



## **Learnings from the Blue Door Clinic:**

**Accessing HIV care & resources for precariously & non-insured people living with HIV in Ontario**

# **HIV Primary Care 1: Basic Approach & Treatment Options**

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**Policy and Practice Leader**, Ontario HIV Treatment Network



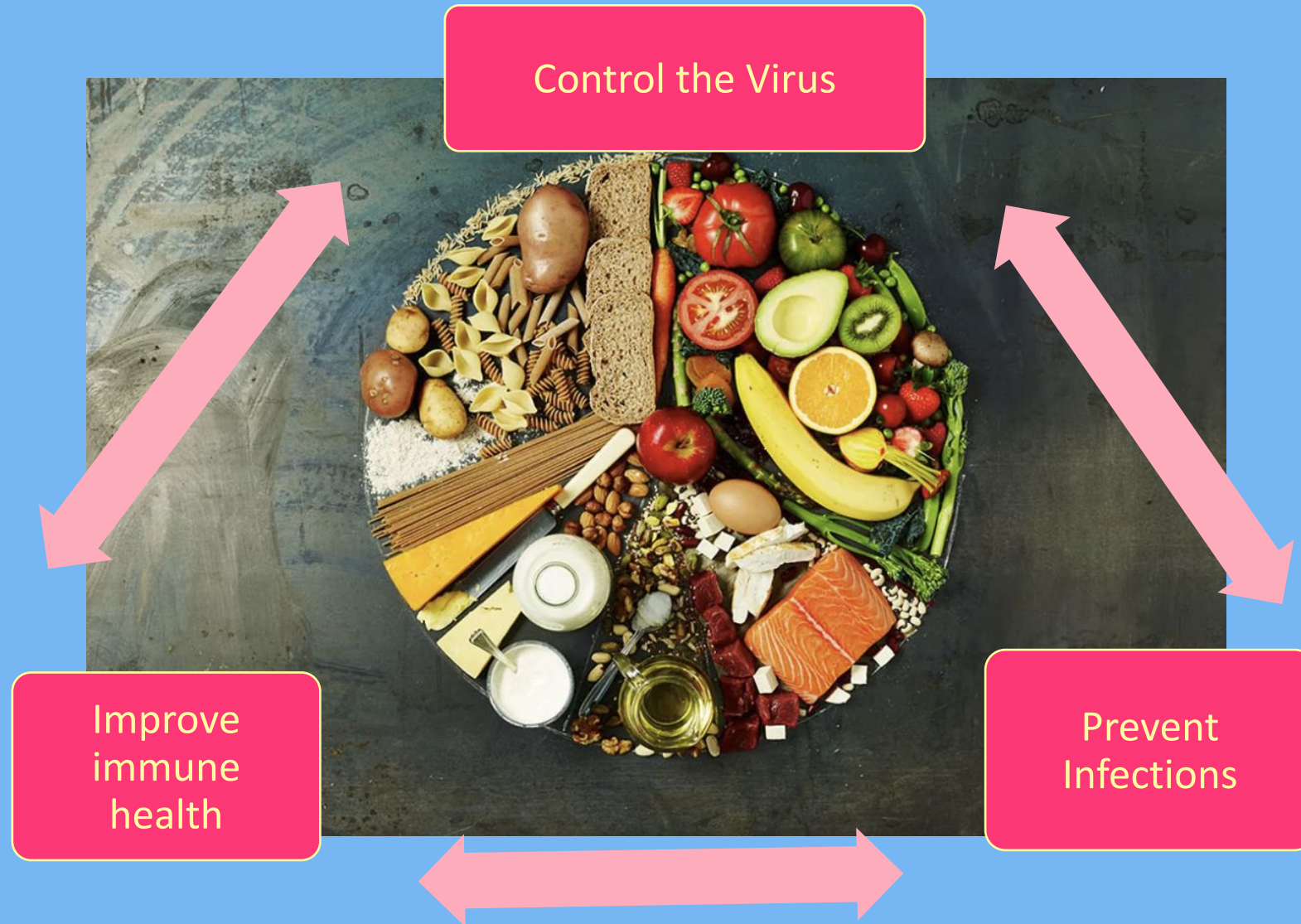
# Conflict of Interest

- Faculty/speaker's name: Alan Li, Gordon Liu
- Relationships with financial sponsors: No relation
- Any direct financial relationships, including receipt of honoraria: None
- Membership on advisory boards or speakers' bureaus: None applicable
- Patents for drugs or devices: None
- All other investments or relationships that could be seen by a reasonable, well-informed participant as having the potential to influence the content of the educational : None

# Learning Objectives for session

1. Overview of baseline approach to HIV primary care
2. Identify unique monitoring tests for HIV care
3. Discuss first line ARV treatment options
4. Review common side effects and drug drug interactions

# Key Components to HIV Treatment



# Key Components of HIV Care

1. Controlling the HIV Virus – anti-HIV treatments
2. Improving Immune System and Overall health  
(including access to social determinants, mental health support, nutritional and lifestyle issues)
3. Preventive Care (Vaccines, OI prevention, Co-morbidity management) – Next Week's Session

# Specific tests for assessing & monitoring HIV disease

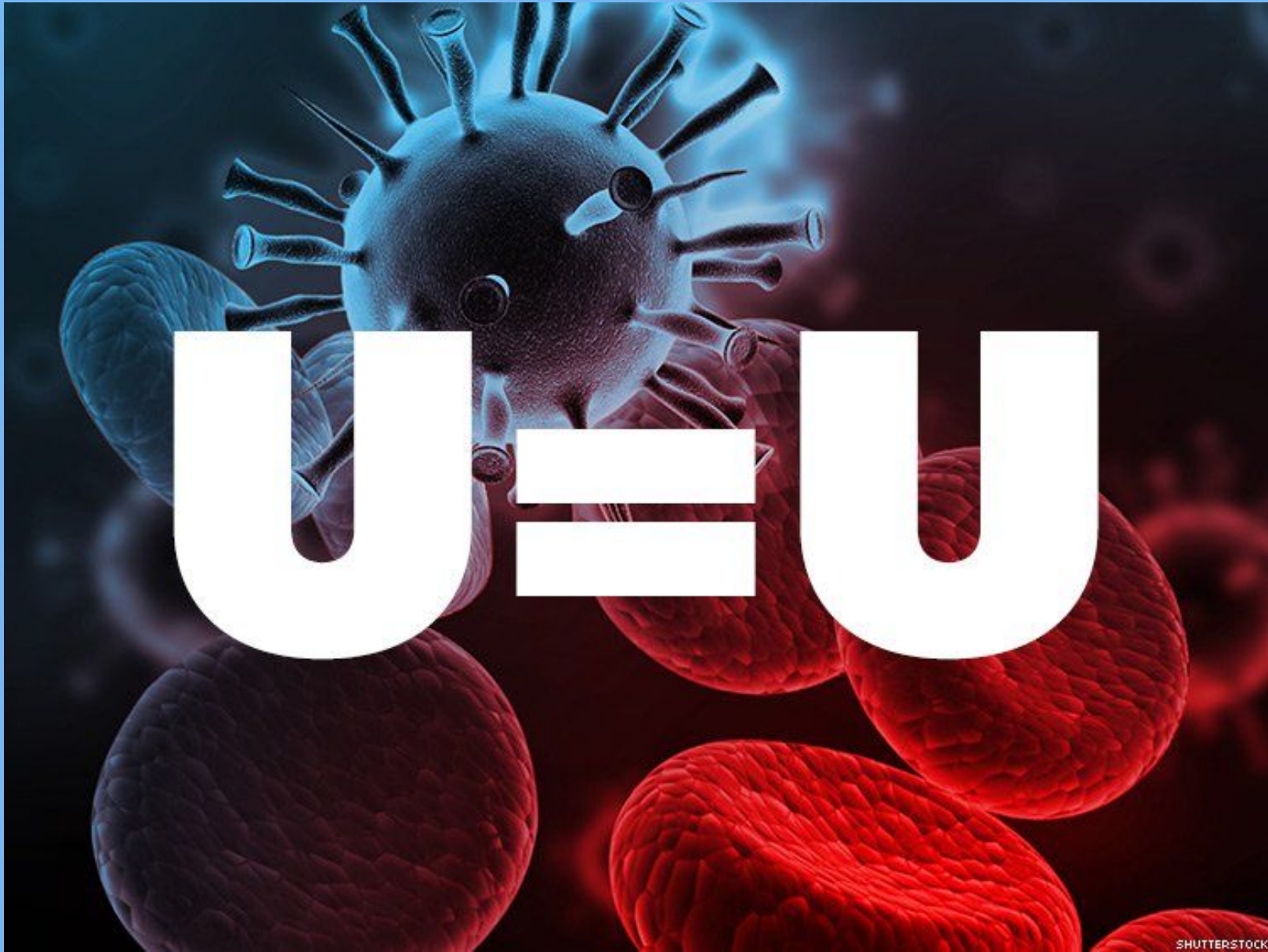
# CD4 count and Viral Load are the Hemoglobin A1C of HIV Care

- CD4 tells us about the state of the patient's immune function and his or her risk of opportunistic infection
- VL tells us whether the medications working

What is the goal viral load?

Undetectable





# Rating Scheme for Recommendations

Strength of Recommendation	Quality of Evidence for the Recommendation
A: Strong Recommendation for the statement	I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
B: Moderate recommendation for the statement	II: One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
C: Optional Recommendation for the statement	III: Expert Opinion

# How often should I check the CD4?

- CD4
  - At entry to care (AI)
  - As a rule, 3 months after initiation of ART (AIII)
  - During first 2 years every 3 to 6 months (BII)
  - After 2 years (CD4 >350 and <500) – 12 months (BII)
  - After 2 years (CD4 > 500) – Optional (CIII)
  - Change in clinical status – as clinically indicated (AIII)

<https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/458/plasma-hiv-1-rna--viral-load--and-cd4-count-monitoring>

# How often should I check the Viral Load?

- Viral Load
  - At entry to care (AIII)
  - 2 to 4 weeks after initiation of ART (AIII), then every 4 to 8 weeks until suppression (BIII)
  - Every 3 to 4 months during the first 2 years (AIII)
  - If viral load suppressed > 2 years every 6 months (AIII)
  - Change in clinical status – every 3 months (AIII)

<https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/458/plasma-hiv-1-rna--viral-load--and-cd4-count-monitoring>

# HLA B5701 Testing

- Recommend to screen for HLA B5701 before starting patients on Abacavir containing regimen to reduce the risk of hypersensitivity reaction (AI)\*
- HLA B5701 positive patients should not be prescribed Abacavir (AI) and positive status should be recorded as an Abacavir allergy in the patient's chart(AII)\*

<https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/7/hla-b--5701-screening>

# Resistance Testing

- Recommended in persons with HIV infection at entry of care, regardless of whether ART will be initiated immediately or deferred (AII) [Help guide choice of ART]
- Genotype drug-resistance testing in ARV-naïve persons involves testing for mutations in reverse transcriptase(RT) and protease (PR) genes. If transmitted INSTI resistance is a concern – may consider INSTI genotype (CIII)
- Recommended in patients with virologic failure with viral load > 1,000 (AI)\*
- Recommended when managing suboptimal viral load reduction (AII)

<https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/6/drug-resistance-testing>

# HIV Antiretroviral therapy

**Who should be started on ART?**



EVERYONE!!!!

# Rationale for starting ART ASAP:

- Reduce/control the reproduction of HIV
- Help preserve/rebuild the immune system (increase CD4 count)
- Decrease the chance of opportunistic infections
- Reduce HIV transmission

# DHHS Recommendations

- ART is recommended for all HIV-infected patients regardless of pre-treatment CD4 count. This is recommended **FOR ALL PATIENTS.** (AI)

<https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>

# WHO Guidelines

- ART should be initiated among all adults with HIV regardless of WHO clinical stage and at any CD4 cell count (strong recommendation, moderate-quality evidence)
  - As a priority, ART should be initiated among all adults with severe or advanced HIV clinical disease (WHO clinical Stage 3 or 4) and adults with CD4 count < 350 (strong recommendation, moderate-quality evidence)

<https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>

**What ARV are available to treat HIV?**

# Available ARV Drugs

## Commonly Prescribed HIV Medications


### Single-Tablet Regimens

<b>Atripla</b> (efavirenz/emtricitabine/ tenofovir disoproxil fumarate) 	<b>Biktarvy</b> (bictegravir/emtricitabine/ tenofovir alafenamide) 	<b>Complera</b> (rilpivirine/emtricitabine/ tenofovir disoproxil fumarate) 	<b>Delstrigo</b> (doravirine/lamivudine/ tenofovir disoproxil fumarate) 	<b>Dovato</b> (dolutegravir + lamivudine) 	<b>Genvoya</b> (elvitegravir/cobicistat/ emtricitabine/ tenofovir alafenamide) 	<b>Juluca</b> (dolutegravir/rilpivirine) 	<b>Odefsey</b> (emtricitabine/rilpivirine/ tenofovir alafenamide) 	<b>Stribild</b> (elvitegravir/cobicistat/ emtricitabine/tenofovir disoproxil fumarate) 	<b>Symfi/Symfi Lo</b> (efavirenz/lamivudine/ tenofovir disoproxil fumarate) 
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### Single-Tablet Regimens (cont.)

<b>Symtuza</b> (darunavir/cobicistat/ emtricitabine/tenofovir alafenamide) 	<b>Triumeq</b> (dolutegravir/abacavir/ lamivudine) 
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### Nucleoside/Nucleotide Analogs (NRTIs)

<b>Cimduo/Temixys</b> (lamivudine/tenofovir disoproxil fumarate) 	<b>Descovy</b> (emtricitabine/tenofovir alafenamide) 	<b>Emtriva</b> (emtricitabine or FTC) 	<b>Epivir</b> (lamivudine or 3TC) 	<b>Epzicom</b> (abacavir/lamivudine) 	<b>Truvada</b> (emtricitabine/tenofovir disoproxil fumarate) 	<b>Viread</b> (tenofovir disoproxil fumarate or TDF) 	<b>Ziagen</b> (abacavir or ABC) 
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### Protease Inhibitors (PIs)

<b>Evotaz</b> (atazanavir/cobicistat) 	<b>Prezcobix</b> (darunavir/cobicistat) 	<b>Prezista</b> (darunavir or DRV) 	<b>Reyataz</b> (atazanavir or ATV) 
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### Non-Nucleosides (NNRTIs)

<b>Edurant</b> (rilpivirine or RPV) 	<b>Intelence</b> (etravirine or ETV) 	<b>Pifeltro</b> (doravirine) 	<b>Sustiva</b> (efavirenz or EFV) 
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### Pre-Exposure Prophylaxis (PrEP)

<b>Truvada</b> (emtricitabine/tenofovir disoproxil fumarate) 	<b>Descovy</b> (emtricitabine/tenofovir alafenamide)   Not indicated for individuals at risk from receptive vaginal sex.
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### Integrase Inhibitors

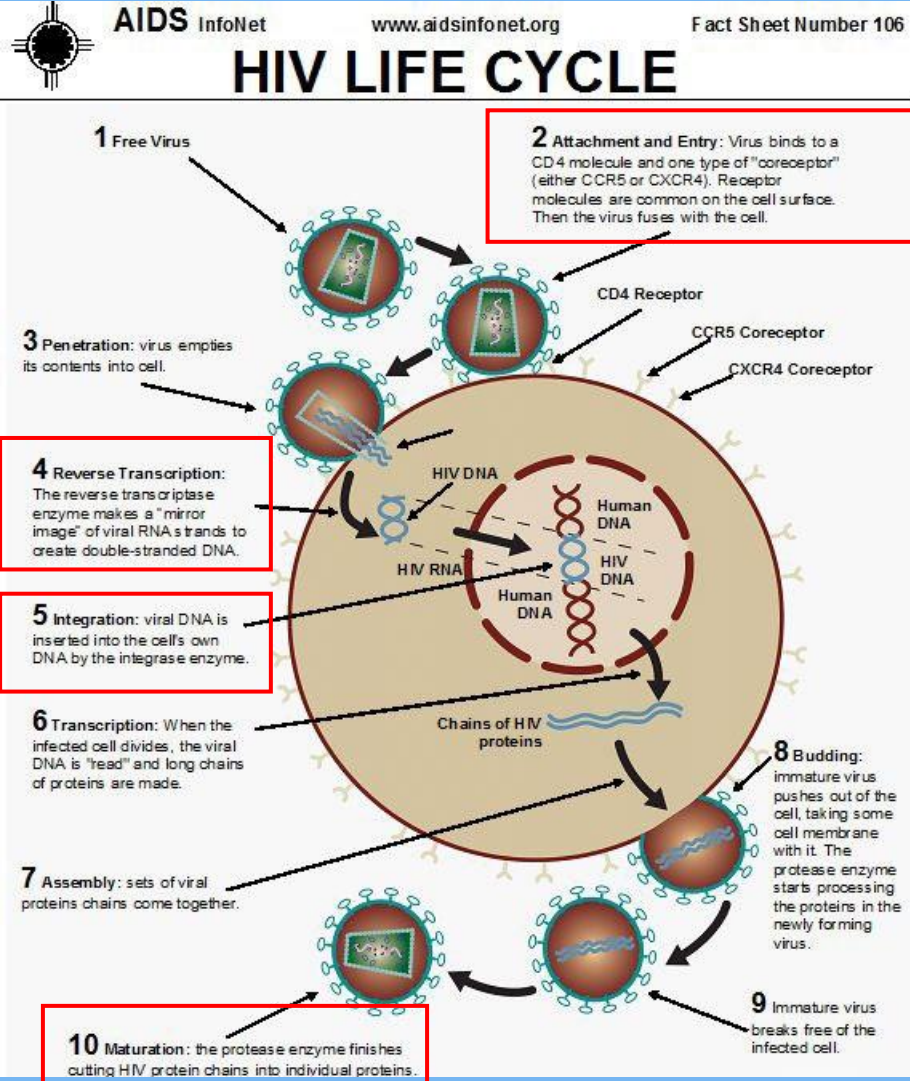
<b>Isentress</b> (raltegravir or RAL) 	<b>Tivicay</b> (dolutegravir or DTG) 
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### Pharmacokinetic Enhancers

<b>Norvir</b> (ritonavir or RTV) 	<b>Tybost</b> (cobicistat) 
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### Entry Inhibitors

<b>Selzentry</b> (maraviroc or MVC) 	<b>Trogarzo</b> (ibalizumab-uiyk)  (for injection)
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# Approved common ARV drugs classes

There are

- Entry inhibitors (EIs) – attack step 2
- Nucleoside reverse transcriptase inhibitors (Nukes) – attack step 4
- Non-nucleoside reverse transcriptase inhibitors (non-Nukes) – attack step 4
- Integrase inhibitors (IIs) – attack step 5
- Protease inhibitor (PIs) – attack step 10

**What ARV regimen to start?**

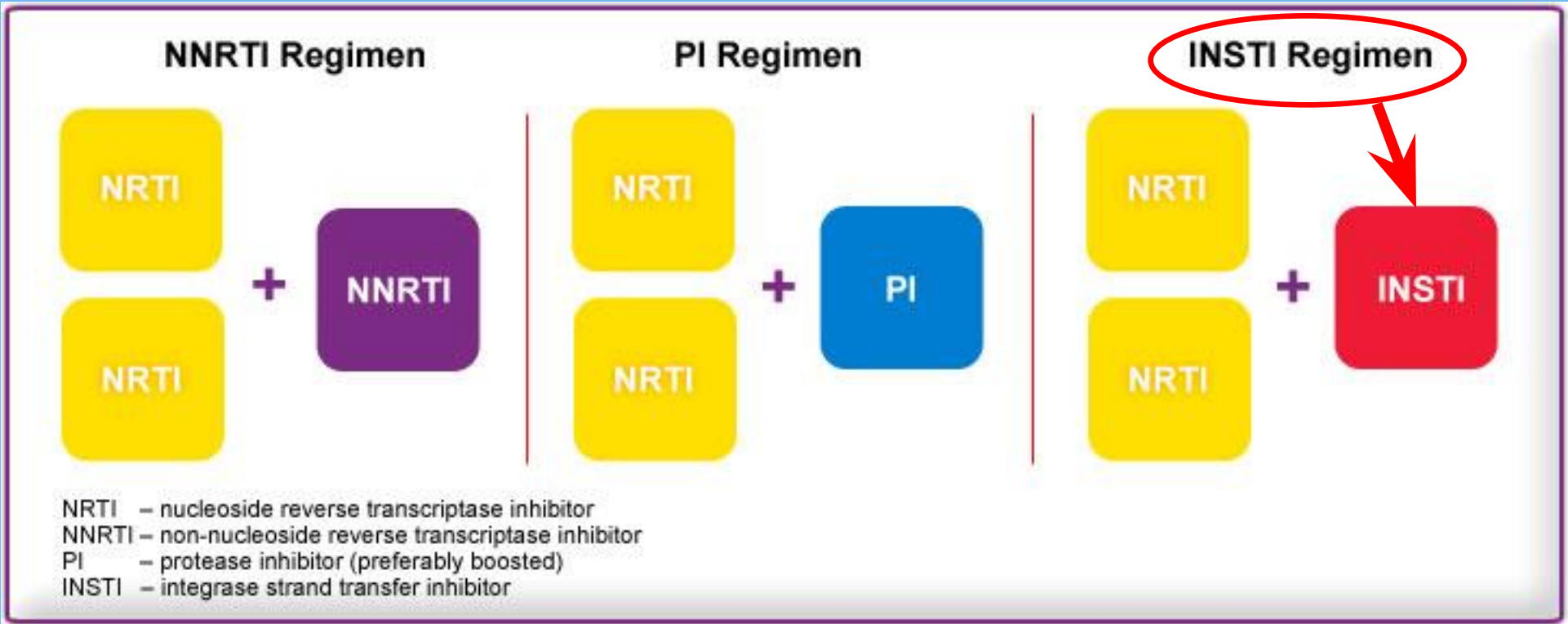


# Case #1 (Poll 1)

Patient is a 19 year old male with a PMHx of HIV presenting to the clinic today for initiation of ART. He has a history of asthma and is currently taking Advair 250/50 2 puffs twice a day. Patient contracted HIV from unprotected receptive anal intercourse. He denies any history of IVDU. CD4 of 180/12% T Cells, Viral load of 150,000, normal creatinine and LFTs.

What ART regimen would you initiate in this patient?

- a) Emtricitabine/TAF/Cobicistat/Elvitegravir (Genvoya)
- b) Emtricitabine/Tenofovir/Efavirenz (Atripla)
- c) Emtricitabine/TAF/Bictegravir (Biktarvy)
- d) Abacavir/Lamivudine/Dolutegravir (Triumeq)
- e) Emtricitabine/TAF/Rilpivirine (Odefsey)



# How to remember preferred regimens



Backbone

# How to remember preferred regimens



Backbone (2 NRTIs)–  
Emtricitabine + Tenofovir Disoproxil  
Aka **Truvada**

# Tenofovir Alafenamide (TAF)

- Pro drug of Tenofovir disoproxil
- Approved for treatment of HIV Infection and Chronic Hepatitis B infection
- Greater antiviral activity, better distribution into lymphoid tissues
- Less renal toxicity
- Less effect on bone mineral density

<https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>

# How to remember preferred regimens



Backbone (2 NRTIs)–  
Emtricitabine + TAF  
AKA Descovy

# How to remember preferred regimens



Backbone (2 NRTIs)–  
Abacavir + Lamivudine  
Aka **Kivexa**

# How to remember preferred regimens



Backbone (2 NRTIs)–  
Emtricitabine + Tenofovir (disoproxil)  
(Truvada)

OR



Backbone (2 NRTIs)–  
Emtricitabine + TAF  
(Descovy)

+



INSTI –  
Raltegravir



# How to remember preferred regimens



+



Backbone (2 NRTIs)–  
Emtricitabine + TAF  
(Descovy)

INSTI –  
Bictegravir

Also known as a 1 pill once a day: **Biktarvy**

# How to remember preferred regimens



Backbone (2 NRTIs)–  
Emtricitabine + Tenofovir (disoproxil)  
(Truvada)

OR

+



Backbone (2 NRTIs)–  
Emtricitabine + TAF  
(Descovy)



INSTI –  
Dolutegravir

# How to remember preferred regimens



+



Backbone (2 NRTIs)–  
Abacavir + Lamivudine  
(Kivexa)

INSTI –  
Dolutegravir

Also known as a 1 pill once a day: **Triumeq**

# How to remember preferred regimens



1 NRTI –  
Lamivudine

+



INSTI –  
Dolutegravir

Also known as a 1 pill once a day: **Dovato\***

# Prior to starting Dovato

- Viral load < 500,000
- No co-infection with Hepatitis B
- Prior to getting resistance testing

<https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>

# Alternative Regimens

# Alternative Regimen



Backbone (2 NRTIs)–  
Emtricitabine +  
Tenofovir (disoproxil)  
(Truvada)

+



INSTI –  
Elvitegravir

+



Cobicistat

Also known as a 1 pill once a day: **Stribild**



# Alternative Regimen



+



+



Backbone (2 NRTIs)–  
Emtricitabine + TAF  
(Descovy)

INSTI –  
Elvitegravir

Cobicistat

Also known as a 1 pill once a day: **Genvoya**



# Alternative Regimen



Backbone (2 NRTIs)–  
Emtricitabine + Tenofovir (disoproxil)  
(Truvada)

OR

+



+



Ritonavir

PI –  
Darunavir



Backbone (2 NRTIs)–  
Emtricitabine + TAF  
(Descovy)

# Alternative Regimen



Backbone (2 NRTIs)–  
Emtricitabine + TAF  
(Descovy)

+



PI –  
Darunavir

+



Cobicistat

Also known as a 1 pill once a day: **Symtuza**

# Alternative Regimen



+



Backbone (2 NRTIs)–  
Emtricitabine + Tenofovir (disoproxil)  
(Truvada)

NNRTI –  
Rilpivirine

Also known as a 1 pill once a day: Complera

# Alternative Regimen



+



Backbone (2 NRTIs)–  
Emtricitabine + TAF  
(Descovy)

NNRTI –  
Rilpivirine

Also known as a 1 pill once a day: Odefsey

# Why is Complera/Odefsey an Alternative Regimen?

- CD4 > 200
- Only for patient with pre-treatment viral load < 100,000
- Needs acid to absorb (contraindicated with PPIs), caution with H2 blockers
- Needs to be taken with food (at least 390 calories)
- Low barrier of resistance
- Transmitted resistance

<https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>

# Why is Atripla (emtricitabine/tenofovir/efavirenz) no longer a preferred regimen?

- Concerns about tolerability
- High Rate of CNS toxicities
- Increase risk for suicidality
- Transmitted resistance
- Dyslipidemia
- Rash

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# Monitoring Labs and Adverse Effects

Laboratory Test	Entry into care	2 to 8 weeks after ART initiation	Every 3 to 6 months	Every 6 months	Every 12 months	Clinically Indicated
Complete Metabolic Panel	x	x	x			x
CBC with Diff	x			x		x
Lipid Profile	x			x If abnormal	x If normal	x
Fasting Glucose or A1c	x		x If abnormal		x If normal	x
Urine Analysis	x			x TDF/TAF		x
Hepatitis C Screening	x				x For at risk patients	x

# Adverse Effects

- NRTI
  - Abacavir
    - Hypersensitivity (HLA B5701)
    - Increase in CV events\*
  - Tenofovir
    - Nephrotoxicity - proximal tubular cell injury (Fanconi Syndrome)
    - Decrease bone mineral density (increase risk for osteoporosis)

# Adverse Effects

- NNRTI
  - Efavirenz
    - CNS toxicity
    - Vivid Dreams
    - Can worsen mental health
    - Dyslipidemia
    - Rash
    - Drug Drug Interactions
- PI
  - Darunavir/Ritonavir
    - CYP 450, Drug Drug Interactions

# Adverse Effects

- INSTI
  - Elvitegravir/Cobicistat
    - CYP 450, Drug Drug Interactions
  - Dolutegravir
    - Lactic Acidosis with dose dependent metformin
    - Increase risk for NTD defects\*
  - Dolutegravir/Bictegravir
    - Potential weight gain\*

<https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>

<https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>



# Dolutegravir

- Based on recent data obtained from Tsepamo study (Botswana Aug 2014 – Aug 2016) : Increased incidence of NTD 4/426 compared to NNRTI therapy.
- WHO guidelines:
  - DTG can be used in women and adolescents of child bearing potential as long as the patients have informed choices and they use consistent and reliable contraception

# Dolutegravir

- Document a negative pregnancy test prior to initiating DTG.
- Provide counseling about the potential risk of NTDs when DTG is taken near the time of conception.
  - NTDs occur within the first 28 days after conception or 6 weeks from the last menstrual period.
- Discuss the risks/benefits with those who are pregnant, taking DTG, and within 8 weeks from last menstrual period
  - If there are other good options to replace DTG, then switching to a non-DTG ART regimen is recommended

# Dolutegravir

- Those who are pregnant and 8 weeks or greater from last menstrual period may initiate or continue DTG-based regimens.
  - Discontinuing DTG-based regimens is unlikely to confer any benefits after the neural tube has formed
  - ARV changes during pregnancy could increase the risk of viremia and transmission of HIV to the infant.
- Not clear if DTG is the only integrase strand transfer inhibitor (INSTI) with the potential to cause NTDs (i.e., a class effect).
  - No reports of NTDs associated with taking DTG or other INSTIs near the time of conception in the prospective portion of the U.S. Antiretroviral Pregnancy Registry
    - Registry is based on voluntary reporting; number of reported INSTI exposures near the time of conception is relatively small.



## Case #2 (Poll #2)

A 52 year old female with a PMHx of HIV, GERD, HLD, HTN, Asthma, DM presents to the clinic to establish care. She is currently taking Emtricitabine/TAF/Cobicstat/Elvitegravir (Genvoya), Omeprazole 40mg PO daily, Atorvastatin 10mg PO daily, Lisinopril 40mg PO daily, Flovent 110mcg 2 puffs daily, Albuterol as needed and Metformin 1000mg PO BID. Which one of the following medications are CONTRAINDICTED with the patient's current ARV regimen?

- a) Omeprazole
- b) Atorvastatin
- c) Lisinopril
- d) Flovent
- e) Metformin

## Case #2

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- a) Omeprazole
- b) Atorvastatin
- c) Lisinopril
- d) Flovent**
- e) Metformin

# Common Drug Drug Interactions: Corticosteroids

Budesonide (Pulmicort, Symbicort)

Fluticasone (Flovent, Flonase, Advair)

Methyl-prednisolone injection

Triamcinolone injection

Prednisone - systemic

Dexamethasone – systemic

All protease inhibitors and  
elvitegravir (boosted with cobicistat) [Stribild or Genvoya]

Consider Beclomethasone (Qvar or QNASL)

## CAUTION!

## Case #3 (Poll #3)

A 47 year old AAF with a PMHx of HIV, GERD , HLD, HTN, DM presents to the clinic to establish care. She is currently taking Triumeq (Abacavir/Lamivudine/Dolutegravir), Omeprazole 40mg PO daily, Atorvastatin 40mg PO daily, Lisinopril 40mg PO daily, HCTZ 25mg PO daily and Metformin 1000mg PO BID. Which one of the following medications are CONTRAINDICTED with the patient's current ARV regimen?

- a) Omeprazole
- b) Atorvastatin
- c) Lisinopril
- d) HCTZ
- e) Metformin

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- a) Omeprazole
- b) Atorvastatin
- c) Lisinopril
- d) HCTZ
- e) **Metformin**

# Common Drug Drug Interactions:

Maximum dose of metformin with the use of dolutegravir is 1000mg PO daily. Dolutegravir will increase the concentration of metformin and can cause lactic acidosis and renal impairment

**CAUTION!**

**Thank you !**

**Questions?**

**Coming up Next:**

**Access to care for precariously insured PHAs**

**Next Week:**

**Preventive Care, Vaccines, COVID updates & Supportive  
Resources**