Clinical Intro to Rapid Start

October 29, 2024

What is a learning collaborative?

- Place to ensure shared foundational knowledge
- Ask questions to understand the basics
- Share knowledge and experience
- Learn together! I'll share why I am here but there is a lot of shared knowledge in the room that we can all learn from.
- Hope this will be interactive as possible while also acknowledging I am here to share information and resources so it may fall more towards the didactic end of the continuum

JD Armstrong (he/him)

- Family Medicine with Obstetrics
- HIV Specialist
- Program Director for Sea Mar Salmon Creek CHC Rapid ART Program
- Based in Vancouver, WA

Learning Objectives

1. Promote treatment as prevention to support ending the HIV epidemic strategies in Oregon
2. Utilize the current antiretroviral therapy (ART) treatment guidelines to improve patient health outcomes
3. Identify opportunistic infections and apply prevention strategies to decrease the likelihood of adverse events
4. Discuss the benefits of rapid start antiretroviral therapy

Case Presentation

- Sammy, a 31 yo cis male, comes to your clinic for HIV exposure
- Cis male partner was recently diagnosed with HIV.
- Has anal receptive intercourse with partner, last encounter was 2 weeks ago
- Had negative POC HIV test yesterday
- No fevers, rash, sore throat, swollen glands
- Wants to start PEP or PrEP, whatever you recommend!

Case Presentation

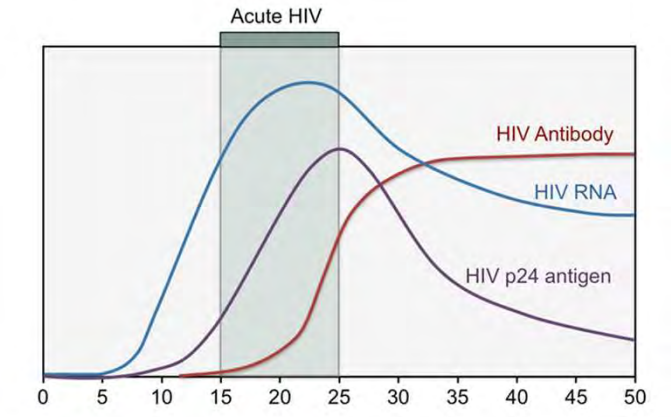
- What do you do?
  - Start PrEP?
  - Start PEP?
  - Do additional testing?

Example of messaging to patients= you are important, adherence is important, we're going to change the way we help you
Healthcare system is not built for this
New idea for non EHE jurisdictions

HIV Testing

Put registration link in the chat

HIV Testing



Credit: National HIV Curriculum

HIV Testing

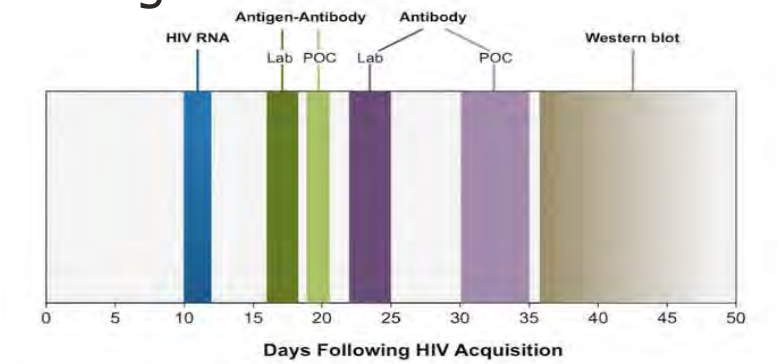


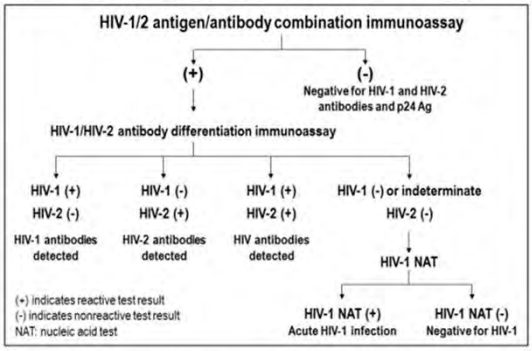
Figure 6 - Timing of Positivity for HIV Diagnostic Tests
This graphic illustrates the approximate time from HIV infection to test positivity.

Source: modified from Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Published June 27, 2013.

Credit: National HIV Curriculum

CDC Diagnosis of HIV

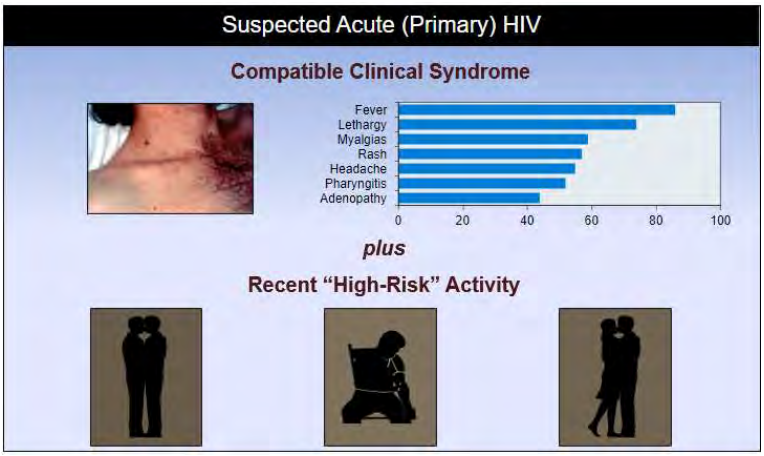
Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



1. Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody combination immunoassay* that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to test for established HIV-1 or HIV-2 infection and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial immunoassay.

Credit: CDC

Acute HIV



Credit: David Spach MWAETC lecture, "Diagnostic Testing"

Case Presentation

- Sammy gets two tests: HIV Antigen/Antibody Lab and HIV RNA quant w/ reflex to genotype today

Case Presentation

	2023 6/23/23 09:01
Time Mark	
HIV	
HIV Antigen/Antibody	REPE... !
HIV 2 ab	NEGATIVE
HIV 1 ab confirm	POSITIVE !
HIV QUANT	
HIV 1 RNA PCR Log 10	
HIV 1 RNA	

- What do you do with these results?
  - Wait for RNA to come back?
  - Wait for genotype testing to know resistance?
  - Start Medications?

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New idea for non EHE jurisdictions

CDC Diagnosis of HIV

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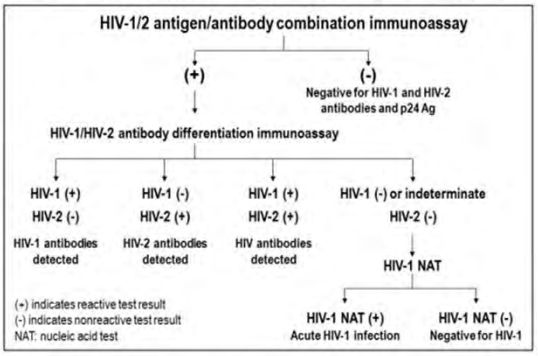

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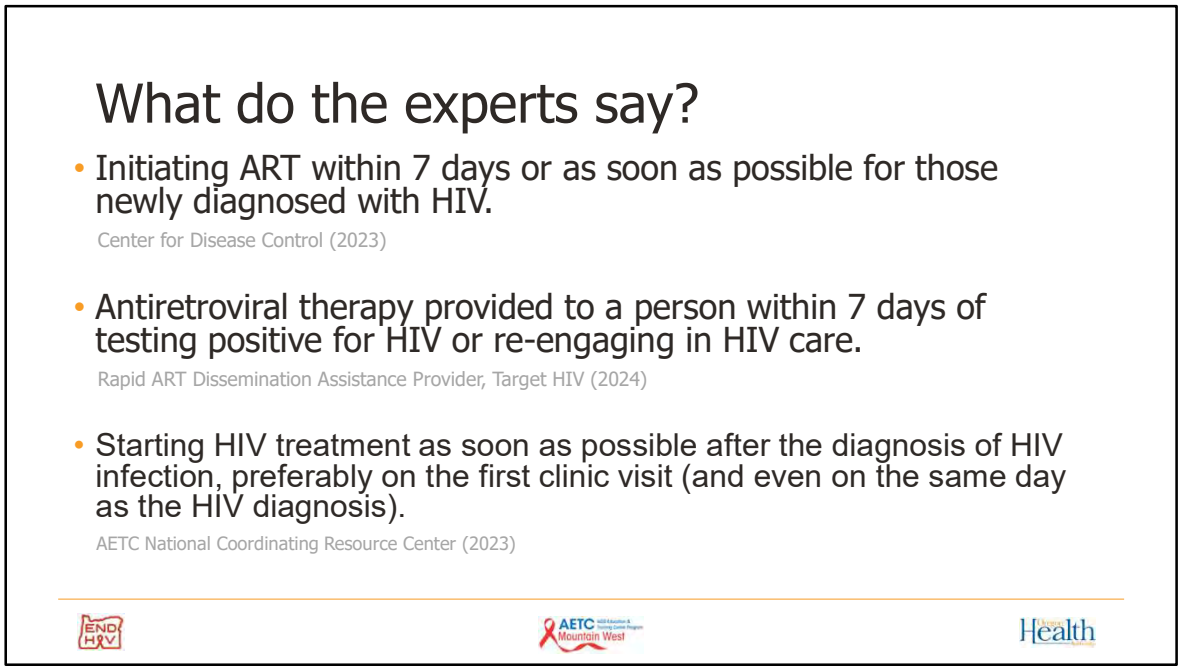
- Taken from CDC

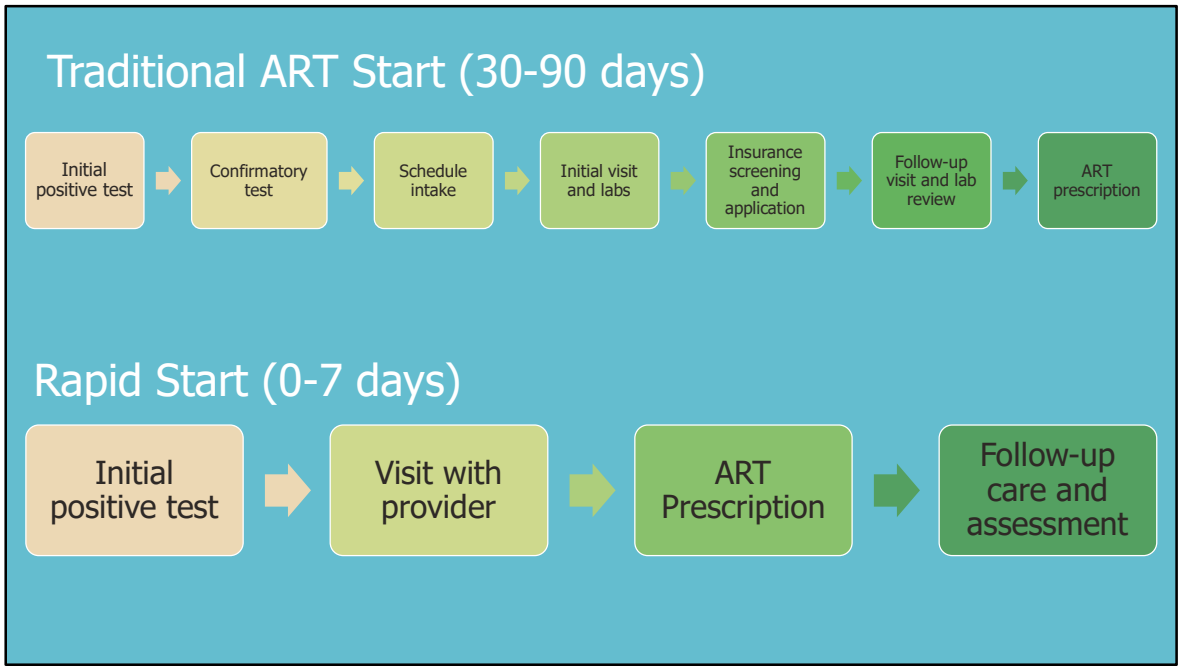
What is Rapid Start?

Also is known as “rapid ART,” “same-day ART,” and “treatment upon diagnosis.”



What similarities do you notice? What differences?
We're going to talk more about the importance of definitions a little later.

https://aidsetc.org/resource/rapid-immediate-art-initiation-restart-guide-clinicians
https://targethiv.org/rapid-art-dap
https://www.cdc.gov/hiv/effective-interventions/library/rapid-antiretroviral-therapy-toolkit/toolkit-rapid-art-toolkit.pdf



Example from the clinic I worked at

Benefits of Rapid Start

- Treatment is prevention
- Earlier viral suppression
- Low barrier, open access model of care
- Improves linkage and retention in care
- Supports early and ongoing adherence
- Now considered a Standard of Care

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What to Start?

Table 6a. Recommended Initial Regimens for Most People With HIV

Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use. Choice of ART during pregnancy should be guided by recommendations from the **Perinatal Guidelines.**

For people who do not have a history of using CAB-LA as PrEP, one of the following regimens is recommended[a]:

- BIC/TAF/FTC **(AI)**
- DTG plus (TAF or TDF)[b] plus (FTC or 3TC) **(AI)**
- DTG/3TC **(AI),** except for individuals with HIV RNA >500,000 copies/mL, HBV coinfection, or in whom ART is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available.

For people who have a history of CAB-LA use as PrEP, INSTI genotype resistance testing should be performed before starting ART. If ART is to be started before results of genotypic testing results, the following regimen is recommended:

- DRV/c[c] or DRV/r with (TAF or TDF)[b] plus (FTC or 3TC)—pending the results of the genotype test **(AIII)**

Exclusion Criteria and IRIS

- "Immune Reconstitution Inflammatory Syndrome"
- Per DHHS guidelines: "**Concerns regarding immune reconstitution inflammatory syndrome (IRIS):** For some OIs, such as cryptococcal and TB meningitis, immediate ART initiation may increase the risk of serious IRIS. A short delay before initiating ART may be warranted.[35-38] After ART initation, the patient should be closely monitored for signs and symptoms associated with IRIS."
  - Cryptococcal or TB meningitis are really the only exclusion criteria
- GFR <30: may used kidney dosed dolutegravir and lamivudine, may need consultation with specialist if more complex

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Case Presentation

- Davey, the clinic's HIV peer navigator, got the patient a ride to clinic for a same day Rapid Start visit when the lab resulted.
- Dr. Armstrong explained the diagnosis of HIV, HIV 101 (U=U, etc), and verified that the patient had no contraindications to Rapid Start
- Dr. Armstrong prescribed Bictegravir/Emtricitabine/Tenofovir alafenamide combo pill, one pill once a day
- The patient had additional labs drawn after the visit, and went to the clinic's pharmacy to pick up their medication and took their first dose in the exam room.
- The patient met with the Elizabeth, the clinic's integrated mental health therapist prior to discharge
- The patient was referred to a local NGO for case management services. Davey helped patient make an intake appointment prior to leaving clinic that day

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Initial Labs

Lab (17)	Diagnosis Codes
HIV ½ AG & AB w/RFLX (4th gen) *if not previously drawn by HSC*	B20
HIV-1 RNA Quant Real Time PCR, Plasma	B20
HIV DNA; Genotype (87901)	B20
HLA B5701	B20
Lymphocyte Subset 4: T cells/Abs CD4/CD8 Count w/Ratio	B20
CBC with Auto Diff	B20
CMP	B20
Hepatitis B Surface AG, EIA with Reflex Confirm	B20 + Z11.59
Hepatitis B Core AB Total	B20 + Z11.59
Hepatitis B Surface AB Quant	B20 + Z11.59
Hepatitis A AB, Total with Reflex to IGM	B20 + Z11.59
Hepatitis C AB w/rflx HCV RNA, QT, RT, PCR	B20 + Z11.59
RPR, Screen (MCHD), (LV5344)	B20 + Z11.3
Toxoplasma Antibody IGG	B20 + Z11.8
TB Quantiferon Gold (OSPHL) (LV3436)	B20 + Z11.1
Pregnancy test, Urine (if patient has a uterus)	B20

- Taken from HHSC Rapid ART protocol

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Case Presentation

- Over the next couple of days, Davey checked in daily with Sammy via text to offer support
- The RNA test resulted:

Time Mark	2023 6/23/23 09:01	6/23/23 09:02
HIV		
HIV Antigen/Antibody	REPE... !	
HIV 2 ab	NEGATIVE	
HIV 1 ab confirm	POSITIVE !	
HIV QUANT		
HIV 1 RNA PCR Log 10		6.24 ▲
HIV 1 RNA		1,730,000 ▲

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Case Presentation

- Sammy had a phone visit with Dr. Armstrong 7 days later to discuss additional lab results, check for signs of IRIS
- 1 month later the patient had another in person visit to recheck viral load:

Time Mark	2023 6/23/23 09:01	6/23/23 09:02	7/26/23 10:56
HIV			
HIV Antigen/Antibody	REPE... !		
HIV 2 ab	NEGATIVE		
HIV 1 ab confirm	POSITIVE !		
HIV QUANT			
HIV 1 RNA PCR Log 10		6.24 ▲	1.53 ▲
HIV 1 RNA		1,730,000 ▲	34 ▲

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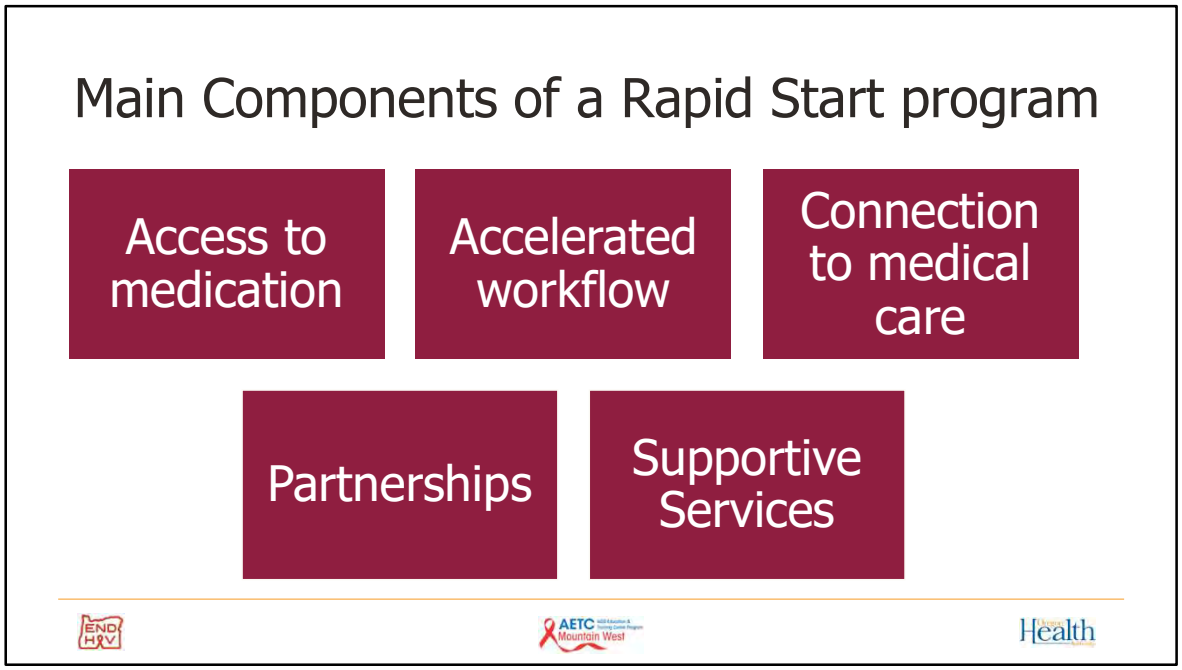
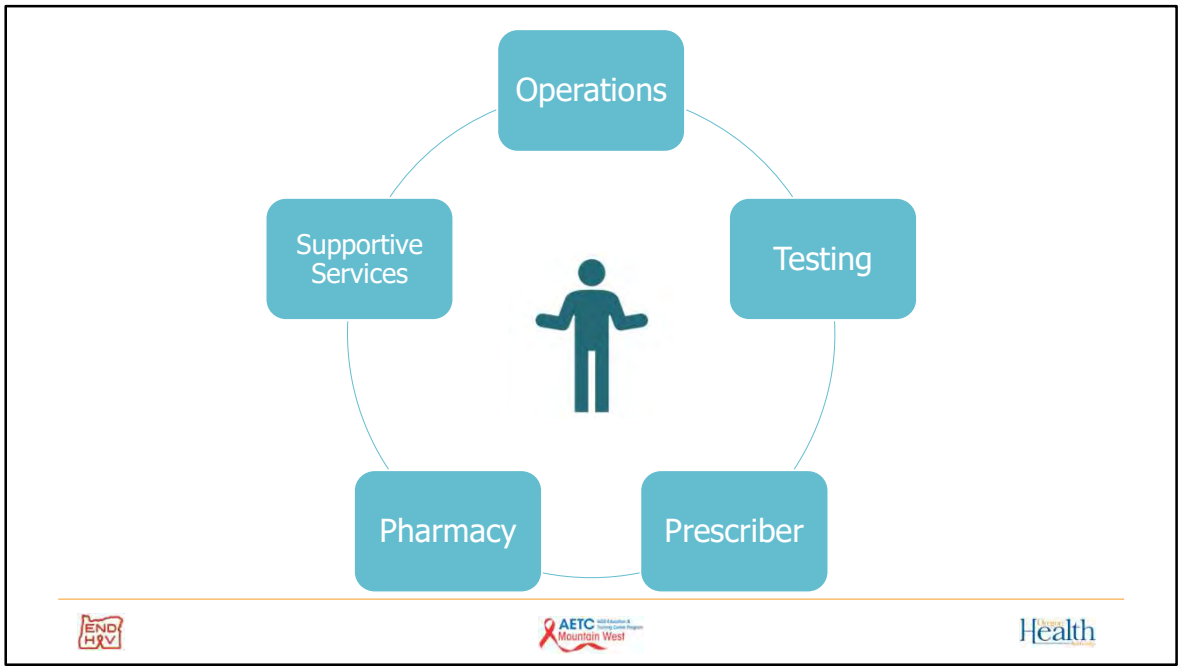
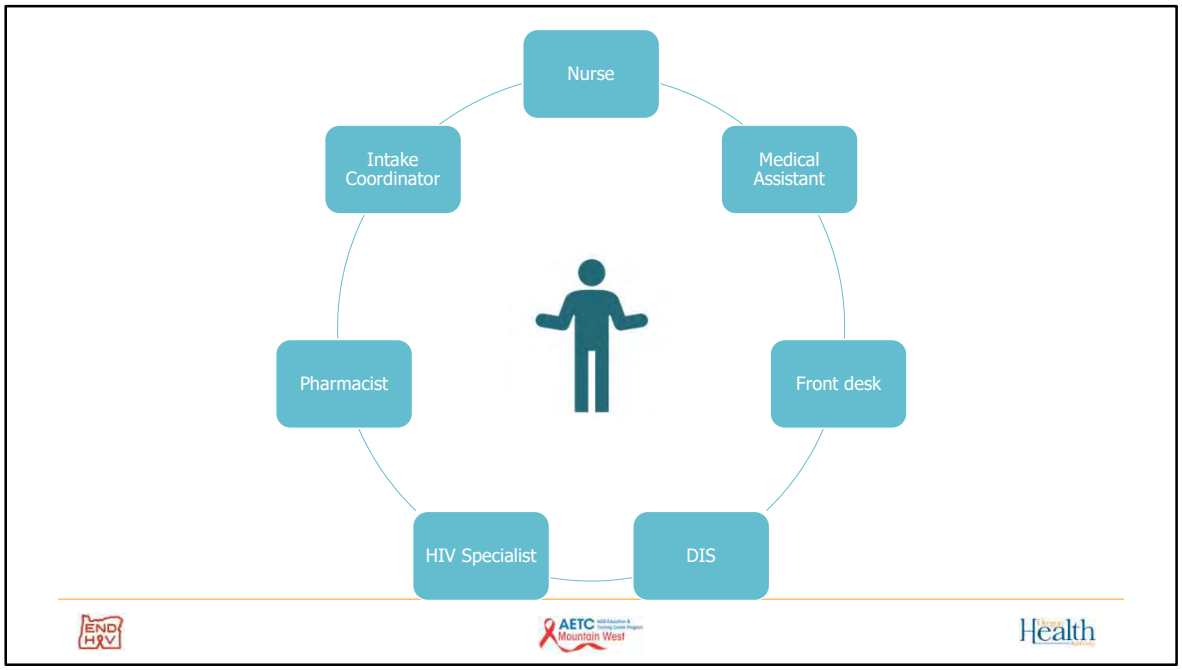
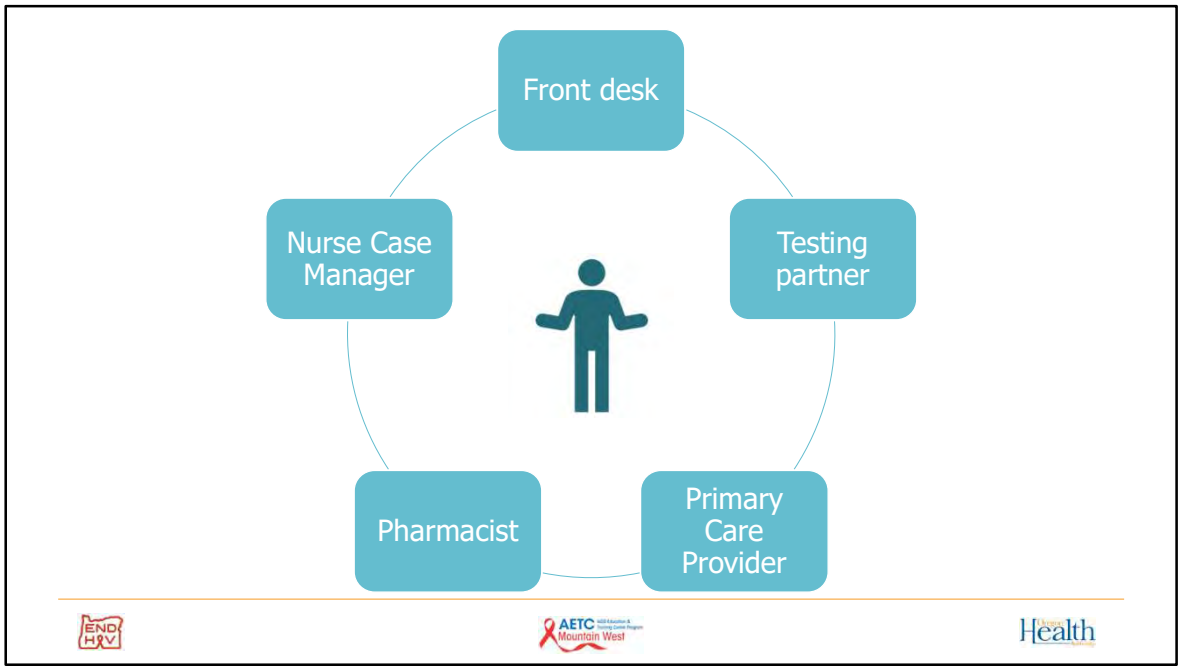
Where to Start?


Main Components of a Rapid Start program
Access to medication
Accelerated workflow
Connection to medical care
Partnerships
Supportive Services

Who Does What?


Operations
Testing
Prescriber
Pharmacy
Supportive Services


Nurse
Medical Assistant
Front desk
DIS
HIV Specialist
Pharmacist
Intake Coordinator


Front desk
Testing partner
Primary Care Provider
Pharmacist
Nurse Case Manager

Who's on your Team?

Who is your Champion?

Another role we will talk more about next session is your Rapid Start champion. This person is a strong supporter of Rapid Start, has some influence/power at your site to make changes or bust barriers, and is critical to securing the buy-in you will need to be successful.

Other Considerations

Also is known as “rapid ART,” “same-day ART,” and “treatment upon diagnosis.”

Rapid Re-Start

- Important to assess prior regimens, prior resistance testing if available
- ART can be effectively prescribed without resistance testing if it's unavailable
- Close monitoring still important, drug pressure will often bring out resistance in lab monitoring
- Important to assess and address reasons for being out of care. Rapid Re-Starts are often less successful if these are not addressed

False Positive Example

- Sarah, 43 yo cis female, was referred to our clinic for positive POC HIV test.
- She uses IV heroin and shares needles intermittently
- She had never been tested for HIV in the past
- What to do?

False Positive Example

- She had an HIV ag/ab test drawn in clinic and was started on

  Dolutegravir + Tenofovir D Fumarate/Emtricitabine (2 pills once per day)

	1 2/19/2022 1627
HIV	
HIV Antigen/Antibody	***REPEATEDLY REA... **** !
HIV 2 ab	***NEGATIVE ****
HIV 1 ab confirm	***NEGATIVE***

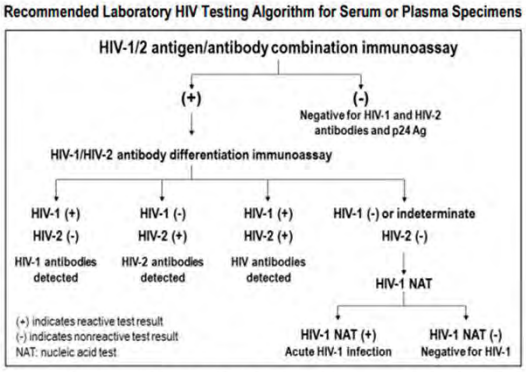
HIV 1 RNA, QL TMA NOT DETECTED

Comment:

HIV-1 RNA is not detected. No laboratory evidence of HIV infection. The HIV-1 RNA Qualitative Real Time PCR assay is recommended for use as part of a multi-test HIV-1/HIV-2 screening and diagnostic algorithm. This assay can also be used to resolve indeterminate HIV-1 antibody assay results, and to test for HIV-1 infection in patients less than 2 years old. When a 4th generation HIV multi-test screening and diagnostic algorithm is used: If the test results include a repeatedly reactive HIV-1/2 Antigen/ Antibody (4th generation) screen, followed by negative confirmatory tests for HIV-1 and 2 antibodies and HIV-1 RNA by PCR, the most likely interpretation is a non-specific ("biological false positive") reaction in the 4th generation screening assay. There is no current laboratory evidence of HIV infection. Repeat testing on a second specimen is not generally indicated but may be appropriate if there are known risk factors for recent HIV exposure.

REFERENCE RANGE: NOT DETECTED

CDC Diagnosis of HIV



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Credit: CDC

False Positive Example

- Dolutegravir was stopped, but Sarah was continued on Tenofovir D Fumarate/Emtricitabine for Pre-Exposure Prophylaxis