University of California
San Francisco

SAN FRANCISCO GENERAL HOSPITAL "RAPID" ANTIRETROVIRAL THERAPY

STANDARD OPERATING PROCEDURES

Updated February 2020

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I. INTRODUCTION

"RAPID" (Rapid ART Program Initiative for HIV Diagnoses) is a clinical program of the Division of HIV, Infectious Diseases and Global Medicine at Zuckerberg San Francisco General Hospital ("Ward 86"). The goal of RAPID is to provide immediate ART to all HIV-infected patients to benefit their health. The RAPID program extends the concept of universal ART to include immediate linkage to HIV care and initiation of ART. The SFGH RAPID program was established at SFGH in 2013 and now is a component of the city-wide RAPID initiative launched with the 2015 San Francisco city Getting to Zero strategic plan.

II. PURPOSE OF THIS DOCUMENT

1. To provide the medical and public health rationale for RAPID
2. To describe the medical, counseling, and care planning components of the SFGH RAPID program
3. To describe evaluation metrics for RAPID

III. RATIONALE FOR RAPID

Rapid ART initiation may confer compelling benefits conferred to the individual with new diagnoses of HIV. RAPID also brings a community level public health benefit by reducing the risk of HIV transmission. We highlight here benefits of immediate and universal ART.

III.A. Individual patient benefits:

Data show that there may be direct benefits to the individual patient if ART is initiated immediately, particularly during acute/early HIV infection. This means not waiting a few days or weeks between HIV diagnosis and starting antiretroviral therapy. These benefits are summarized below.

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

- Initiating ART during 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^3 were unable to achieve CD4+ T cell counts >500 cells/mm^3 even after >7 years of suppressive ART[1].
- 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^3[2-4].

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[5-7].
- 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[8].
- In some individuals, early initiation of ART during acute HIV infection may lead to prolonged control of HIV after the subsequent cessation of ART[9].
- Immediate initiation of ART during extremely early HIV infection (Fiebig Stages I-III) may protect long-lived central memory CD4+ T cells from becoming infected and decrease the size of the long-term reservoir[10,11, 12].

III.A.3. Immediate initiation of ART may improve linkage to care and retention in care. In our experience, most patients, when provided with the opportunity to start ART, choose it. Community awareness about universal ART means that many newly diagnosed HIV+ patients come in expecting and wanting to start medications. And 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.

- The lack of immediate access to HIV Care and Treatment has historically been a barrier to HIV testing, linkage to care, ART initiation, and retention in care.
- Accumulating data suggest that reducing the time from HIV testing to ART initiation enhances retention in care and has no detrimental effect on HIV clinical outcomes.

III.A.4. In both an initial pilot study of RAPID and in the subsequent RAPID clinical program at Ward 86, immediate 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[13, 14].

- Analysis of the first 39 RAPID patients vs. 47 patients treated using standard of care (universal ART) shows the following:
  - 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:
    - 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 December 2019 over 300 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.

III.A.5

The Getting to Zero San Francisco multisector initiative in San Francisco has prioritized RAPID ART initiation in newly-diagnosed HIV+ individuals as part of an overall effort to improve HIV prevention and care. Adoption of RAPID ART by many clinics in San Francisco has resulted in significant decreases in median time from HIV diagnosis to ART initiation and to virologic suppression in the years studied, 2013-2016[15]:

- Time from HIV diagnosis to first HIV care visit decreased from 8 days to 5 days
- Time from 1st 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

Demonstration projects of rapid ART initiation in 2 United States settings have shown decreases in time to ART start and to first virologic suppression[15.16]. 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) increased rates of linkage to care[18], ART initiation[19] and reaching first virologic suppression[16, 1] ; increased retention with virologic suppression, and reduced mortality.[20]

The Guidelines of the United States Department of Health and Human Services, the International AIDS Society-USA, and the World Health Organization now recommend offering immediate ART to persons newly diagnosed with HIV[21, 22, 23].

III.B. Public health benefit:

Viral suppression resulting from ART is highly effective in preventing HIV transmission.[24, 25] Earlier ART initiation and earlier viral load suppression will decrease the risk of subsequent HIV transmission events. This is particularly true for patients who are in the acute stages of HIV infection and who may be hyperinfectious because of high viral loads, but it also applies to the larger pool of patients diagnosed >6 months from infection.

IV. Appropriate persons FOR RAPID ART start

- Newly diagnosed persons with HIV (inclusive of acute and chronic infection)
- Persons with discordant HIV testing (eg, Ag/Ab test positive and differentiation test negative or indeterminate, or Ag/Ab negative but HIV RNA detectable) if there is a suspicion of acute HIV infection
- Patients with previously-diagnosed HIV who are re-engaging in HIV care, especially those with low CD4 cell counts (<200) and/or significant co-morbidities; see section V for additional information.

V. OPERATIONS

V.A. Overview

The operations of the Ward 86 RAPID program allow for an accessible HIV health team to see a newly diagnosed (or newly reengaged) patient on the same day as their diagnosis, offer therapy, and put a counseling and sustainable care plan into action. Generally, a new HIV diagnosis is made through a San Francisco community HIV testing site or in a medical setting such as primary care, emergency department or urgent care, specialty clinics (methadone, TB, prenatal, renal), inpatient hospital service, or psychiatry. Our Testing and Linkage to care team (PHAST) is paged either by the community testing site or by the San Francisco General Hospital Clinical Laboratory, via pager Monday-Friday 8-5pm, for any HIV+ antibody (or antigen/antibody) test result or a detectable HIV RNA level in the absence of an HIV+ antibody test result. The Ward 86 RAPID team then determines whether the diagnosis is a new diagnosis and whether it is likely to be an acute infection.

After the patient receives the HIV test result and post-test counseling at the testing site, they are invited to the San Francisco General Hospital Ward 86 clinic for a RAPID program intake appointment. Upon arrival, the patient is welcomed and meets with a social worker for additional post-test counseling and education as well as psychosocial assessment and initiation of insurance paperwork (if needed). Then the patient meets with the RAPID provider for a focused medical history and evaluation, further counseling, and ART initiation. Intake laboratory tests are done. The majority of RAPID occur on weekday afternoons, and are expected to last 1-2 hours.

V.B. The Initial "RAPID" visit (Day 1):

V.B.1. Counseling: A key component of the RAPID program is 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. At that time, assessment is started to identify potential barriers to successful linkage to care (medical insurance including drug benefits, mental health conditions, substance use, unstable housing, immigration status, legal challenges). The initial session also addresses partners who may be at risk.

RAPID is different than the previous standard approach to ART initiation is that instead of performing all the counseling up front before therapy starts, the counseling starts on the same day as treatment initiation, and continues after a patient is started on treatment. With RAPID, all the standard individualized counseling components are covered, but they a) do not delay therapy initiation and b) offer the opportunity to continue counseling while the patient is starting therapy.

V.B.2. Establishing a sustainable long-term care plan: Successful outcomes in HIV depend not only on the rapid initiation of therapy but also on the rapid establishment of a sustainable HIV care plan. Based on the initial assessment of potential barriers to successful linkage to and retention in care, a plan is put in place with the RAPID team social worker 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, and counseling and referrals to address immigration or other legal issues. All patients receive 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, discussion is initiated about current and recent sexual partners and other persons at risk for infection such as persons with whom they share IV drugs and drug paraphernalia. A plan is formulated for disclosure and testing of persons at risk. Patients are counseled that they will be contacted by the Department of Public Health Partner Services branch.

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.

V.B.3. Medical Evaluation:

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

1. HIV testing history and date of last negative HIV test
2. PrEP use
3. PEP use
4. Sexual practices and serostatus of partners, if known
5. Injection drug use and practices; and serostatus of injecting partners, if known

Medical history: A full 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 and 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 antigen/antibody (4^{th} generation assay),
- HIV viral load,
- HIV genotype (including integrase genotype),
- CD4+ T cell count,
- HLA-B5701 polymorphism testing,
- Comprehensive metabolic panel (including creatinine and liver function tests),
- RPR; gonorrhea and chlamydia NAAT tests at sites of sexual exposure
- HAV IgG antibody, HBsAg, HBcAb, HBsAb, and HCV antibody.
- Pregnancy test (if appropriate)
- Quantiferon, Toxoplasma IgG antibody, and G6PD testing may also be considered.

ART counseling on the risks and benefits of immediate ART: A full discussion occurs with the patient regarding the potential benefits and risks of immediate ART. The role of viral load monitoring is included in this discussion to introduce the concept and therapy goals, and preventing HIV transmission is addressed, including the concepts of prevention though continuous viral suppression on ART (treatment as prevention, or U=U). Patients are told about the possibility of developing an immune reconstitution syndrome (IRIS). They are also reminded about the importance of being in close contact with the health system during the early months of treatment should any complications arise related to medications or to 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 that the team is ready to address.

V.B.4. Initiation of immediate ART:

- The provider reviews with the patient his/her plan for long-term ART and follow-up care.
- Unless there is a clear contraindication or the patient declines, the provider selects (in consultation with the patient) and prescribes an ART regimen. If starter packs of ARV medications are available, the patient is given a starter pack and takes the first dose of ART at that time.
- If patient elects not to start ART immediately, they should be scheduled for an early follow-up visit and should be re-offered) ART. The RAPID team will work with the patient to try to reduce any barriers to ART initiation (see **V.D**., below)

Contraindications to RAPID ART initiation include the presence of untreated central nervous system (CNS) opportunistic infections (OIs), such as cryptococcal meningitis or TB meningitis, in which initial treatment of the OI should be undertaken before ART is started.

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 (e.g., HIV viral load, genotype, creatinine, liver function tests, hepatitis B status, HLA-B5701). 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.

Our **preferred** RAPID ART regimens 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) are:

- Dolutegravir[a], 50 mg once daily + tenofovir alafenamide [TAF]/emtricitabine (FTC) (or tenofovir disoproxyl fumarate [TDF]/FTC or TDF/3TC), 1 tablet once daily
- Bictegravir/TAF/FTC, 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:

- 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)[b] 1 tablet once daily

[a] Dolutegravir has been associated with a small increased risk of neural tube defects in infants born to women who were taking dolutegravir at the time of conception. No data are available on the safety of bictegravir for fetuses exposed at time of conception or early in pregnancy. For persons of childbearing age who may become pregnant while taking dolutegravir (or bictegravir) (eg, cisgender women who have male sex partners and are not using effective contraception), providers should discuss possible risks and benefits of dolutegravir and alternative ARVs, and select ARVs through shared decision making.

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

For patients who have had recent PrEP or PEP exposure: we generally recommend a 3-class regimen that includes an integrase inhibitor, a boosted protease inhibitor, and 2 NRTIs, pending the patient's genotype results, eg, dolutegravir 50 mg once daily + darunavir/cobicistat/TAF/FTC, 1 tablet once daily. If the patient's transmission partner has HIV with known viral resistance, an individual regimen should be tailored. Patients with comorbidities such as severe renal disease also may need individualized RAPID regimens.

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

During Pregnancy*, the following RAPID ART regimen options are recommended by HHS guidelines[21]:

- Dolutegravir 50 mg once daily + TDF/FTC 1 tablet once daily
- Raltegravir 400 mg twice daily + TDF/FTC 1 tablet once daily
- 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)

*TAF, bictegravir, and elvitegravir/cobicistat/TAF/FTC are not currently recommended in pregnancy.

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

- 2-ARV regimens, eg, dolutegravir/3TC (Dovato), dolutegravir/rilpivirine (Juluca), others (high risk of virologic failure if transmitted resistance is present)
- 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 (efavirenz, rilpivirine, doravirine, etravirine) (results of pre-treatment genotype will not be available and likelihood of transmitted NNRTI mutation is relatively high)

V.B.5. Prescription of Antiretroviral Medications

- Once an ART regimen has been selected, the health care provider creates an order (prescription) for a standard 30-day supply of the medication(s) and faxes it to the appropriate pharmacy (and records the order in the medical record).
- If medication (starter pack) is available, the clinician dispenses a 5-day supply the selected ART regimen. The patient is encouraged to take the first dose, witnessed, at that time.
- The patient is advised to go to the pharmacy directly to be sure his/her ADAP/insurance is active and that the pharmacy is able to supply a standard monthly supply. The patient is instructed to call the Ward 86 social worker immediately if there are problems with obtaining the medication (e.g., issues with insurance coverage). For patients who (with the help of our social workers) are applying for/establishing emergency access to insurance, we preferentially use pharmacies that are able to process the new insurance information rapidly.

- The patient is encouraged to take the first dose of ART that same day, if he/she has not already taken the first dose in clinic.

V.C. Follow-up RAPID visits

V.C.1. **Day 2:** The social worker 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.

V.C.2. **Day 5-10:** The patient has an appointment with a medical provider who provides follow-up on clinical care and laboratory tests that are ordered. At that visit, CD4+ T cell count, HIV RNA, and HLA-B5701 results are reviewed with the patient. Assessment is made for HIV symptoms or medication side effects. Treatment may be adjusted as appropriate. Care is then transitioned to a permanent provider, preferably the same one who saw the patient as the RAPID provider, for routine primary HIV care.

V.C.3. **Ongoing:** Enhanced 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, partners/family/friends disclosure and other barriers (e.g., 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 immediate follow-up for any missed appointment is done, including 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.

V.D. Persons who are not started on RAPID ART at the first clinic visit:

Any patients who are not started immediately on ART (whether by the provider's decision or the patient's decision) should be followed closely (eg, 1-2 weeks) and offered (or re-offered) ART at the earliest possible time. The RAPID team will work closely with any patients who elect not to start ART at the first clinic visit, to try to mitigate any barriers to ART initiation (see **V.D**., below).

VI. Rapid restart of ART for persons re-engaging in care

Persons with known HIV diagnoses who are not on ART (eg, a lapse of >4-8 weeks) who are returning to care may benefit from immediate ART restart (or initial start, if not previously treated). ART restart is particularly urgent in persons with CD4 counts <200 cells/mm³. We recommend rapid ART restart at the first clinic reengagement visit (for the willing patient), if the ART and HIV resistance history is known or can be predicted (based on previous resistance testing, HIV viral load while on ART, and adherence history) and if an appropriate ART regimen can be devised without information from current resistance test results.

Patients who are reengaging in care will receive enhanced clinical supports to optimize the likelihood of successful reengagement in care and adherence with ART, as is done for RAPID patients with new HIV diagnoses (see V.B and V.C, above).

ART for RAPID restart:

ART regimens should be selected on an individual basis, and in consultation with an expert HIV clinician. Resistance testing (generally a genotype) should be ordered, unless acquired resistance is unlikely (resistance testing may not be needed for patients who had viral suppression while last taking ART and who did not take ARVs intermittently before stopping). *ARVs can be modified, if indicated, when results are available.*

Common scenarios:

- The patient was taking a 1st or 2nd ART regimen and there is no suspected resistance: can start one of the recommended regimens (see V.B.4, above), or (unless contraindications) can restart the patient's previous regimen.
- Patient has known or suspected history of virologic failure with acquired ART resistance: select ART regimen based on suspected resistance mutations.
    - If there is concern for NRTI and/or NNRTI resistance, we typically start a boosted protease inhibitor + 2 NRTIs + an integrase inhibitor (eg, darunavir/cobicistat/TAF/FTC + dolutegravir).
    - If there is concern for NRTI and/or INSTI resistance, we may start a boosted protease inhibitor + 2 NRTIs + a 2nd generation NNRTI (if no history of treatment with an NNRTI) (eg, darunavir/cobicistat/TAF/FTC + doravirine).
    - If more extensive resistance may be present, we may start a multi-class regimen comprising a boosted darunavir + an integrase inhibitor +/- an NNRTI +/- NRTIs +/- other ARVs as indicated.

Contraindications to rapid restart include known or suspected untreated CNS OIs (as for newly-diagnosed patients, see V.B.4, above) and known or suspected complicated HIV resistance for which results resistance testing would be critical to deciding on ARVs.

For patients who do not restart immediately:
Re-engaging patients who are not immediately restarted on ART (or who decline RAPID restart) should be followed closely (eg, in 1-2 weeks) and restarted at the earliest appropriate time.

VII. 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, care plan is 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."

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 quantitation (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 in or 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).

VIII. METRICS AND OUTCOMES

VIII.A. Baseline information: The following information is recorded at the time of RAPID referral for tracking purposes:

VIII.A.1. Information on the referral:

- Locations of testing, disclosure, and referral
- Type of referral (on-campus inpatient/on-campus ambulatory clinic/off-campus clinic or private MD/testing site/jail or prison)
- New diagnosis/first initiation of care?

VIII.A.2. Prior engagement in medical care

- Insurance status
- Identified primary medical provider
- Identified HIV care or PrEP provider

VIII.A.3. Clinical characteristics:

- HIV stage on date of referral, as determined by testing history (acute/non-acute/AIDS)
- PrEP or vaccine use
- PEP use
- Presence of active opportunistic infection
- Presence of medical contraindications to immediate ART start (per medical provider)
- CD4+ T cell count and HIV RNA viral load at ART start date

VIII.A.4. Demographics

- Age
- Race/ethnicity
- Sex and gender

VIII.A.5. Presence of major mental health disorders

VIII.A.6. Active substance use

VIII.A.7. Housing status (stably or unstably-housed, homeless, residential treatment, incarcerated)

VIII.A.8. Immigration status

VIII.B. Outcomes: Outcomes data are collected to assess program performance and impact. They are summarized overall and according to specific patient categories above.

VIII.B.1. Time to specific milestones. RAPID tracks dates at which each patient achieves specific care milestones. This allows analysis of the time delays that occur at each step of the disclosure, referral, linkage. and engagement process. Dates for the following milestones are collected (they need not occur in order):

- First positive diagnostic test
- Test result disclosure
- Clinic contact/referral
- First kept clinic visit
- First clinic medical provider visit
- First kept clinic visits with:
  - Mental health provider if applicable
  - Substance use counselor if applicable
  - Clinic-assigned primary medical provider
- Number of missed appointments
- First ART prescription date (after diagnosis of infection)
- First viral load suppression <1500, <200 and <50
- Achievement of specific milestones
- Linkage to ward 86 (program definition) within 1, 3, 6 or 12 months
- Engagement in care (program definition) within 12 months
- Viral suppression <200 and <50 by 3, 6 and 12 months

IX. FAQs

- ***Should a patient wait to start ART until a relationship with a long-term HIV provider has been established?*** The RAPID program places greatest importance on the benefit to the patient of starting therapy immediately, receiving psychosocial support, and establishing a care plan. This means that for patients who do not have an established health care provider, the initial RAPID visit may be conducted by a provider for whom a long term relationship has not been established. This situation is similar to initiation of treatment for HIV or any disease that occurs in the hospital.

- ***Should providers wait for genotype results before ART initiation?*** For patients who are newly diagnosed with HIV, genotypes are essential for patient management. However, in most cases treatment can safely be started before the genotype result is back and then an ART regimen can be modified as needed. We perform a baseline genotype test followed by immediate ART initiation (without waiting for genotype results). We have selected certain ART regimens as preferred RAPID regimens for newly diagnosed patients, with the knowledge of current rates of transmitted drug resistance in San Francisco. However, individual ART regimens may need to be tailored for patients who have had recent PrEP or PEP exposure, or who had a transmission partner with drug-resistant HIV. For patients who are re-engaging in care and have complex ART histories, there may be circumstances where the provider chooses to wait for the genotype result before re-initiating therapy.
- ***Should providers wait for psycho-social stabilization before ART initiation?*** Patients with untreated mental health, active substance use, immigration issues, and/or marginal housing face considerable barriers to successful adherence and linkage to care. That being said, they deserve the highest standard of HIV care which includes immediate ART initiation. Often, a RAPID visit is the first time that a patient has come into contact with an integrated model of care which will address both their medical as well as their psycho-social needs. In addition, it is accepted that providers are generally not good at judging whether or not their patient will be adherent. With appropriate counseling and contingency management combined with careful selection of an ART regimen with less potential for resistance, all patients can have a chance at achieving viral suppression while working on stabilization to ensure long-term retention.

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