RAPID INITIATION OF ANTIRETROVIRAL THERAPY IN AN HIV CLINIC–"A Collaborative Effort ".

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LEARNING OBJECTIVES

*Understand the success of initiating Antiretroviral Therapy (ART) for People Living With HIV (PLWHIV).

* Define the terms- rapid initiation of ART, immediate ART, or same day ART initiation?

*Discuss how to implement a Rapid Stat ART in an HIV Clinic.

Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults

2020 Recommendations of the International Antiviral Society–USA Panel

Disclosure

No disclosures-

TERMS-

*Rapid ART- refers to initiation of ART as soon as possible (within 7 days) after HIV diagnosis.

*Immediate ART- refers to as starting ART on the day of diagnosis or at the first clinic visit.

*Same-day ART- can be interchange as immediate initiation of ART as well.

Benefits of Rapid or Immediate ART

*Increase care retention and population-level viral suppression.

The study from South Africa and Haiti showed that rapid initiation of ART was associated with higher rates of viral suppression.

Although a new study suggested that this favorable virological outcome may not be sustained beyond 12 months.

Success of Antiviral Therapy Initiation

*Increase in survival - leading to PLWHIV living a near-normal lifespan.

*Viremia control

*Increase number of PLWHIV of over age 50.

*Increase CD4 count - healthy immune system.

*Reduction in HIV - associated morbidity

*Prolonged duration of survival.

*Prevent HIV transmission - U=U

Class of ART

1- Single-Tablet Regimens-

2- Entry Inhibitors

3- Long-Acting Injectable regimens

4- Nucleoside Reverse Transcriptase Inhibitors-(nRTIs)

5- Non-Nucleoside Reverse Transcriptase Inhibitors.

6- Integrase Inhibitors (InSTI)

7- Nucleoside Reverse Transcriptase Translocation Inhibitors- NEW

8- Protease Inhibitors

9- Pharmacokinetic Enhancers-Boosters

Initiating and Implementing Rapid Stat ART- Policies and Procedure in an HIV Clinic- considerations

Implementing Rapid Stat ART- Policies and Procedure in an HIV Clinic- considerations

PATIENT CONSIDERATIONS

- Concomitant medications
- Comorbidities and coinfections (especially in older patients)
- Prior side effects
- Baseline resistance
- Inconsistent access to medication
- Access/coverage
- Adherence potential today and over the course of the patient's lifetime

TREATMENT CONSIDERATIONS

- Virologic efficacy
- Barrier to resistance
- Potential short- or long-term side effects
- Pill size/burden
- Dosing frequency
- Drug-drug interactions and potential short- or long-term toxicities
- Convenience
- Food effects
- Ability to use regardless of baseline viral load and CD4 count

Rapid Stat ART

WHO IS ELIGIBLE

NO previously treated HIV &

- Two positive HIV rapid tests -**or**-
- Positive 4th gen HIV test by blood -**or**-
- Detectable HIV RNA "viral load" -**and**-
- ≥ 18 years of age
- Medically & psychologically stable
- Substance use is NOT a contraindication to Rapid stat ART

(Those previously on PrEP are okay to start on rapid ART, if concerns around resistance to PrEP, consider combo regimens)

WHO IS NOT ELIGIBLE

- Previously treated HIV
- Known kidney failure
- Confirmed pregnancy
- Appears medically or psychologically unstable: specifically signs of TB or cryptococcal meningitis. Rapid ART should be delayed in any person with signs or symptoms suggestive of meningitis, including headache, nausea or vomiting, light sensitivity, and changes in mental status (clinical discretion).
- Less than 18 yrs of age.

Initial Recommended ART for PLWHIV

According to the International Antiviral Society (IAS) and the USA 2020 ART for treatment and prevention of HIV Infection in adults, the recommended initial ART regime for individual with HIV includes: optimal regimens with high rate of viral suppression, minimal toxicity, low pill burden, and few drug interactions.

The initial recommended regimens consist of 3 drugs-

2 Nucleoside Reverse Transcriptase Inhibitors (nRTIs) and

1 Integrase Inhibitors (InSTI)

OR

2-drug regimen of Dolutegravir/lamivudine.

A1a- evidence rating

Making the Right Choice- consideration

Comparing ART regimens-

Cost and health care access are important considerations including insurance coverage.

Other factors-

*High rates of viral suppression

*Minimal toxicity

*Low risk of drug interactions

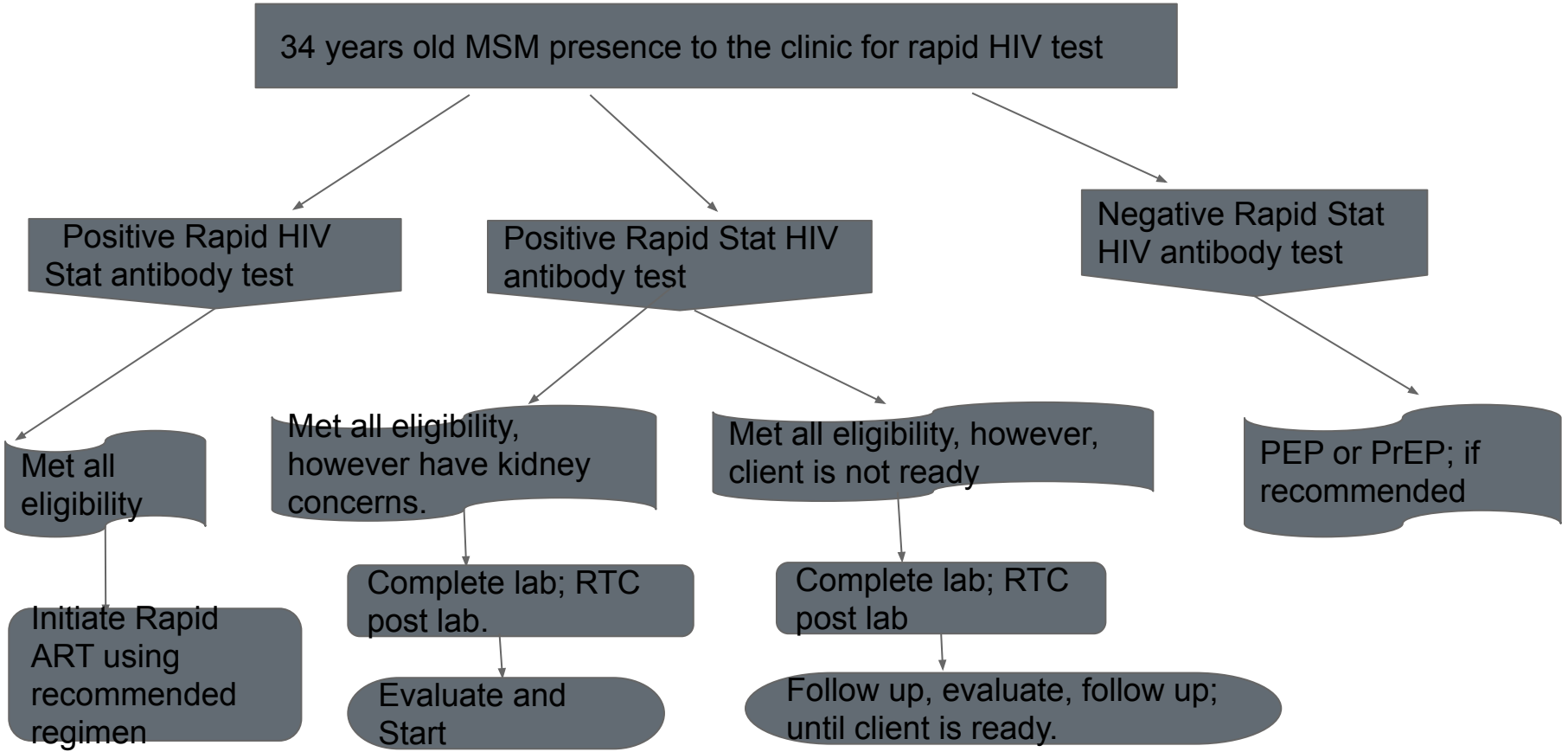
*High barrier to resistance

*Higher amount of pill burden eg Raltegravir

*Effects on renal

*Effects on the bone

* Weight gain


34 years old MSM presence to the clinic for rapid HIV test
Positive Rapid HIV Stat antibody test
Positive Rapid Stat HIV antibody test
Negative Rapid Stat HIV antibody test
Met all eligibility
Met all eligibility, however have kidney concerns.
Met all eligibility, however, client is not ready
PEP or PrEP; if recommended
Initiate Rapid ART using recommended regimen
Complete lab; RTC post lab.
Complete lab; RTC post lab
Evaluate and Start
Follow up, evaluate, follow up; until client is ready.

RAPID ART CARE DELIVERY METHODS.

DELIVERY METHODS

- ART starter pack (Clinic Provider and Clinic Nurse)
- Counseling (Clinic team and CHW)
- Discussion (Clinic Provider)
- Risk-reduction plan (Clinic team and CHW)
- Same-day appointments (Clinic Nurse and MCM)

*Insurance/ Ryan White / ADDP Application (MCM)

- Transportation (Clinic Secretary)

LAB REQUIREMENT.

- HIV-1/2 antigen/antibody assay (if not already done)
- HIV quantitative viral load
- Baseline HIV genotypic resistance profile (PR-RT resistance and integrase resistance)
- Baseline CD4 cell count
- HLA-B*5701
- Testing for hepatitis A, B, and C viruses
- Comprehensive metabolic panel (creatinine clearance, hepatic profile)
- Sexually transmitted infection screening: urine, pharyngeal, and/or rectal + syphilis screening
- Urinalysis

Pregnancy test for individuals of childbearing potential.

Provide Rapid Stat ART:	
Prescribe ONE of the below medication regimens. Prescriptions usually 2 weeks on “starter pack”	
Biktarvy (Tenofovir alafenamide/ emtricitabine/bictegravir (TAF 25 mg/FTC/BIC) **Dovato** (Dolutegravir/ Lamivudine (DTG 50mg/3TC300mg)	● ***Single-tablet***, taken once daily, w or w/o food ● should not be used in patients with a creatinine clearance (CrCl) <30 mL/min; re-evaluate after baseline laboratory testing results are available. ● Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after BIC; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.
Tivicay + Descovy (dolutegravir and Tenofovir alafenamide/Emtricitabine; DTG & TAF 25mg/FTC)	● ***Two pills***, taken together once a day, w/ or w/o food ● Should not be used in patients with CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available. ● Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after DTG; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.
Symtuza (darunavir/cobicistat/tenofovir alafenamide/emtricitabine TAF 10 mg/FTC/DRV/COBI)	● ***Single-tablet***, taken once a day with food ● should not be used in patients with a creatinine clearance (CrCl) <30 mL/min; re-evaluate after baseline laboratory testing results are available. ● Interaction with certain statins, inhaled steroids, oral steroids and other cyp3a4 inhibitor meds. (Avoid in polypharmacy) hiv-druginteractions.org ● May boost recreational substances

Limitations

* Patient readiness
* Insurance ????
* Housing
*Unemployment
* Food
*Other health conditions

Case study 1

START OR NO START

A 26 years old MSM walked into your clinic for HIV testing. Patient report exposure to HIV with new sexual partner. Denies any medical condition, however report treatment of syphilis a year before. Denies any allergies. No history of current medication. HIV rapid stat in the office was positive. Staff brought in patient to you for rapid stat or immediate ART.

What would you do?

- Patient Readiness including Mental health, Psychological/ psychosocial health, Support system etc)
- Others.

Case study 2

START OR NOT START

36 years old female arrived at your clinic for HIV testing. Patient report she is a sex walker, howeve, shared a needle with an HIV positive person a day before. Patient has a negative HIV result done a week ago from another HIV clinic. She is requesting HIV treatment because she is very certain about her current exposure. Her rapid stat test result was negative.

What would you do?

*Classic candidate for PEP and then PrEP.

*Pregnancy test

*Lab work

Case study 3

START OR NO START

48 years old AAM referred to your clinic for rapid stat HIV treatment by the CHW. Patient tested positive for HIV at the mobile unit a day before. According to report, Patient denies any medical conditions, no report of previous medication including PrEP. Patient denies allergies.

However, upon medical interview with the Provider, Patient report he was told by his medical provider that he had a kidney condition 2 years ago, although he stopped following with the provider and he is also unknown of the diagnosis.

What would you do?

Providers Role in initiating ART

* Provide HIV counseling:
  - HIV basics: viral loads, CD4, transmission, prevention, etc.
  - Risks of not treating HIV
  - Potential risks of starting HIV medicine today:
    - Immune reconstitution syndrome (rare, usually CD4<100). Create a plan should they feel worse: ER, Office Visit, TeleMedicine Visit, etc.
  - Side Effects - now rare, but if any side effects develop, create a plan to communicate with clinic. Some GI upset is normal, can take with food or before bedtime to reduce symptoms. A side effect free regimen should be possible for most patients..
  - Undetectable = Untransmittable: condoms should be used until undetectable
  - Partner notification
  - Adherence Counseling
    - Identify any barriers to adherence: housing, transportation, etc.
    - Connect with HIV community organization to help decrease barriers
  - Ever been on PrEP/PEP? If so, when?
- Assess interest in Rapid ART initiation.
  - If not interested.

Clinic Staff Roles

- Insurance:
  - Confirm medical insurance status
    - Uninsured → use starter packs/ samples + complete ADDP application.
    - Insured → Contact pharmacy to begin expedited prior authorization, or provide "starter pack" if available
- Additional Needs

If needed, refer to mental health, social work, HIV patient navigation, community case workers, substance use treatment, syringe exchange referral, etc.

Once Rapid ART initiated:

- *IF* rapid ART provider is not managing long-term follow up, schedule with new provider before Rapid ART prescription runs out (recommend 7 days)
  - Scheduled before pt leaves clinic during Rapid ART initiation
    - Visit can be in-person or TeleMedicine
- 48 hr check in by nursing, patient navigator, social worker, etc
  - Side Effects?
  - Psycho-social support needed?
  - Clarify any questions about Rapid ART/HIV

Adherence Supporting Strategies.

By
The Provider
Clinic Nurse
MCM
CHW

FOLLOW UP!!!

* Contact 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.

* Follow-up every 2 weeks until virological suppressed, and then monthly for 2 months and then every 3 months.

*Adjust ART /Change or adjust initial ART regime based on initial lab results and resistance testing

Care Continuum

1. Complete lab every 3 Months (4 labs in a year) if CD4 < 200, detectable viral load and abnormal lab results.

2. In-office consultation every 3 Months (4 visits in a year) if CD4 < 200, detectable viral load and abnormal lab results.

3. Complete lab every 6 Months (2 labs in a year) if CD4 >200, undetectable viral load and normal lab results.

4. In-office or Telehealth visit every 4 months (3 visits in a year) - if CD4> 200, undetectable viral load and normal lab results.

Recommendations

-Promote Team effort in the clinic setting

-Staff Education

-Patient Education

-Encourage Partner testing and treatment especially in the presence of STI exposures.

-Encourage Adherence

-Promote the term -U=U

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