sup>st</sup> care first | 8    | 7    | 7    | 5    | 4    |
| 1 <sup>st</sup> care first to ART start | 27   | 17   | 7    | 1    | 0    |
| ART to VL <200 c/mL                     | 70   | 53   | 50   | 38   | 46   |
| Diagnosis to VL <200 c/mL               | 134  | 92   | 77   | 62   | 92   |

### San Francisco General Hospital Ward 86 RAPID Program (2013-2017):<sup>2</sup>

- Highly acceptable to newly-diagnosed persons (98% accepted RAPID)
- Very high rate of viral suppression: 95.8% by 1 year

**In San Francisco, RAPID has been implemented in community-based clinics, public health clinics, HMO clinics, hospitals, and private practices.**

## IAS-USA Guidelines advise immediate ART<sup>3</sup>

“ART should be initiated as soon as possible after diagnosis, including immediately after diagnosis, unless patient is not ready to commit to starting therapy.”

## The World Health Organization (WHO) Guidelines recommend immediate ART, within 7 days of HIV diagnosis<sup>4</sup>

“WHO strongly recommends that rapid ART initiation should be offered to people living with HIV following confirmed diagnosis and clinical assessment.”

### Immediate ART also benefits the community.<sup>5-8</sup>

- **HPTN 052 study:** NO linked transmissions (in 1,763 serodiscordant couples) when the partner living with HIV had stable HIV viral load suppression on ART.
- **PARTNER studies:** NO HIV transmission (in 1,600 serodifferent couples including 1,100 gay male couples, with >94,000 sex acts) by either anal or vaginal condomless sex if the partner with HIV had viral suppression on ART.

The CDC endorses ART for HIV prevention (also called “U=U”): “effectively no risk of sexually transmitting the virus” if the HIV viral load is continuously suppressed on ART.

## RAPID through one patient’s eyes

*It’s one of the best things to do to put your mind at ease, that it’s not as devastating as it could be to be HIV-positive ... **It made me feel great that I live in a time that doesn’t take weeks or months to get treatment [instead of being] kept in doubt or guessing what are you going to do or ... dealing with the stress of that. So, it felt nice to just be able to say, “Oh, I can get treatment right away.”***

—RAPID patient

## RAPID through one provider’s eyes

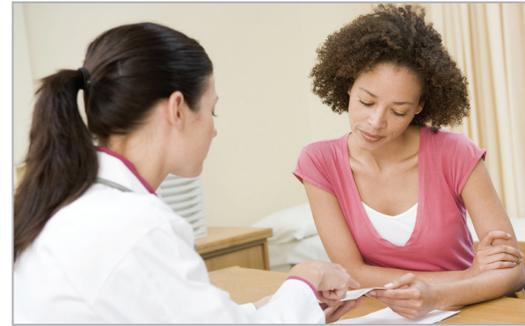
*We talk all about the benefits to the client but we never talk about how much it makes it easier on the provider. **I can’t imagine ever disclosing again without being able to offer immediate treatment.***

—RAPID provider Pierre-Cedric Crouch, PhD, NP, clinician at Magnet, a nurse-led community-based clinic

# RAPID Implementation: Overview

**GOAL: First care appointment within 0-5 days of new HIV diagnosis; start ART at first visit**

- **Create a single point-of-contact for RAPID referrals:**  
e.g., a dedicated RAPID pager or knowledgeable front desk.
- **Form a committed team to handle RAPID roles**  
(Counseling, Benefits Navigation, Clinical/Prescription).
- **Educate entire clinic staff about RAPID**, even if they aren't interacting directly with the patient.
- **Minimize handoffs on Day 1:** Every handoff should be warm.
- **Develop a plan for medication access\*:**
  - Emergency ADAP
  - Presumptive Medi-Cal
  - Pharma Patient Assistance Cards
  - Starter packs of 5-7 days of medication are helpful but are not essential
  - Partner with a local specialty (HIV) pharmacy to expedite medication dispensing.



\* Insurance coverage for ART medications is often the biggest barrier to RAPID ART start; it is important to establish systems for rapid access to coverage for uninsured persons and to have benefits navigators or social workers with expertise in establishing insurance and medication coverage.

## Immediate ART is appropriate for:



- Anyone with a new, confirmed HIV diagnosis unless there is a clear contraindication
- Persons with possible acute HIV (see p. 5 for further information)
- Returning-to-care HIV+ persons with an uncomplicated ART history (e.g., stopped first-line therapy for reasons other than regimen failure) may be restarted immediately if possible drug resistance can be predicated and accounted for in the new ART regimen

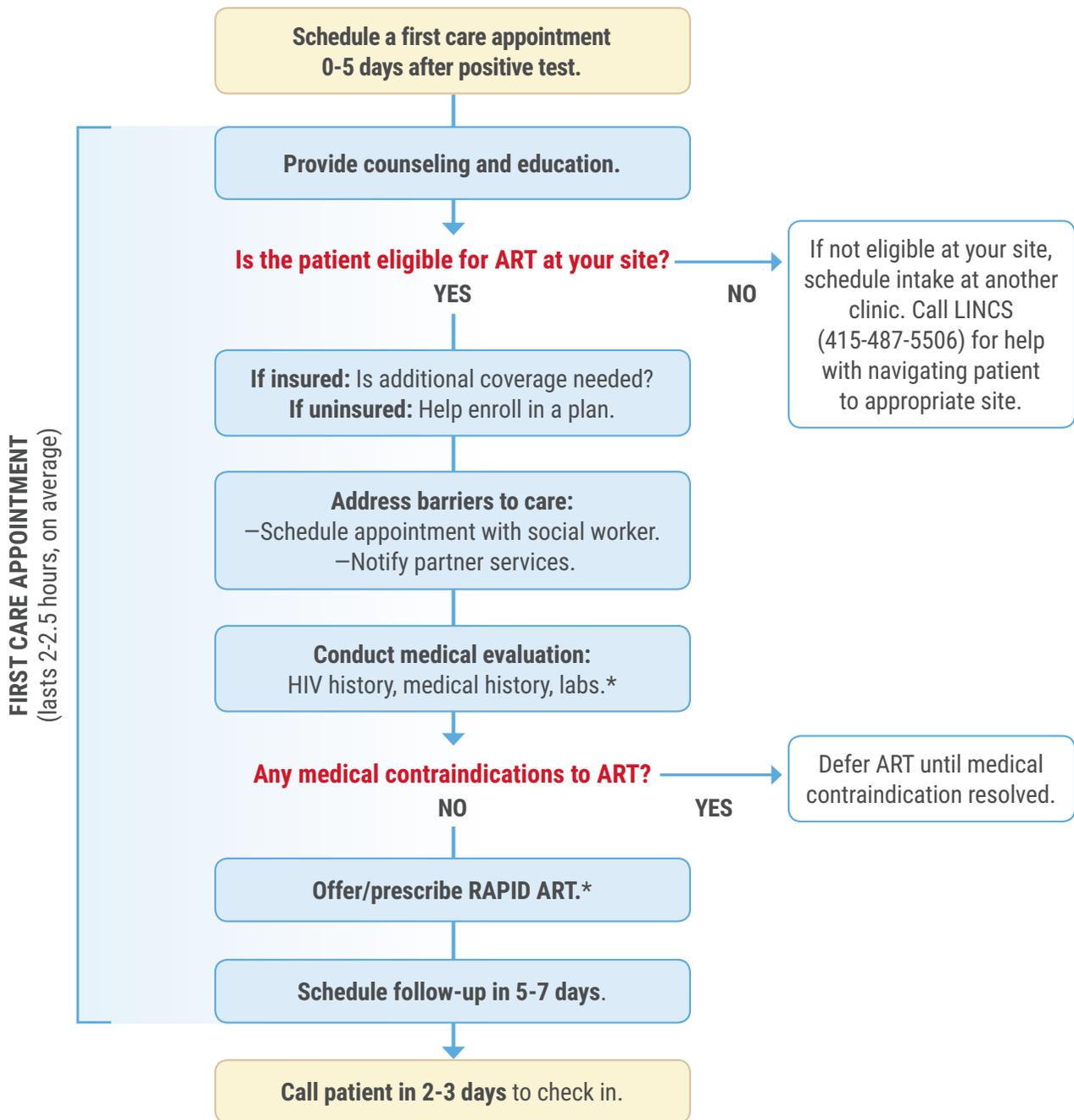
## Immediate ART is **not** appropriate for:



- Patients for whom immediate ART might be medically dangerous (e.g., untreated cryptococcal meningitis)
- Patients likely to have multiple ARV mutations (e.g., treatment experienced with known or suspected resistance), for whom the results of resistance testing would likely influence regimen choice

# How to implement RAPID at your healthcare facility

## RAPID CARE FOR PATIENTS TESTING HIV POSITIVE



\* See pages 6-7 for labs and recommended treatment regimens.

# HIV Testing

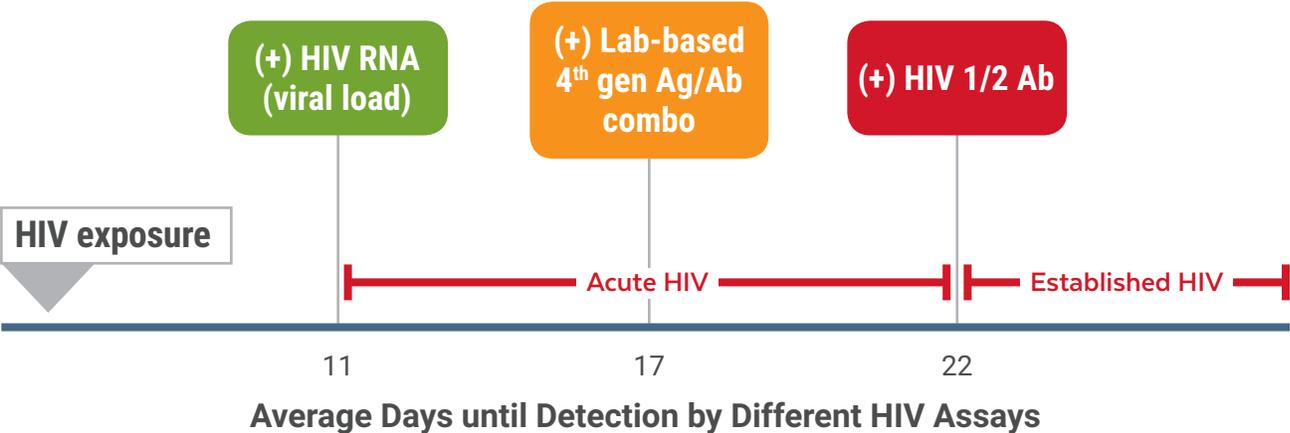
Usually, patients start RAPID with a confirmed positive HIV test.

- A confirmed positive test will depend on the testing algorithm used:
  - reactive lab-based 4<sup>th</sup> gen antigen/antibody + reactive differentiation antibody
  - reactive antibody + reactive confirmatory antibody
  - 2 different reactive rapid fingerstick antibody tests

Occasionally, a patient will present with:

- **(+) HIV RNA (quantitative or qualitative) + negative antibody:** Indicates acute HIV infection, and warrants immediate ART initiation before confirmatory testing results are available.
- **Reactive lab-based 4<sup>th</sup> gen Ag/Ab test + nonreactive differentiation antibody:** Indicates either acute HIV infection or false positive Ag/Ab test. If the patient is at high risk for HIV infection, he or she may be referred for RAPID initiation before the results of the “tiebreaker” HIV RNA is available.

## HIV testing during acute vs. established infection



*Interpreting HIV test results can be difficult; seek expert advice in cases with discordant test results or complicated clinical scenarios.*

# Recommended labs and ART regimens

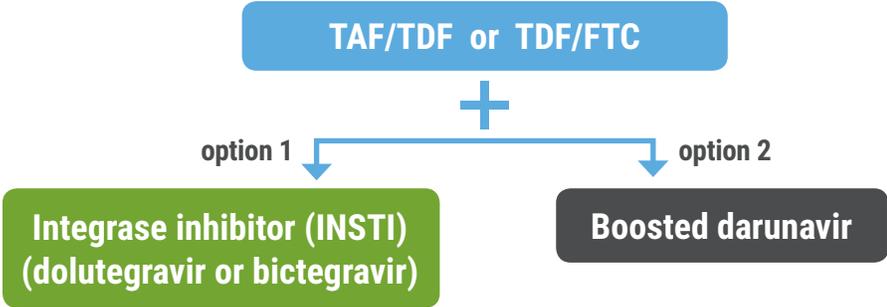
## Laboratory evaluation for RAPID patients

|   |  |
|---|--|
| <input type="checkbox"/> Confirmatory HIV testing (if needed)   | <input type="checkbox"/> HAV IgG antibody  |
| <input type="checkbox"/> HIV viral load   | <input type="checkbox"/> Hepatitis B serology (sAb, cAb, Ag)   |
| <input type="checkbox"/> HIV genotype, including integrase  | <input type="checkbox"/> HCV antibody  |
| <input type="checkbox"/> CD4+ T cell count  | <input type="checkbox"/> Pregnancy test (if indicated)   |
| <input type="checkbox"/> HLA B*5701 polymorphism  | <input type="checkbox"/> Syphilis screening  |
| <input type="checkbox"/> Comprehensive metabolic panel (including creatinine and liver function)      | <input type="checkbox"/> Gonorrhea and chlamydia NAAT at all sites of exposure (could be urine, vaginal, pharyngeal, rectal) |
| <input type="checkbox"/> <b>Also consider:</b> Quantiferon, Toxoplasma IgG antibody, and G6PD testing |  |

## RAPID treatment regimens

Initial RAPID ART will be given before the results of baseline lab testing are available. Thus, it is important to choose RAPID regimens that are likely to be effective even if the most common transmitted resistance mutations are present and if the viral load is >100,000 c/mL. They should have minimal pill burden and side effects.

### >> Recommended:



Can be modified once the results of baseline genotyping, HLA B\*5701, viral load, and serum creatinine are available.

### >> Acceptable if recommended agents are not available:

1<sup>st</sup> generation INSTIs (raltegravir or elvitegravir) + TAF/FTC (or TDF/FTC)  
 Lower genetic barrier to resistance than recommended INSTIs

## » Patients with positive HIV test while on PrEP

- Take a thorough medication history to determine the last time that they took PrEP, and their PrEP-taking pattern.
- If the patient took any PrEP in the last 3 weeks, consider starting an enhanced regimen consisting of INSTI (dolutegravir or bictegravir) + boosted darunavir + TAF/FTC (or TDF/FTC) while awaiting results from the genotype.

## » Pregnancy and RAPID ART

For women who may become pregnant while taking ART, and women who are in the first trimester of pregnancy:

- **raltegravir 600mg, 2 po once daily + TAF/FTC or TDF/3TC**, 1 po once daily; seek expert consultation.

### **ARVs to AVOID** until results of genotype and HLA B\*5701 are known:

- **NNRTIs: efavirenz, etravirine, rilpivirine, doravirine, nevirapine**
  - NNRTI class is most associated with transmitted drug resistance.
  - Rilpivirine is less potent if baseline viral load >100,000 c/mL.
- **Abacavir-containing regimens, including co-formulations (Epzicom®, Triumeq®)**
  - High risk of fatal abacavir hypersensitivity reaction if HLA B\*5701(+)
- **2-drug regimens: dolutegravir/rilpivirine, dolutegravir/3TC, boosted darunavir/3TC, and others**
  - Risk of transmitted drug resistance and virologic failure; not studied as RAPID regimens

# Take home messages

- Ensure patients can access a care appointment within 0–5 days of HIV diagnosis.
- Draw baseline labs and offer ART to newly-diagnosed patients at the first visit.
- Discuss how the medications work, the importance of daily adherence, and potential side effects.
- Follow up with the patient by phone in 2–3 days, and in the clinic in 1–2 weeks. Subsequent visits should be at 1 month and then at least quarterly until patient is well established in care and HIV viral load is suppressed.
- Intervene immediately for missed visits and refer to LINCS (415-487-5506) if unable to locate.

## COUNSELING TIPS

### 1. Check in and offer support

- What questions or concerns do you have as we start the visit?
- How are you doing with this diagnosis? It's often overwhelming at first, but with time, you will realize that you have control of your HIV and that it does not define you.
- Do you know anyone living with HIV? It's like other manageable diseases—you monitor it, take medications daily, and check in with your care team regularly.

### 2. Destigmatize and normalize

- People from every background and every profession are working and living with HIV. It is illegal to discriminate against anyone living with HIV.
- Do you know how HIV is (and isn't) transmitted? People who take HIV medications daily and keep their viral load undetectable will not infect sexual partners.

### 3. Medical management

- To control your virus and keep you as healthy as possible, take your HIV medications daily. Find a time that fits your daily routine to help ensure you don't miss doses.
- Use pill dispensers to keep track of your medications.
- Most people have few or no side effects from HIV medications. If you have any side effects, let us know and we can help you minimize them.

**ACKNOWLEDGMENTS:** We would like to acknowledge the contributions of Ward 86, ZSFGH, for contributing their experience in implementing RAPID.

**REFERENCES:** (1) Bacon O, et al. The Rapid Art Program Initiative for HIV Diagnoses (RAPID in San Francisco). In: Program and abstracts of the 2018 Conference on Retroviruses and Opportunistic Infections; March 4–7, 2018; Boston. Abstract 93. (2) Coffey S, et al. RAPID ART: High virologic suppression rates with immediate ART initiation in a vulnerable urban clinic population. *AIDS* 2019, 33(5):825–832. (3) Saag MS, 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. (4) World Health Organization. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. July 2017. [www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/](http://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/). (5) Cohen MS, et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. *New Engl J Med*. 2016 Sep 1;375(9):830–9. (6) Rodger AJ, et al; PARTNER Study Group. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. *JAMA*. 2016 Jul 12;316(2):171–81. (7) Rodger A, et al; PARTNER Study Group. Risk of HIV transmission through condomless sex in MSM couples with suppressive ART: the PARTNER2 Study extended results in gay men. International AIDS Conference; July 23–27, 2018. Abstract WEAX0104LB. (8) CDC, Dear Colleague letter, Sept. 27, 2017. Available at: [www.cdc.gov/hiv/library/dcl/dcl/O92717.html](http://www.cdc.gov/hiv/library/dcl/dcl/O92717.html).

