

# SAN FRANCISCO PROGRAM FOR RAPID ART INITIATION AND LINKAGE TO CARE STANDARD OPERATING PROCEDURES



SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH



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## I. INTRODUCTION

“RAPID” (The Rapid ART Program Initiative for HIV Diagnoses) is a clinical program being implemented throughout San Francisco as part of the [Getting to Zero](#) (G2Z) initiative, the goals of which are a 90% reduction in HIV diagnoses, a 90% reduction in HIV-related deaths, and zero HIV-related stigma by the year 2020. RAPID extends the concept of universal ART to include immediate linkage to HIV care and initiation of ART at the time of HIV diagnosis. The potential benefits of RAPID are: 1) Improving individual patient health by decreasing the time to virologic suppression and 2) Improving rates of early engagement and possibly long-term retention in care. Citywide Rapid builds on the SFGH RAPID program, established at the HIV/AIDS Division at SFGH (“Ward 86”) in 2013.

## II. PURPOSE OF THIS DOCUMENT

1. To provide the medical and public health rationale for RAPID
2. To serve as a practical guide for the medical, counseling, and care planning components of the citywide RAPID program
3. To propose evaluation metrics for RAPID

## III. RATIONALE FOR RAPID

City and national guidelines currently recommend universal ART (ART initiation for all HIV-infected patients regardless of CD4 count)<sup>1</sup>. The main rationale for the RAPID program is the compelling benefit to HIV-infected individuals conferred by immediate ART. RAPID also may confer a community level public health benefit by reducing HIV transmission. We highlight here benefits of immediate and universal ART.

### A. Individual patient benefit:

There are increasing data showing that there may be direct benefits to the individual patient if ART is initiated as soon as possible, particularly during acute/early HIV infection. This means not waiting weeks to months between HIV diagnosis and starting antiretroviral therapy. These benefits are summarized below.

III.A.1. Viral load suppression alone is not sufficient to restore immunologic health.

- Initiating ART later in chronic HIV infection is associated with dampened CD4+ T cell recovery. In one study, 25% of patients who start ART at CD4+ T cell counts <200 cells/mm<sup>3</sup> were unable to achieve CD4+ T cell counts >500 cells/mm<sup>3</sup> even after >7 years of suppressive ART<sup>2</sup>.
- The inability to restore a normal CD4+ T cell count in the setting of ART is associated with an increased risk of AIDS- and non-AIDS related complications, and this risk persists even with restoration of CD4+ T cell counts above 500 cells/mm<sup>3</sup><sup>3-5</sup>.

III.A.2. Initiating ART during acute/early infection may improve CD4+ T cell recovery and decrease the overall size of the HIV reservoir.

- When ART is initiated during chronic HIV infection, there is ongoing low-level viral replication detected by sensitive assays despite long-term, suppressive ART<sup>6-8</sup>.
- Earlier initiation of ART during acute HIV infection may lead to improved CD4+ T cell count recovery, decreased on- treatment immune activation, and decreased HIV reservoir size<sup>9</sup>.
- In some individuals, early initiation of ART during acute HIV infection may lead to prolonged control of HIV after the subsequent cessation of ART<sup>10</sup>.
- Immediate initiation of ART during extremely early HIV infection (Fiebig Stages I-III<sup>11</sup>) may protect long-lived central memory CD4+ T cells from becoming infected<sup>12</sup> and decrease the size of the long-term reservoir.

III.A.3. Randomized clinical trial data<sup>13</sup> show decreased HIV-related and non-related morbidity and mortality when ART is started at a CD4+ T cell count > 500 cells/mm vs. < 350 cells/mm.

III.A.4. In a pilot study of RAPID at the SFGH/UCSF HIV clinic (“Ward 86”) immediate (same-day) ART was highly acceptable to patients and providers, significantly reduced time from diagnosis to undetectable viral load, and was associated with very high rates of linkage to and retention in care.

- The HIV clinic at SFGH initiated a RAPID protocol in 2013.
- Analysis of the first 39 RAPID patients vs. 47 patients treated using standard of care (universal ART) shows the following<sup>14</sup>:
  - Shorter time to virologic suppression using the RAPID protocol (56 days) vs. universal ART (132 days) (p value<0.001)
  - High retention in care among RAPID participants 90% at 6 months (RAPID) vs. 85% (Universal ART)
  - 100% patient acceptance of immediate ART vs. 85% (Universal ART)
  - High provider acceptance of RAPID
- Analysis of the 219 patients started on RAPID ART between mid-2013 and the end of 2017 shows the following<sup>15</sup>:
  - 95.8% achieved viral suppression to <200 copies/mL by one year after intake
  - 92.1% had virologic suppression at the last recorded HIV viral load
  -

As of July 2018 over 250 patients had started ART as part of the RAPID program at SFGH Ward 86. In our experience, most patients, when provided with the opportunity to start ART, want it. Community awareness of Universal ART means that many newly diagnosed HIV+ patients come in expecting and wanting to start medications. Many patients report that deciding to start ART and rapidly achieving

viral suppression provides them with the first experience of feeling empowered to successfully live with HIV.

- III.A.5. A multisector initiative in San Francisco (Getting to Zero San Francisco) to prioritize RAPID ART initiation in newly-diagnosed HIV+ individuals (as part of an overall effort to improve HIV prevention and care) resulted in significant decreases in time from HIV diagnosis to ART initiation and to virologic suppression in the years studied, 2013-2016:<sup>16</sup>
- Time from HIV diagnosis to first HIV care visit decreased from 8 days to 5 days
  - Time from 1<sup>st</sup> HIV care visit to ART initiation decreased from 27 days to 1 day
  - Time from HIV diagnosis to HIV suppression to <200 copies/mL decreased from 134 days to 61 days
- III.A.6. Randomized clinical trials of immediate ART done in developing world settings have shown that immediate ART at diagnosis (compared with starting according to the local standard of care) has been shown to increase rates of linkage to care<sup>17</sup>, ART initiation<sup>18</sup> and reaching first virologic suppression;<sup>17,18</sup> to increase retention with virologic suppression, and reduce mortality.<sup>19</sup>
- III.A.7. Data from 2 demonstration projects of rapid ART initiation in United States settings have shown decreases in time to ART start and to first virologic suppression.<sup>21,22</sup>

The World Health Organization and the IAS-USA now recommend offering immediate ART to all persons newly diagnosed with HIV.<sup>20,24</sup>

#### **B. Public health benefit:**

Earlier ART initiation and earlier viral load suppression will likely decrease the risk of subsequent HIV transmission events<sup>23</sup>. While this is particularly true for patients who are in the acute stages of HIV infection and may be hyperinfectious because of peak viremia, it also applies to the larger pool of patients diagnosed >6 months from infection.

#### **IV. ELIGIBILITY FOR RAPID**

- Newly diagnosed HIV patients (inclusive of acute and chronic infection), defined as:
  - Acute Infection: antibody(-)/RNA(+) or p24 antigen(+)/antibody(-)
  - Recent Infection: antibody(+) with last documented antibody(-) within prior 6 months
  - Chronic Infection: antibody positive with no prior HIV test result or last documented antibody(-) > 6 months before
- Patients with known HIV infection who are re-engaging in care with CD4 count <200 cells/mm<sup>3</sup> and no contraindications to starting ART may also benefit from immediate ART. Contraindications include a complicated or unknown ART history with possibility of acquired resistance; or a medical contraindication such as a suspected intracranial OI.

## V. OPERATIONS

**Overview: The goal of the RAPID program is for a newly diagnosed or newly re-engaged patient (if safe to do so: see IV. Eligibility for RAPID, above) to see an HIV health team, be offered ART, receive counseling, and agree on a sustainable care plan on the day of their diagnosis or re- engagement, or as soon as possible (within 2-5 days) if same-day initiation is not possible.**

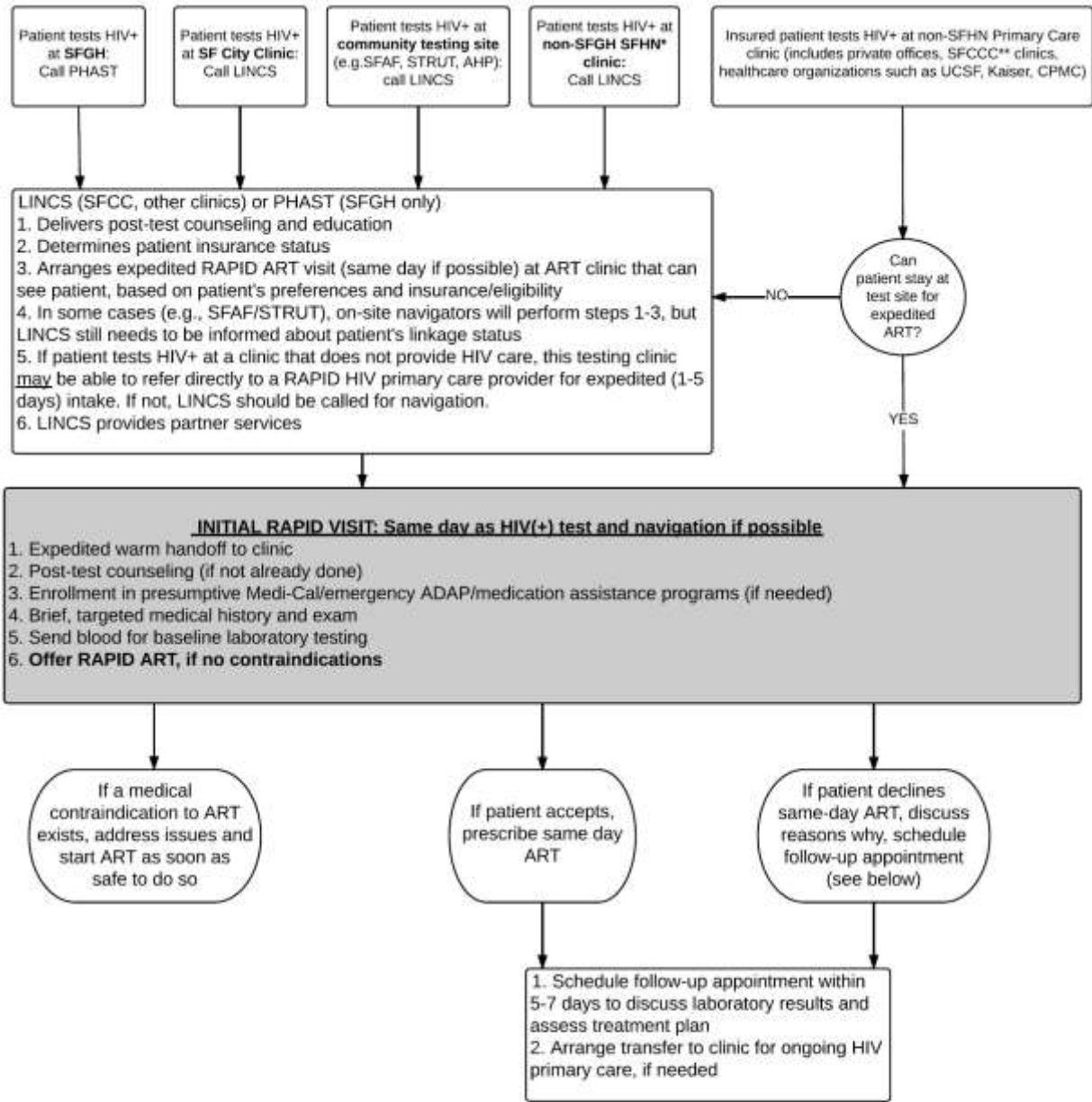
Generally, a new HIV diagnosis is made through a San Francisco Community HIV testing site (e.g., Alliance Healthcare Program, STRUT/San Francisco AIDS Foundation) or in a medical setting such a private practice office, a DPH clinic, such as San Francisco City Clinic or Castro Mission Health Center, a hospital-associated clinic (such as UCSF, California Pacific Medical Center, St. Mary's, Kaiser San Francisco), a hospital emergency department or urgent care, in specialty clinics (methadone, TB, Prenatal, Renal), or during inpatient hospitalization.

Schematically, RAPID consists of several basic steps, once HIV diagnosis is confirmed (see **RAPID Patient Flow Chart**, below):

- Post-test counseling including potential benefits of immediate ART and assessment of patient's interest in immediate ART
- Assessment of where the client should be linked for RAPID initiation of ART (this involves finding out patient's current insurance status and whether s/he has a primary careprovider)
- Communication of a new diagnosis to the clinic where the patient will be evaluated for immediate ART (a single point of contact— such as a dedicated pager or cellphone -- for the RAPID team at a treatment site is highly recommended).
- The initial RAPID visit, including ART initiation. Expedited linkage to ongoing HIV primary care (which may continue at RAPID site, if available, or at another HIV primary care site appropriate for and acceptable to the patient).

Some details of the RAPID process will differ, depending on where a patient is diagnosed with HIV infection and where they can receive immediate ART.

# RAPID Patient Flow Chart



**\*Non-SFGH SFHN Clinics** include: Castro Mission Health Center; Southeast; Tom Waddell Urban Health Center; Maxine Hall; Chinatown Public Health Center; Ocean Park Health Center; Potrero Hill Health Center; Silver Avenue Family Health Center; Larkin Street Medical Clinic; Cole Street Clinic; Dimensions Clinic; 3rd Street Youth Center and Clinic

**\*\*SFCCC Clinics** include: Tenderloin Health Center; HealthRIGHT360; Lyon-Martin Health Services; Curry Senior Center; Native American Health Center; North East Medical Services; Saint Anthony Medical Clinic; San Francisco Free Clinic; South of Market Health Center; Women's Community Clinic

## STEP ONE

### Referral of NEW HIV+ patient to linkage/navigation for expedited care

- *Patients who test at SFGH:* Patients with a confirmed new HIV+ diagnosis are referred by the SFGH lab to the **PHAST** team for linkage to care, insurance navigation
- *Patients who test at SF City Clinic, Community Testing Sites, SFHN clinics not on the SFGH campus, and all primary care clinics (Private or SF Community Consortium) that cannot themselves provide immediate ART:* Patients with a confirmed new HIV+ diagnosis are referred to **LINCS/Partner Services** for linkage to care, insurance navigation. Some testing sites (e.g., SFAF, STRUT/Magnet) may have **in-house linkage navigators** who can navigate patients to care; in this case LINCS should also be notified to reduce duplication and enhance co—ordination of care
- *Patients who test at a clinic that provides HIV Primary Care:* Patients with a confirmed new HIV+ diagnosis can stay at that clinic for RAPID initiation of ART without being referred for navigation. If the patient tests HIV+ at a multidisciplinary healthcare organization (HCO) (e.g., Kaiser, UCSF, St. Mary's Hospital, CPMC/Sutter) that has internal HIV capacity, (s)he can be referred to that HCO's HIV clinic for RAPID ART initiation. LINCS, which is notified of all new HIV+ cases in San Francisco, can help with rapid linkage to HIV care, if needed.



**STEP TWO:**  
**Linkage of a newly diagnosed HIV+ patient to RAPID ART initiation**

**A. Patients Who Test HIV+ on the SFGH Campus *or* are referred to Ward 86 at SFGH after testing HIV+ at an outside site or clinic**

The SFGH Testing and Linkage to care team (**PHAST**) is paged [415-443-3892] either by the community testing sites or by the San Francisco General Hospital Clinical Laboratory, via pager Monday-Friday 8-5pm, for any HIV+ antigen/antibody test result or a detectable HIV RNA (sent for the purposes of diagnosis) in the absence of an HIV+ antibody test result. Determination is then made whether the diagnosis is a new diagnosis and whether it is likely to be an acute infection.

After receiving test result disclosure and post-test counseling at the testing site, *patients who are eligible for care in the DPH clinics* are invited to the San Francisco General Hospital Ward 86 RAPID program. All efforts should be made to transfer the patient to Ward 86 for RAPID the same day. Upon arrival, the patient is welcomed and meets with a health counselor for additional post-test counseling and education as well as psychosocial assessment and initiation of insurance paperwork. Then the patient meets with the RAPID clinician for further counseling and ART initiation. The majority of RAPID visits will occur on weekday afternoons, and are expected to last approximately 2 hours (**See STEP THREE, below, for a description of the RAPID visit**).

**B. Patients who test HIV+ at San Francisco City Clinic (SFCC) or are referred to SFCC after testing HIV+ an outside testing site or clinic**

A clinician trained in HIV medicine sees all new HIV diagnoses made at SFCC to assist with post-test counseling and to answer clinical questions related to an HIV diagnosis. In addition, the LINCS/Partner Services (LINCS/PS) team provides post-testing counseling, linkage to care and Partner Services. What happens next depends on insurance status.

Patients *without insurance*, or with pending Medi-Cal or pending commercial insurance and no HIV primary care provider, may remain at SFCC to initiate ART through the Early Care Clinic. In this case, the patient meets with the RAPID clinician for ART initiation, with the expectation that patients will be referred for ongoing care once their insurance is in place and they have an appointment with a qualified HIV primary care provider. Medi-Cal eligible patients without insurance or with presumptive Medi-Cal may be referred that day to Ward 86 at SFGH for RAPID initiation (through notifying the PHAST team). Patients with active Medi-Cal can be referred to Ward 86 or another DPH clinic that provides ART for expedited intake.

## **C. Patients who test HIV+ at sites *other* than SFGH or SFCC, and are *not* referred to Ward 86 at SFGH or to SFCC for RAPID**

Patients with *commercial insurance* and a qualified HIV provider in their network should be referred for expedited intake (same day if possible, but within 5 days at most) to a provider in their network who accepts commercial insurance (including Kaiser if (s)he is a Kaiser member). The majority of RAPID visits are expected to last approximately 2 hours. (See **STEP THREE**, below, for a description of the RAPID visit).

**In all cases, the site that makes the diagnosis of HIV should inform LINCS/PS of the new diagnosis, as LINCS/PS is ultimately responsible to SFDPH for making sure that HIV+ patients are linked to care.** (A list of RAPID clinic options is available at: <https://drive.google.com/file/d/0B2mW-8p2dyYVVJpRk5INExpWVE/view?ths=true>)

**The key to making RAPID work in this setting is for the receiving clinic to have a system in place to accept rapid referrals.** One successful approach is to designate a “RAPID Officer of the Day:” a team member who will be the single point of contact for receiving the referral and will organize the RAPID response to the newly diagnosed patient. The RAPID Officer of the Day can be a case manager, MD, NP/PA, RN, or social worker, who will marshal the personnel needed to treat the patient that day (front desk/registration, counseling, phlebotomy, eligibility and benefits counseling and navigation, medical evaluation and ART prescription, notification of Partner Services), with the goal of same-day evaluation and ART initiation. In some clinics, it might make sense to have an on-call schedule (in which one person is designated RAPID Officer of the Day). In other clinics, it might make sense for the patient’s primary care provider to organize the RAPID response. The patient undergoes counseling, psychosocial assessment, and a RAPID clinician visit for further education and ART initiation and establishment of a care plan (see **STEP THREE**, below).

### **STEP THREE The Initial “RAPID” visit:**

One of the lessons learned during the RAPID pilot at Ward 86 was that patients should be subjected to as few handoffs as possible, and that “all handoffs should be warm handoffs.” Never let the patient wait in the waiting room, but escort him or her from team member to team member.

One of the worries that patients have during their RAPID visit is whether they will be able to afford their care. It is helpful to address this up front, but without letting the discussion of insurance dominate their clinical care (it’s also important to make sure that patients will not be stuck with an unexpected and large bill for their initial visit). Here is a sample script that an eligibility/registration worker can use to help address the insurance issue when the patient arrives at the clinic:

“My goal is to help you receive excellent HIV care. In order to do this, I need to ask you a few

questions about your health insurance situation. I know health insurance can be confusing and tricky. – I'm here to help you navigate it and get you into care as quickly as we can."

**A. Counseling:** A key component of the RAPID program is to insure that the patient has individualized post-test counseling and education. This includes but is not limited to discussion of the patient's new HIV diagnosis, psychosocial assessment/intervention, discussion of risks/benefits of treatment, and education on HIV and safer sex practices. Once that is accomplished, assessment is started to identify potential barriers to successful linkage to care (medical insurance including drug benefits, mental health issues, substance use, unstable housing, immigration status, legal challenges). The initial session also addresses partners at risk. **In the RAPID program, the counseling starts after diagnosis, and continues after a patient is started on treatment.** With this approach, all the standard individualized counseling components are covered, but they a) do not delay ART and b) offer the opportunity to continue counseling while patient is starting therapy.

**B. Establishing a sustainable long-term care plan:** Successful outcomes in HIV depend on not only the rapid initiation of therapy but also upon the rapid establishment of a sustainable HIV care plan. Based on the initial assessment of potential barriers to successful linkage to care, a plan is put in place with a social worker, case manager, or clinician to address both immediate and long-term barriers. This may include emergency housing, emergency access to insurance and drug benefits, expedited access to mental health services or residential drug treatment programs, counseling and referrals to deal with immigration or other legal issues. All patients require an assessment of the impact of HIV stigma and how they will cope with this as well as whether they will need additional resources (support groups, ability to meet with an HIV+ peer advocate, counseling, etc.).

In addition, a RAPID team member should notify the LINC/Partner Services Coordinator (**415-487-5506**) about the new patient, so LINC/PS can discuss current and recent sexual partners and other persons at risk for infection such as children or persons sharing IV drugs and drug paraphernalia, and who might need HIV testing, including those who might have been exposed within the past 72 hours and might benefit from post-exposure prophylaxis (PEP). Patients are counseled that the Department of Public Health Partner Services branch will contact them to assist with partner services.

**Based on the identification of barriers to linkage and retention in care, a contingency plan is identified for potential problems such as missed appointments, missed doses of ART, inability to fill medications at the pharmacy, etc. Patients are given clear guidance on how to get help and support and remain connected to the clinic.**

**C. Medical Evaluation:**

**HIV history:** An HIV risk/prevention history will be taken and recorded, including:

1. Date of last negative HIV test and prior HIV tests
2. PrEP use

3. PEP use
4. Sexual practices and serostatus of partners, if known
5. Injection drug practices, if any

**Medical history:** A quick medical history will be taken, particularly since patients will be started on ART before most laboratory test results have returned:

1. Co-morbidities (especially kidney/liver problems)
2. Medications
3. Drug allergies
4. Review of systems (to alert for the presence of OIs or seroconversion syndrome)

**Laboratory studies:** As part of standard intake labs, all newly diagnosed patients will have the following laboratory tests performed on the day of the initial RAPID visit: HIV antibody or antigen/antibody (if confirmed HIV antibody test not already on record), HIV viral load, HIV genotype, integrase genotype if available, CD4+ T cell count, HLAB5701 polymorphism testing, comprehensive metabolic panel (including creatinine and liver function tests), RPR, gonorrhea and chlamydia screening (NAAT) in urine, throat, and rectum, HAV IgG antibody, HBsAg, HBcAb, HBsAb, and HCV antibody. Quantiferon or PPD for tuberculosis, toxoplasma IgG antibody, and G6PD testing may also be considered.

**D. ART counseling on the risks and benefits of immediate ART:** A full discussion occurs with the patient regarding the risks and benefits of immediate ART. The role of viral load monitoring and the importance of adherence will also be included in this discussion to introduce the concepts and therapy goals. Patients are told about the possibility of developing an immune reconstitution syndrome. They are also advised of the importance of being in close contact with the health system during early months of treatment, and about contacting the clinic immediately should any complications arise related to medication or HIV disease. **Emphasis is placed upon listening to patient concerns, and conveying to the patient that they will likely have additional questions through this process and that the team is happy to address these questions.**

**E. Initiation of immediate ART:**

- The provider reviews the patient's plan for long-term ART and follow-up care.
- Unless there is a clear contraindication or the patient declines, the provider offers, selects (in consultation with the patient), and prescribes immediate ART.
- **Selection of Antiretroviral Therapy:** The selection of a particular ART regimen for an individual patient will be guided by the patient's preferences, co-morbidities, potential drug interactions, and drug allergy history.

Most RAPID patients will be initiated on ART before the results of laboratory tests are available (in particular the HIV viral load, genotype, CD4 count, creatinine, liver function tests, hepatitis B status, and HLA B5701 for predisposition to abacavir hypersensitivity).

Thus, regimens for RAPID ART should be effective in a broad range of clinical situations, at

least in the short period until lab results are available and regimens can be modified if needed. RAPID ART regimens should be potent even at high HIV RNA levels and have a high genetic barrier to resistance (in case some level of transmitted resistance is present). Ideally they also are tolerable, easy to take, and involve few pills.

## ART REGIMENS FOR RAPID

Our **preferred** RAPID ART regimen for most patients, based on these criteria and our RAPID clinical experience, as well as pragmatic cost issues (eg, purchase of ARVs for RAPID starter packs) is:

- Dolutegravir<sup>a</sup>, 50 mg once daily + (tenofovir alafenamide [TAF]/emtricitabine [FTC] or tenofovir disoproxil fumarate [TDF]/FTC<sup>b</sup>), 1 tablet once daily

The following also are **reasonable options**, though may have less supporting data or clinical experience for use in RAPID ART, more potential adverse effects, or higher costs:

- Bictegravir/TAF/FTC, 1 tablet once daily
- Darunavir/cobicistat/TAF/FTC, 1 tablet once daily
- Darunavir 800 mg once daily + ritonavir 100 mg once daily + (TAF/FTC or TDF/FTC<sup>b</sup>) 1 tablet once daily

These alternatives **may be considered** if access to the above regimens is limited:

- Elvitegravir/cobicistat /TAF/FTC, 1 tablet once daily
- Raltegravir 1200 mg once daily + (TAF/FTC or TDF/FTC<sup>b</sup>) 1 tablet once daily)

<sup>a</sup> Dolutegravir recently has been associated with a higher risk of neural tube defects in infants born to women who were taking dolutegravir at the time of conception. For women of childbearing age who may become pregnant while taking dolutegravir (ie, have male sex partners and are not using effective contraception), the FDA currently recommends that providers discuss risks and benefits of dolutegravir and alternative ARVs, and consider alternatives.

<sup>b</sup> Tenofovir alafenamide (TAF)/emtricitabine is preferred (except in pregnant women), but tenofovir disoproxil fumarate (TDF)/emtricitabine may be used instead.

**For Pregnant Women\***, the following RAPID ART regimen options are recommended:

<8 weeks from last menstrual period:

- Darunavir 600 mg twice daily + ritonavir 100 mg twice daily + TDF/FTC 1 tablet once daily (consider addition of raltegravir 400 mg twice daily for faster reduction in HIV RNA)
- Raltegravir 400 mg twice daily + TDF/FTC 1 tablet once daily

≥8 weeks from last menstrual period:

- Darunavir 600 mg twice daily + ritonavir 100 mg twice daily + TDF/FTC 1 tablet once daily (consider addition of dolutegravir 50 mg once daily for faster reduction in HIV RNA)
- Dolutegravir 50 mg once daily + TDF/FTC 1 tablet once daily
- Raltegravir 400 mg twice daily + TDF/FTC 1 tablet once daily

\*TAF, bictegravir, and elvitegravir/cobicistat/TAF/FTC are not currently recommended in pregnancy. Dolutegravir is not recommended at the time of conception or the first 8 weeks of pregnancy.

**The following should NOT be prescribed for RAPID ART:**

- Abacavir (results of HLA B5701 testing will not be available, and risk of abacavir hypersensitivity reaction in persons with HLA B5701 allele is substantial)
- NNRTIs (results of pre-treatment genotype will not be available and likelihood of transmitted NNRTI mutation is relatively high)

Individual ART regimens may need to be tailored for certain patients, e.g.:

- Persons who have had recent PrEP/PEP exposure, or a source partner with known viral resistance (for example, a 3-class regimen that includes an integrase inhibitor, a protease inhibitor, and NRTIs may be indicated, pending the patient's genotype results)
- Pregnant women, or women planning pregnancy (many of the preferred ARVs are not recommended in pregnancy)
- Patients with known renal disease

Selected ARVs must be covered by the patient's insurance plan and available in the patient's pharmacy.

## **F. Prescribing and/or Dispensing Initial ART**

### *Option A: Medication Available on-site*

- Once an ART regimen has been selected, the health team dispenses a 5-day supply of medications (having recorded the order in the medical record). The goal is to provide sufficient ART until the patient's ADAP or insurance is active and covers a standard monthly supply. In situations where this period is anticipated to be longer than 5 days, additional pills may be dispensed.
- The patient is encouraged to take the first dose of ART, witnessed, during the initial RAPID visit.
- In the patient's medical record, create an order for a standard 30-day supply of the same ART regimen and FAX it to the appropriate pharmacy.
- The clinician CALLS the pharmacy to alert them to the incoming ART prescription, and that it is to be filled as soon as possible.

### *Option B: Medication NOT Available on site*

- Once an ART regimen has been selected and emergency ADAP or presumptive Medi-Cal is initiated, or if the patient already has insurance, the clinician writes a 30-day prescription and faxes it to the appropriate pharmacy. If there are any delays to the ADAP or Medi-Cal activation, the use of pharmaceutical company medication assistance coupons is highly recommended, to ensure same-day initiation (see Appendix I: RAPID Treatment Site Checklist).
- The clinician CALLS the pharmacy to alert them to the incoming ART prescription, and that it is to be filled as soon as possible (this will also alert the clinician to any stock-outs or other problems at the pharmacy).



**STEP FOUR:  
Follow-up Care**

**Day ART Initiation + 1:** The health counselor (this can be a social worker or nurse) calls the patient on the day after ART initiation to provide psychosocial support, assess for any clinical symptoms, or medication side effects, and provide any support for the patient to fill his/her long-term ART prescription. This may involve contacting the patient's pharmacy to work out any potential problem with access to medications. Any medical symptoms or questions are conveyed to the provider for the appropriate follow-up.

**Day 5-10:** The patient has a follow-up appointment with the long-term provider who provides follow-up on clinical care and laboratory tests that are ordered. At that visit, CD4, HIV RNA and HLAB5701 results are reviewed with the patient. Assessment is made for HIV or medication side effects. Treatment may be adjusted as appropriate. Care starts or resumes with the provider as per routine primary HIV care.

**Ongoing:** Access to social workers is provided during this time period and over the next 3 months to continue working on the stabilization plan, and to provide ongoing support and education for coping with stigma, disclosing to partners/family/friends, and tackling other barriers to optimal health (e.g., issues with mental health, substance use, housing, immigration, insurance). Patients are offered a session with a Clinical Pharmacist to support adherence and provide additional education on ART.

Appointment reminders are made and any missed appointments are addressed immediately, including via outreach and home visits.

For patients deemed at continued risk for poor retention in care, referrals are made to case managers and overlapping support is provided until patient has established a relationship with the case manager.

**VI. OPERATIONAL DEFINITION OF TERMS RELATED TO ENGAGEMENT IN HIV CARE**

All patients start as "active patients." After 6 months, they may progress to "engaged" patients where viral suppression is achieved and care plan established, and psychosocial needs have stabilized. Patients who transfer to another system are classified as "transferred patients." Patients for whom no information or contact can be gained are classified as "Lost to follow-up."

## **Glossary of Terms:**

**ACTIVE PATIENTS:** These patients have maintained linkage to the clinic either through primary care or urgent care and continue to need support (appointment reminders, follow-up on missed appointments, nursing care coordination, education regarding medication refills, scheduling, psychosocial stabilization, appropriate utilization of urgent care or emergency services); this includes all patients newly enrolled (within past 6 months).

**ENGAGED PATIENTS (“HIV CARE ENGAGEMENT”):** Engaged in HIV care for at least 6 months; health insurance established; plasma HIV-1 RNA below the level of detection (e.g., <40 copies/mL) for at least 3 months on ART; demonstrated ability to maintain engagement in primary care independently including scheduling and rescheduling appointments, refilling medications, and utilizing urgent care and emergency services appropriately; attended at least 3 primary care appointments; filled and refilled long-term ART prescriptions; have a self-identified medical home.

**TRANSFERRED PATIENTS:** Includes patients admitted to Laguna Honda Hospital or any other skilled nursing facility, or any community hospice programs; patients who become incarcerated; patients who chose to transfer their care to a clinic out of county; patients with insurance change that mandates care transfer.

**LOST TO FOLLOW UP PATIENTS:** Have made no contact with long-term HIV provider during the past 6 months, and no contact information exists after verification of lost contact with San Francisco DPH Surveillance.

**LINKAGE TO CARE:** One initial medical encounter post HIV diagnosis, with baseline HIV laboratory testing and assignment of ongoing primary care (medical home + primary care provider).

## **VI. ACKNOWLEDGEMENTS**

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## VII. REFERENCES

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# APPENDICES

## **APPENDIX I:**

### **RAPID Clinical Site Checklist**

**Rapid ART Program Initiative for HIV Diagnoses (RAPID):** The goal of RAPID is to provide immediate antiretroviral therapy (ART) to all HIV-infected patients at the time of diagnosis (same day if possible). Everyone in your clinic plays a key role in making this program work.

#### **Is your clinic ready to offer RAPID?**

- i. **Front-desk staff** are familiar with RAPID, are aware that it is provided, understand the time sensitivity of the visit, and are able to triage patient calls and visits accordingly.
- ii. **Clinical staff** have received training on prescribing immediate ART.
  1. **Prescribers and nursing staff** are familiar with the RAPID Standard Operating Procedures in order to properly prescribe RAPID and counsel patients about RAPID treatment.
    - a. During a RAPID visit, providers should do the following:
      - i. HIV history
      - ii. Medical history
      - iii. Laboratory tests
      - iv. ART counseling on the risks and benefits of immediate ART
      - v. Initiation of immediate ART
  2. **Social workers and counselors** (or other members of the team) can provide psychological counseling and assist patients in navigating insurance coverage and access to other benefits, if necessary.
    - a. During a RAPID visit, the following issues also need to be considered:
      - i. Insurance navigation if needed (if navigation cannot be done by on-site staff, patient may need immediate referral to an outside navigator, including the LINCIS team or SF AIDS Foundation)
      - ii. Socioeconomic issues (i.e. employment, housing, etc.)
      - iii. Health issues (i.e. mental health, substance abuse, etc.)
      - iv. Legal Issues (i.e. immigration)
      - v. Other persons at risk for infection (notify LINCIS-partner services)
  3. **Laboratory staff** are prepared to test for HIV antibody, HIV viral load, HIV genotype, CD4+ T cell count, HLAB5701 polymorphism testing, comprehensive metabolic panel (including creatinine and liver function tests), RPR, HAV IgG antibody, HBsAg, HBcAb, HBsAb, and HCV antibody on the day of the initial RAPID visit. QFT/toxoplasma IgG antibody and G6PD testing may also be considered.

4. **Participating pharmacies** are prepared to expedite 30 day prescriptions of ART (dispense on the day prescribed) and know how to process patient-assistance coupons for antiretrovirals, when needed.
5. The following **resources** are available for patients:
  - a. Educational materials
  - b. A mechanism for providing same-day ART (e.g., starter packs, same-day enrollment in emergency ADAP and/or presumptive Medi-Cal, or pharmaceutical coupons for initial RAPID treatment prescription)
  - c. A list of pharmacies that are aware of RAPID ART and can provide same- day dispensing

## **APPENDIX II:**

### **Recommended RAPID Treatment Regimens (as of 12.8.2018)**

#### **Preferred RAPID ART regimens for most patients:**

- Dolutegravir\*, 50 mg once daily + tenofovir alafenamide (TAF)/emtricitabine (FTC) (or tenofovir disoproxil fumarate [TDF]/FTC or TDF/3TC), 1 tablet once daily
- Bictegravir/TAF/FTC, 1 tablet once daily
- Darunavir/cobicistat/TAF/FTC, 1 tablet once daily
- Darunavir 800 mg once daily + ritonavir 100 mg once daily + TAF/FTC (or TDF/FTC or TDF/3TC) 1 tablet once daily

These **alternatives** may be considered if access to the above regimens is limited:

- Elvitegravir/cobicistat /TAF/FTC, 1 tablet once daily
- Raltegravir 1200 mg once daily + (TAF/FTC or TDF/FTC) 1 tablet once daily

\*Dolutegravir recently has been associated with a higher risk of neural tube defects in infants born to women who were taking dolutegravir at the time of conception. For women of childbearing age who may become pregnant while taking dolutegravir (ie, have male sex partners and are not using effective contraception), the FDA currently recommends that providers discuss risks and benefits of dolutegravir and alternative ARVs, and consider alternatives.

#### **For Pregnant Women\*, recommended RAPID ART regimen options:**

- <8 weeks from last menstrual period:
  - Darunavir 600 mg twice daily + ritonavir 100 mg twice daily + TDF/FTC 1 tablet once daily (consider addition of raltegravir 400 mg twice daily for faster reduction in HIV RNA)
  - Raltegravir 400 mg twice daily + TDF/FTC 1 tablet once daily
- ≥8 weeks from last menstrual period:
  - Darunavir 600 mg twice daily + ritonavir 100 mg twice daily + TDF/FTC 1 tablet once daily (consider addition of dolutegravir 50 mg once daily for faster reduction in HIV RNA)
  - Dolutegravir 50 mg once daily + TDF/FTC 1 tablet once daily
  - Raltegravir 400 mg twice daily + TDF/FTC 1 tablet once daily

\*TAF, bictegravir, and elvitegravir/cobicistat/TAF/FTC are not currently recommended in pregnancy. Dolutegravir is not recommended at the time of conception or the first 12 weeks of pregnancy.



**ARVs to AVOID** until results of genotype, HLAB5701 are known:

- NNRTIs (results of pre-treatment genotype will not be available and likelihood of transmitted NNRTI mutation is relatively high)
- Abacavir (results of HLA B5701 testing will not be available, and risk of abacavir hypersensitivity reaction in persons with HLA B5701 allele is substantial)
- 2-drug ART regimens (risk of virologic failure)

Individual ART regimens may need to be tailored for patients who have had recent PrEP or PEP exposure, or a source partner with known viral resistance (for example, a 3-class regimen that includes an integrase inhibitor, a protease inhibitor, and NRTIs may be indicated, pending the patient's genotype results). They may also need to be tailored for a patient with known renal disease.