2020-04-13

Overview & History of HIV: Epidemiology, ART, 1st line treatment & monitoring

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Lawrence Family Medicine Residency

Overview & History of HIV: Epidemiology, ART, 1st line treatment & monitoring

SESSION 1

HIV/HBV DIDACTIC SERIES

APRIL 13, 2020

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FAMILY MEDICINE RESIDENT

LAWRENCE FAMILY MEDICINE RESIDENCY

LAWRENCE, MA, USA

Hello, from a distance.
Thanks SARS-CoV-2…

Please be in contact ☺

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Flipped classroom format

Virtual interaction is hard, but let's TRY!

Your preparation will make all the difference for your learning & the group experience

- Spend 20 minutes prepping prior to each session

Please "interrupt" – this is not a lecture!

I'll ask questions and you'll answer some post-session assessments

- When I don't know an answer I'll say so, and look it up after the session
  - (we can also poll the group for wisdom)
- This is NOT a test
- I don't grade you ☺
- Goal: to gauge where we are and how we can be better going forward for our patients

Overall Outline

5 session, 2 hours each

1. HIV & ART overview
   - History, Epidemiology, transmission/risk, staging
   - Med Class Overview, ART initiation
2. Treatment monitoring & Failure
   - 2nd & 3rd line ART, toxicity/complications, monitoring
   - Prevention
3. Opportunistic Infections & Hepatitis B
   - OIs, ART considerations, Prophylaxis
   - HBV dx, tx, surveillance, & HIV-HBV co-infection
4. Special Populations:
   - Pregnancy, antenatal & intrapartum, infant care & pediatric
5. HIV/HBV Case-Based Application
   1. Case Application
   2. Wrap-up/review, miscellaneous items

Source Materials

Liberia Integrated Guidelines for Prevention, Testing, Care, and Treatment of HIV and AIDS
- 5th edition, August 2019

WHO HIV Diagnosis, Treatment, and Opportunistic Infection Guidelines
- 2016, 2018 ART update
- https://www.who.int/publications/guidelines/hiv_aids/en/

WHO Hepatitis B treatment guidelines (2015)
- https://www.who.int/hepatitis/publications/hepatitis-b-guidelines/en/

Reference Materials

Department of Health & Human Services. HIV Guidelines. USA. https://aidsinfo.nih.gov/guidelines

Fundamentals of HIV Medicine. American Academy of HIV Medicine. Oxford University Press. 2017 Edition.

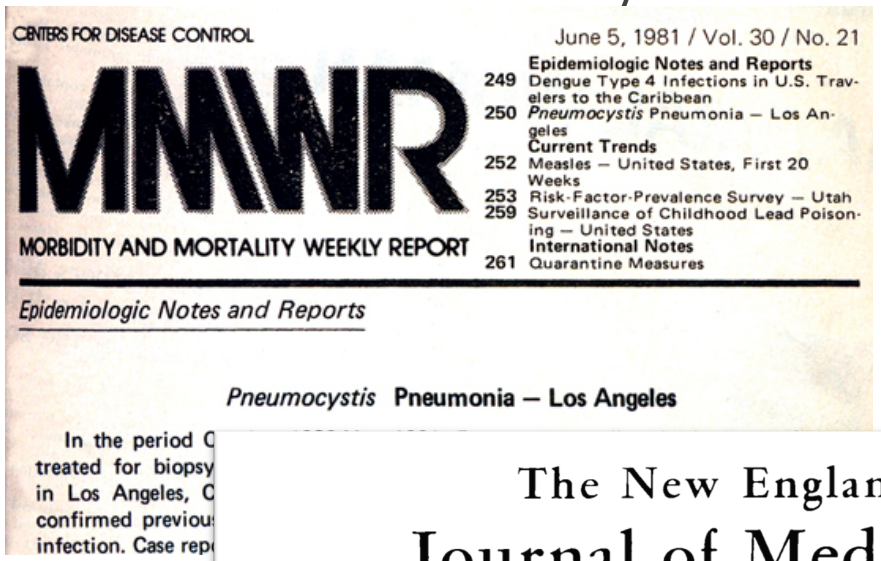
National HIV Curriculum. University of Washington & CDC. USA. https://www.hiv.uw.edu/

HIV History

1981

1983 - 1984

AIDS identified as a clinical syndrome of immunodeficiency



CENTERS FOR DISEASE CONTROL

June 5, 1981 / Vol. 30 / No. 21

MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

Epidemiologic Notes and Reports

249 Dengue Type 4 Infections in U.S. Travelers to the Caribbean

250 *Pneumocystis* Pneumonia — Los Angeles

Current Trends

252 Measles — United States, First 20 Weeks

253 Risk-Factor-Prevalence Survey — Utah

259 Surveillance of Childhood Lead Poisoning — United States

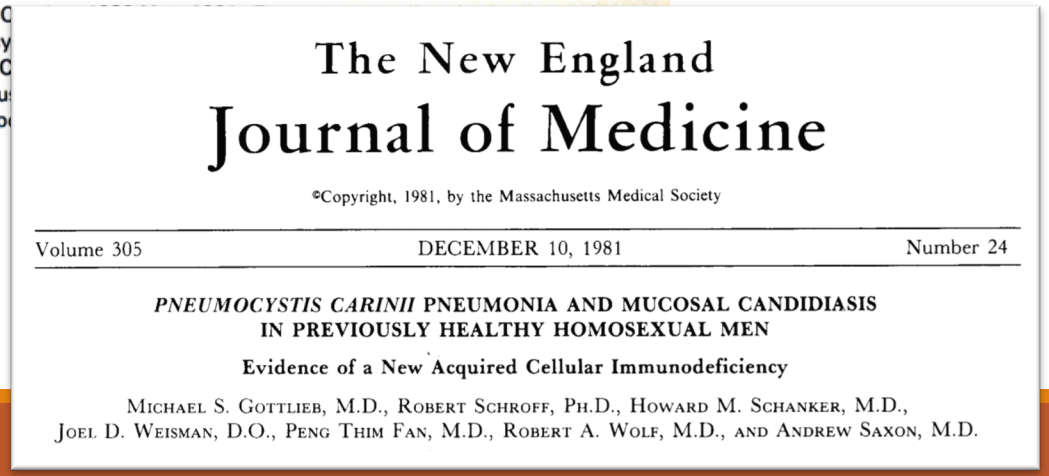
International Notes

261 Quarantine Measures

Epidemiologic Notes and Reports

Pneumocystis **Pneumonia — Los Angeles**

In the period C
treated for biopsy
in Los Angeles, C
confirmed previou
infection. Case rep



The New England

Journal of Medicine

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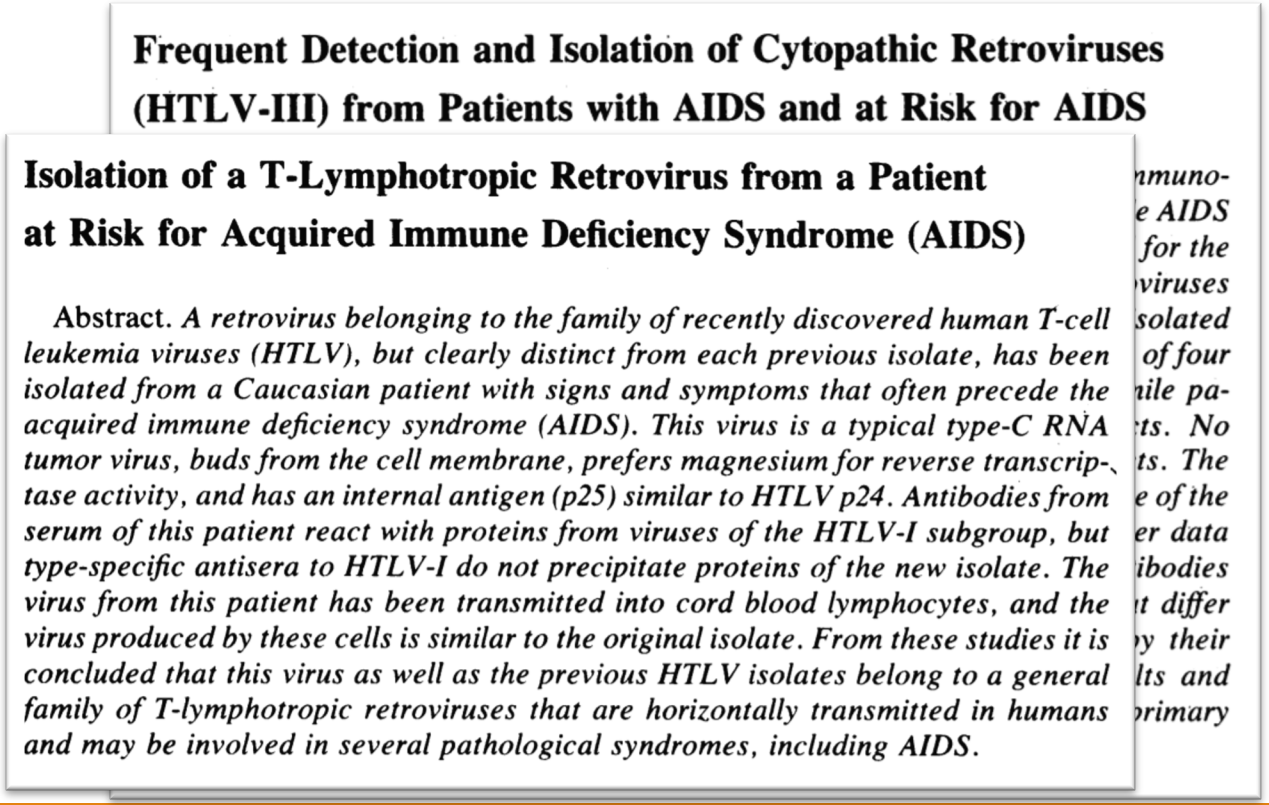
Volume 305 DECEMBER 10, 1981 Number 24

PNEUMOCYSTIS CARINII PNEUMONIA AND MUCOSAL CANDIDIASIS IN PREVIOUSLY HEALTHY HOMOSEXUAL MEN

Evidence of a New Acquired Cellular Immunodeficiency

MICHAEL S. GOTTLIEB, M.D., ROBERT SCHROFF, PH.D., HOWARD M. SCHANKER, M.D., JOEL D. WEISMAN, D.O., PENG THIM FAN, M.D., ROBERT A. WOLF, M.D., AND ANDREW SAXON, M.D.

HIV-1 identified as the causative agent of AIDS



Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and at Risk for AIDS

Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)

Abstract. *A retrovirus belonging to the family of recently discovered human T-cell leukemia viruses (HTLV), but clearly distinct from each previous isolate, has been isolated from a Caucasian patient with signs and symptoms that often precede the acquired immune deficiency syndrome (AIDS). This virus is a typical type-C RNA tumor virus, buds from the cell membrane, prefers magnesium for reverse transcriptase activity, and has an internal antigen (p25) similar to HTLV p24. Antibodies from serum of this patient react with proteins from viruses of the HTLV-I subgroup, but type-specific antisera to HTLV-I do not precipitate proteins of the new isolate. The virus from this patient has been transmitted into cord blood lymphocytes, and the virus produced by these cells is similar to the original isolate. From these studies it is concluded that this virus as well as the previous HTLV isolates belong to a general family of T-lymphotropic retroviruses that are horizontally transmitted in humans and may be involved in several pathological syndromes, including AIDS.*

Gottlieb et al 1981; Barre-Sinoussi et al 1983; Gallo et al 1984

Simian Immunodeficiency Virus (SIV)

Red-Capped Mangabeys

Greater Spot-Nosed Monkey

Chimpanzees

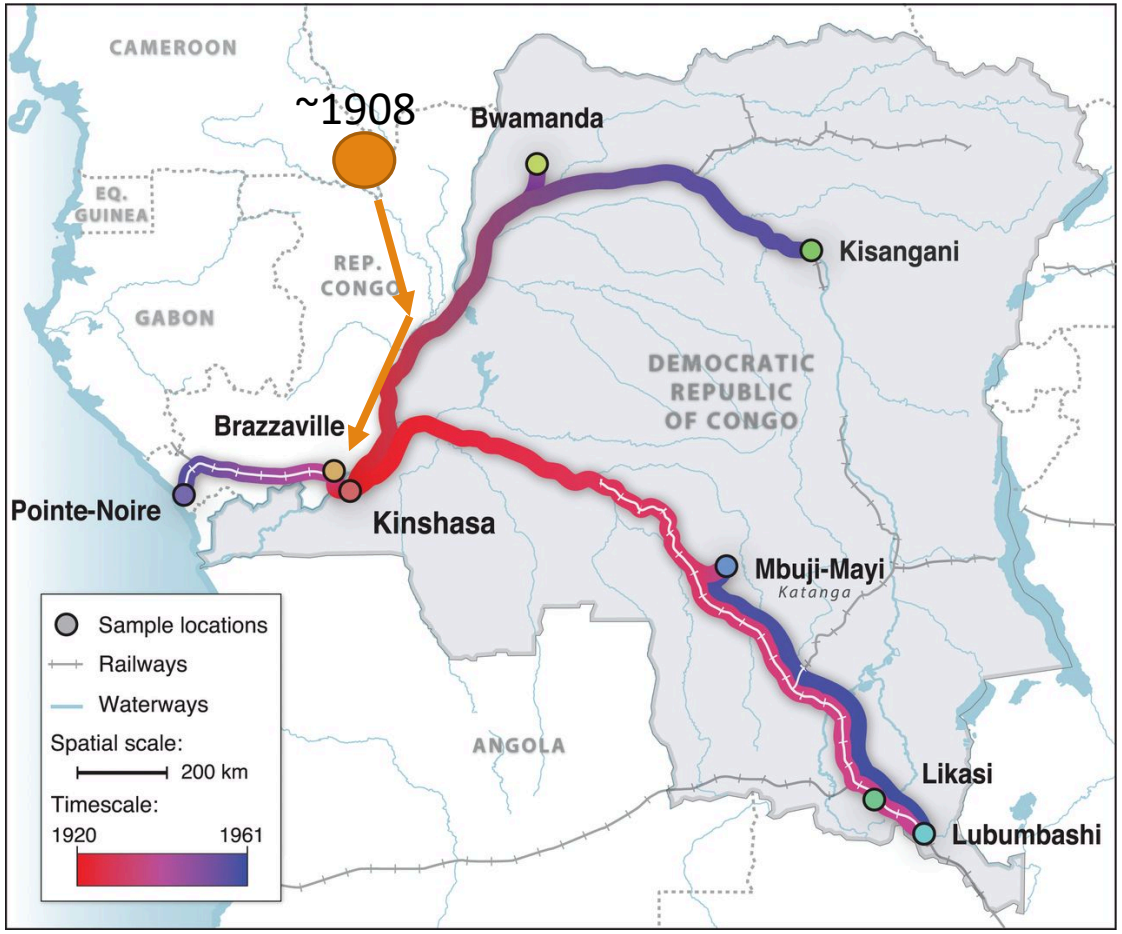
~1908

Southeast Cameroon

Origin & Spread of HIV-1

Colonialism & forced labor

- Belgium & German control of Cameroon & Congo
- Ivory & Rubber industry
- Transportation Networks
  - Trails, waterways, railways



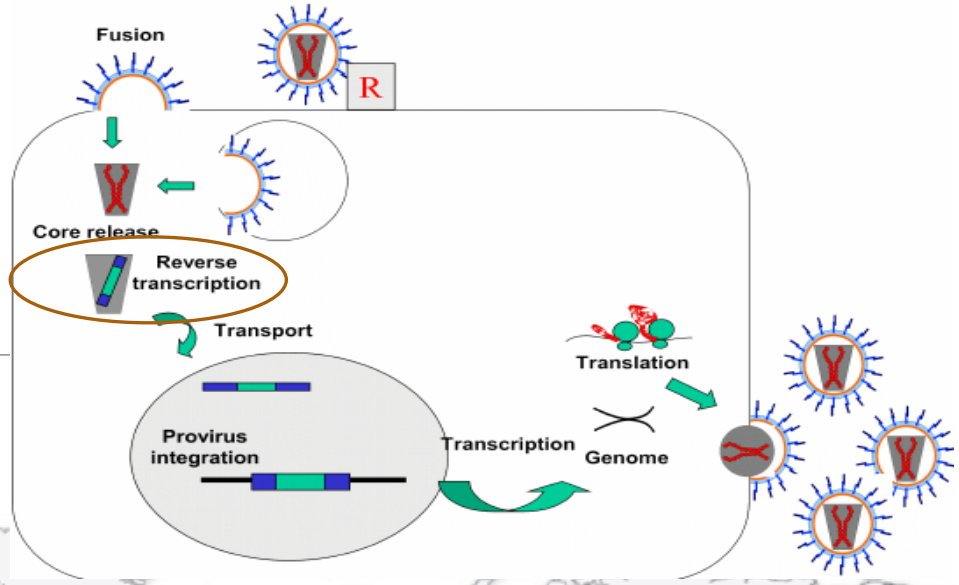
Faria et al 2011; Timberg & Halperin 2012

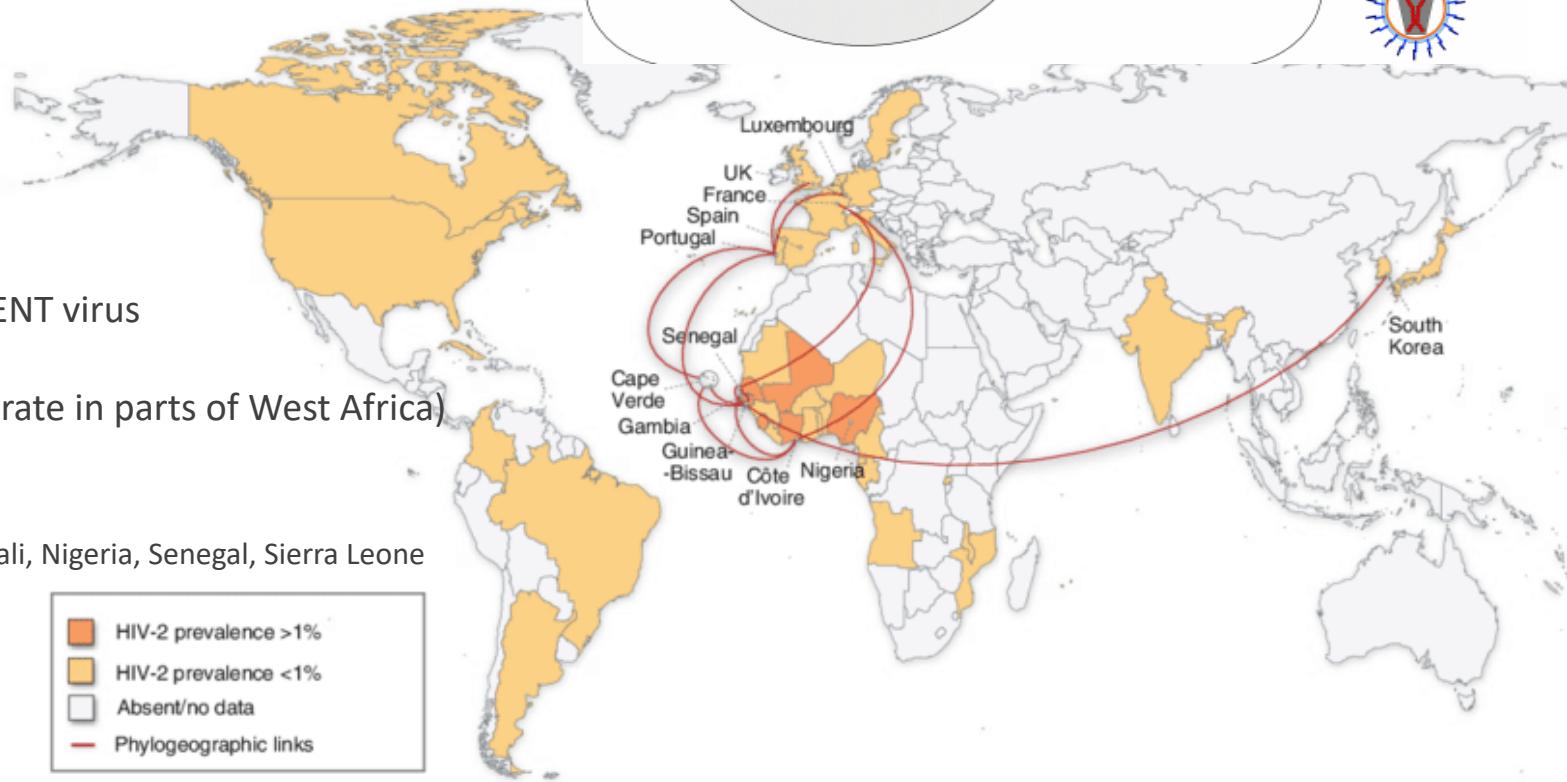
HIV Types

Lentivirus
- Retrovirus

HIV-1
- Groups M = 90-95% of HIV-1
  - Further subtypes & clades
    - Of little clinical relevance
- Most recent common ancestor = 1920

HIV-2
- 30-40% homology with HIV-1 == a DIFFERENT virus
- 2-5% of global HIV infections
- Co-infection with HIV-1 is high (up to 20% rate in parts of West Africa)
- HIV-2 mono-infection is likely declining
- Found in parts of West Africa
  - Guinea-Bissau, Gambia, Senegal, Cote d'Ivoire, Mali, Nigeria, Senegal, Sierra Leone
  - Immigration distributes it more widely
- Most recent common ancestor = 1940



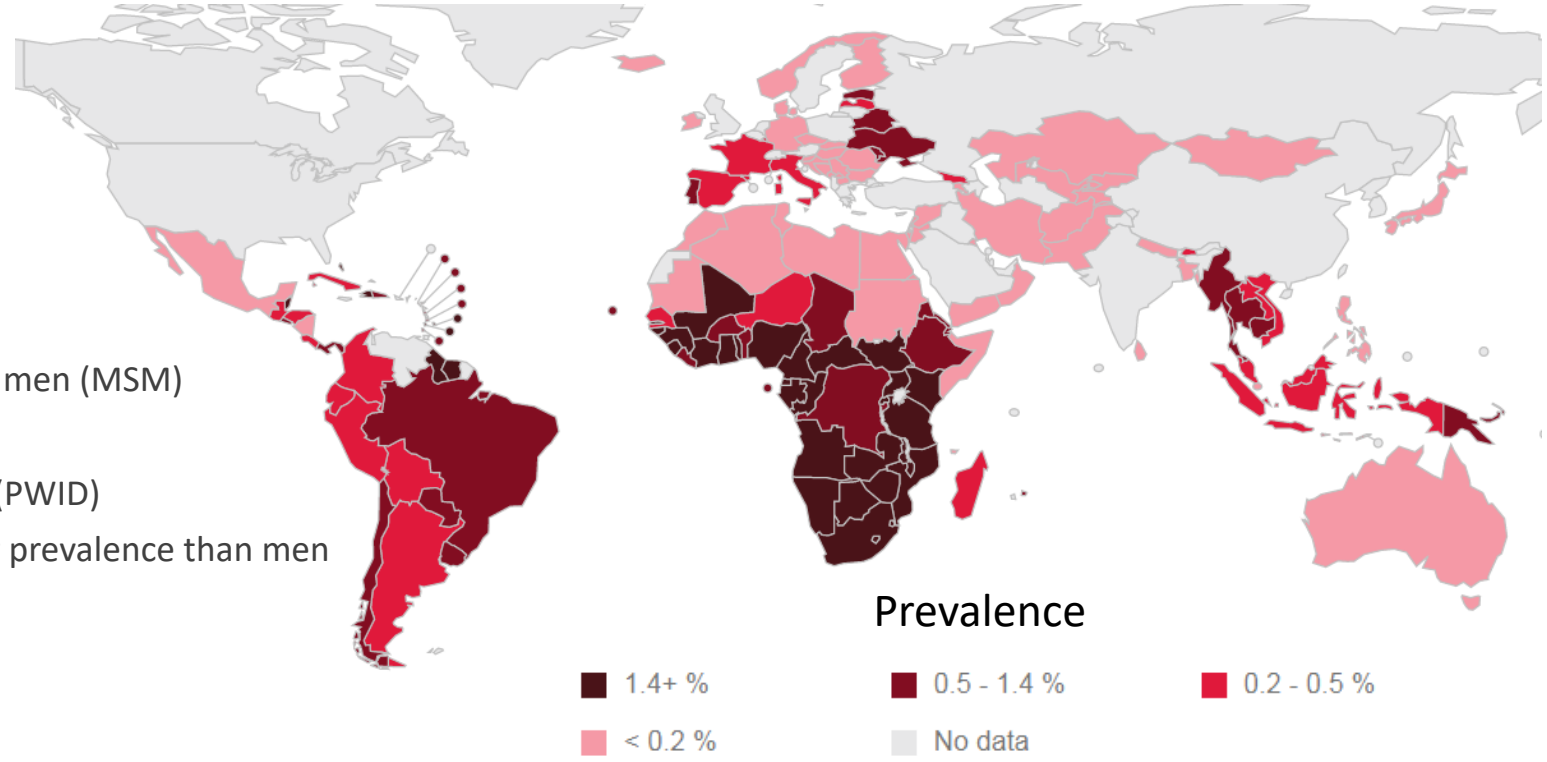


Kirchner 2017; Faria et al 2014

Basic Epidemiology

Liberia (2016)

- Prevalence: 39,000 (1.4%)
  - 32% do **not** know they are HIV +
  - 35% on **ART**
  - 13% with suppressed viral load
- Key Populations
  - 20% prevalence in men who have sex with men (MSM)
  - 10% prevalence in sex workers
  - 4% prevalence in people who inject drugs (PWID)
  - Reproductive age women have **60%** higher prevalence than men
- Since 2010:
  - 31% **decrease** in incidence
  - 34% **decrease** in AIDS-related deaths



UNAIDS 2020

Your experience

What do you estimate the HIV prevalence to be in your community, in your hospital, clinic?

- What are your communities high risk or key populations?

How do your patients perceive personal risk of infection?

What are harmful & helpful beliefs of HIV common in your community?

How have societal institutions (religious, educational, governmental, local leadership) responded to HIV in your experience?

Transmission Risk

*** acute HIV, high viral load, concurrent STI, and mucous membrane injury all **increase** risk ***

	Risk per 10,000 exposures	Average exposures per infection
Blood Transfusion	9,250	~1
Needle Sharing during Injection Drug Use	63	159
Needle Stick Injury	23	435
Receptive Anal Intercourse	138	72
Insertive Anal Intercourse	11	909
Receptive Vaginal Intercourse	8	1,250
Insertive Vaginal Intercourse	4	2,500
Oral Intercourse	Low	
Biting, spitting, or body fluids on intact skin	Very low	
Mother-to-child transmission without ART	2,500 (25%)	4
MTCT including breastfeeding without ART	4,500 (45%)	2.2

unprotected

Patel et al 2014

Testing overview

HIV Enzyme Immunoassays (EIA)

- 1st gen – 1980s, high false +
- 2nd gen – 1980s, blood bank screening
- 3rd gen – 1990s, sandwiched **Antibodies** IgG / IgM
- 4th gen – 3rd gen **Antibody** & p24 **Antigen** combo

HIV Rapid Testing

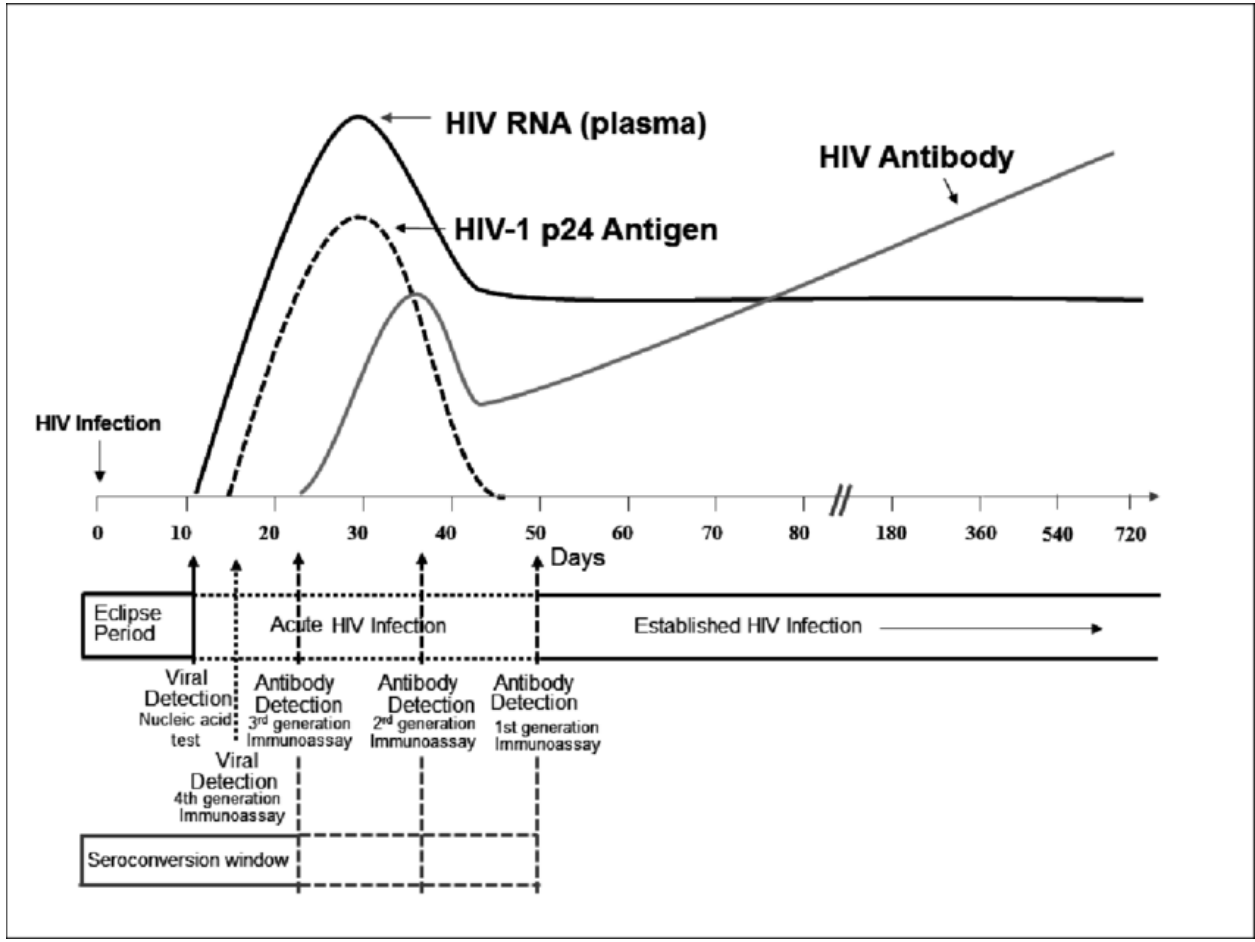
- Determine: Ab / Ag with HIV 1/2 differentiation
- Bioline: IgG / IgM Ab with HIV 1/2 differentiation
- Uni-Gold: Ab with HIV 1/2 differentiation

HIV Nucleic Acid Amplification Test (NAAT / "viral load")

- RNA, DNA

HIV Western Blot

- HIV lysate protein band identification in gel electrophoresis
- ~2 months until positive

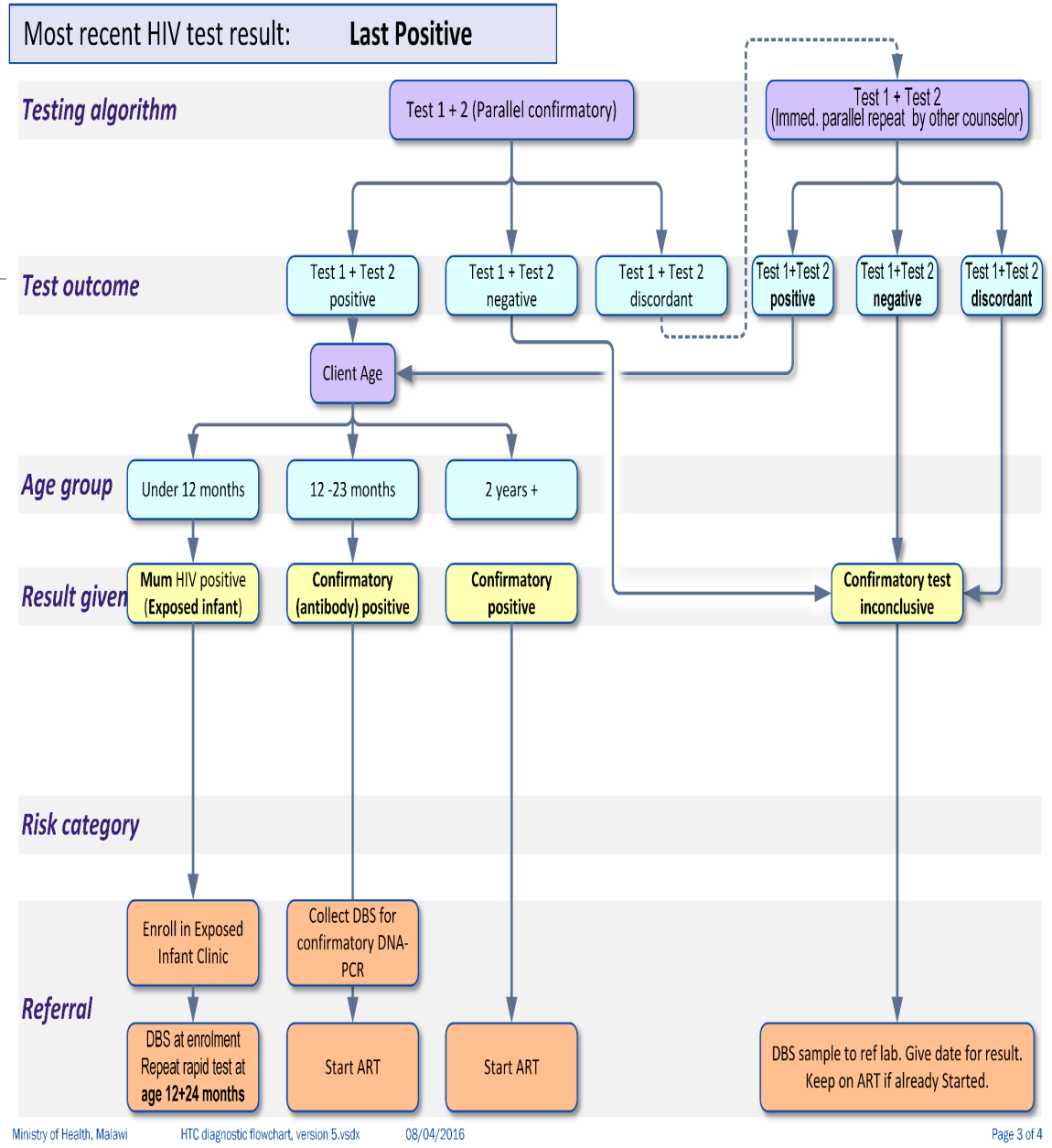


Branson et al 2014

Diagnosis by Rapid Testing

Liberia: after initial positive test > send 2 parallel confirmatory
- Confirmatory 1 & 2 positive = **HIV +**
- Confirmatory 1 & 2 discordant = **repeat test** after quality review
- Confirmatory 1 & 2 negative = **Dried Blood Sample for NAAT**

WHO: recommendation by prevalence
- If >5% prevalence in population tested:
  - Diagnosis requires 2 consecutive positive tests
    - If 1/3 assays is reactive = HIV negative
    - If assays are reactive > non-reactive > reactive == inconclusive, repeat in 14 days
- <u>If <5% prevalence in population tested:</u>
  - Diagnosis requires 3 consecutive positive tests
    - If Assay 1 is reactive > Assay 2 is nonreactive == HIV negative
    - If assays are reactive > reactive > nonreactive == inconclusive, repeat in 14 days



Testing

Liberia guideline – offer HIV testing to all patients at any facilities if:

- Never tested or no documentation of a test
- Tested negative > 3 months ago (if test indicated risk-assessment)
- To children under 24 mo if:
  - Mother's HIV status is unknown
  - If the child is sick (even if documentation of prior negative maternal test)
- Index Testing:
  - Test with partner (or via Partner Referral Slip)
  - Test with family/children (or via Family Referral Slip)
- For negative tests, link to:
  - Prevention services
  - Retesting by risk assessment

Liberia HIV Testing Program Goals

1. Identify as many HIV+ people as possible
2. Identify patients **early** after infection
3. Start **ART** as soon as possible

Case

22 year old male

Negative HIV rapid test 1 year ago

Since that time has had 2 female sexual partners

- Most recent encounter was with a sex worker 2 weeks ago, unprotected vaginal intercourse

What testing scheme do you recommend, if:

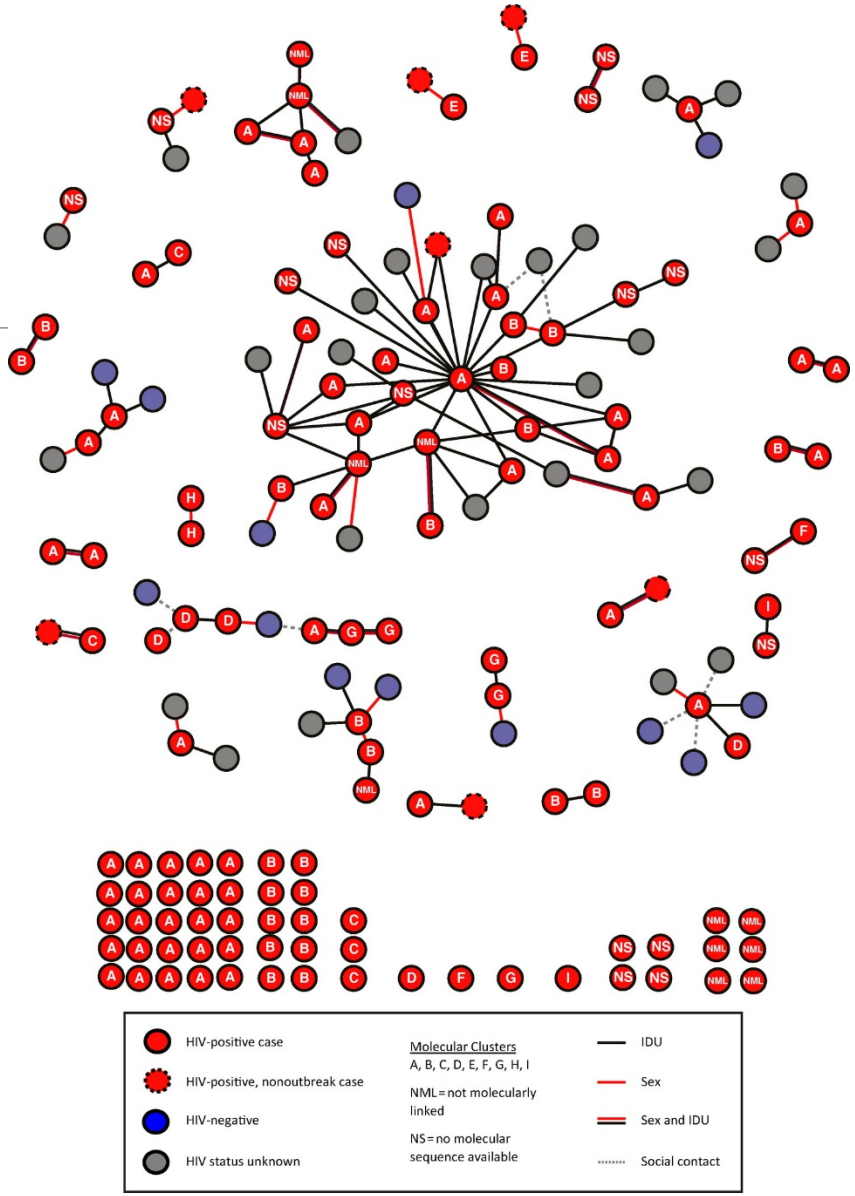
1. He is asymptomatic
2. He describes fever, malaise, pharyngitis
3. He has weekly high risk sexual exposures
    1. What if monthly, twice yearly…?

What would network testing mean here?

HIV & Networks

High HIV risk networks

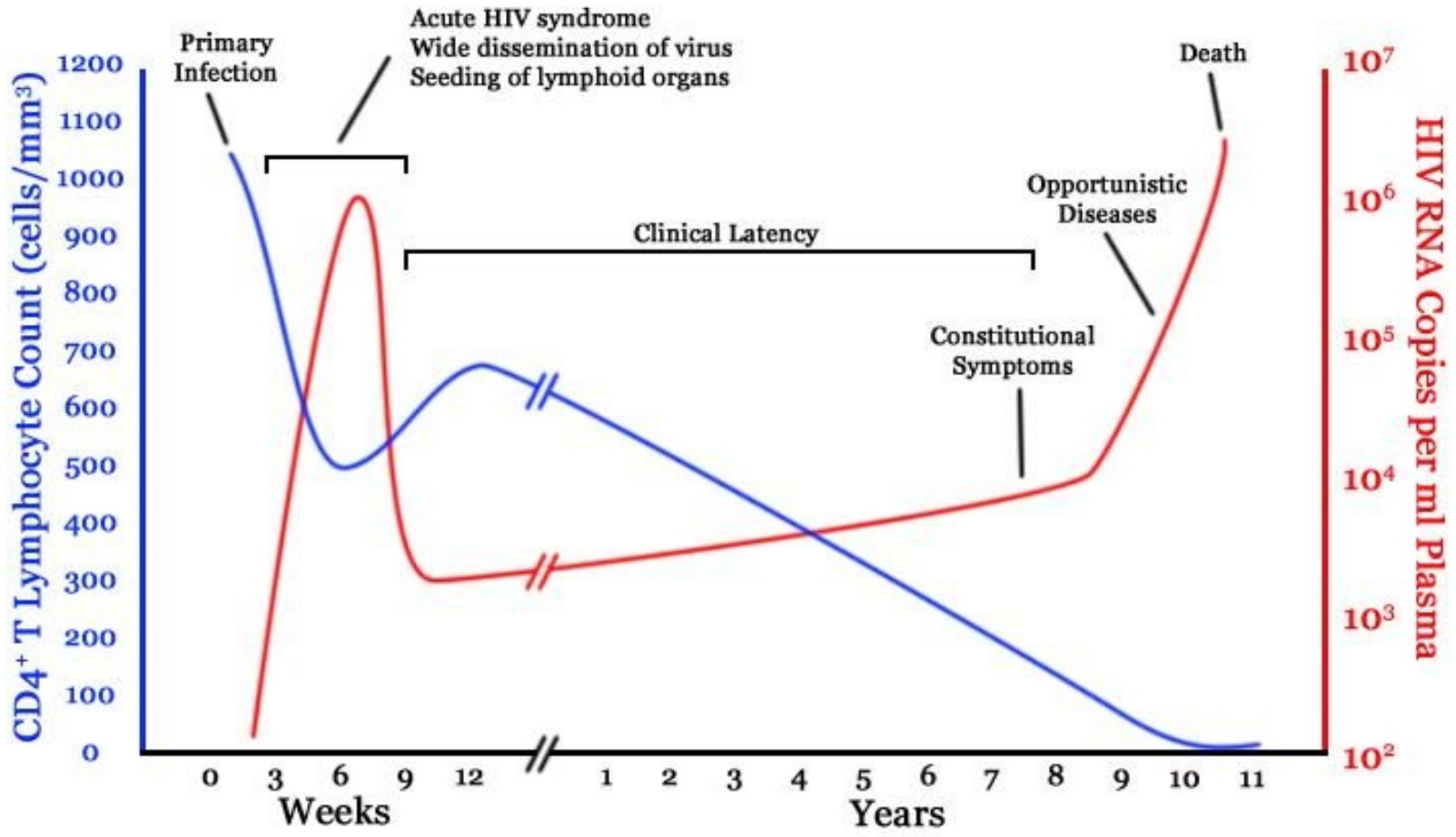
- Testing in high prevalence populations is high yield for:
  - Treatment as prevention
  - Case identification
- Often socially marginalized, stigmatized
  - Testing requires *trust*
- Social Network Strategies can identify:
  - **More** cases
  - The cases **highest risk** for transmission to others
  - **Leverage** social influence to encourage testing



Network analysis of HIV outbreak in USA

Alpren et al 2020

Natural History of HIV



Popoola & Olufunsho 2016

WHO Staging

Stage		Features	Approximate CD4
1	asymptomatic	Generalized lymphadenopathy	>500
2	Non-AIDS defining condition	<10% weight loss Recurrent respiratory infections Zoster, oral ulcers, dermatologic conditions	200 - 500
3	AIDS & non-AIDS	>10% weight loss Unexplained fever or diarrhea >1mo MTB (P or EP) Severe systemic bacterial infections Oral candidiasis, gingivitis HBV/HCV con-infection	<200
4	AIDS-defining	OI HIV wasting syndrome	<200

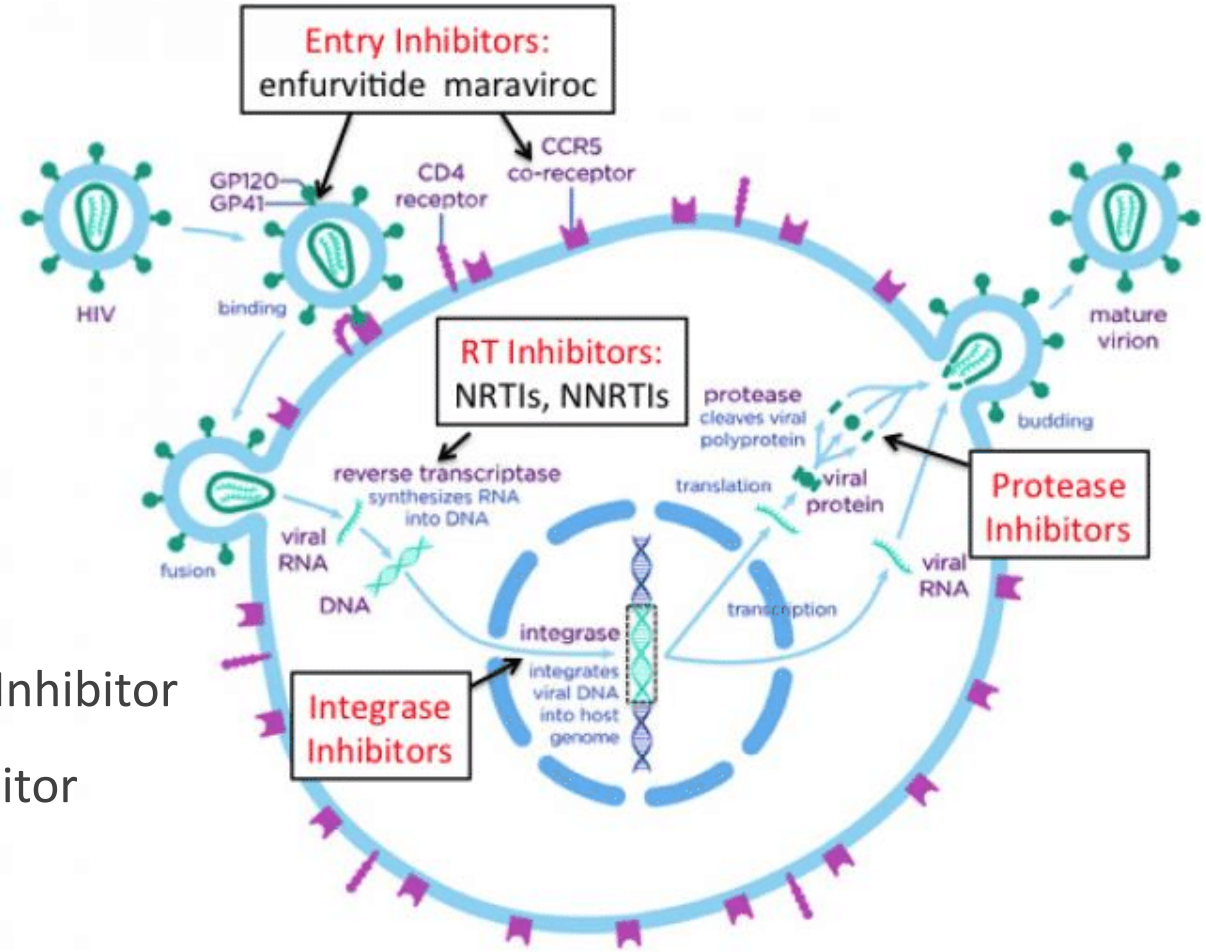
Presumed Severe HIV Disease in Infants (PSHD)

Infant <12 months with positive rapid antibody test PLUS:		
Combination of 2:		At least 1:
• Oral thrush • Severe pneumonia • Severe sepsis	**OR**	• Severe unexplained wasting / malnutrition not responding to treatment • Pneumocystis pneumonia • Candidiasis of oesophagus, trachea, bronchi or lungs • Cryptococcal meningitis • Toxoplasmosis of the brain (from age 1 month)

START ART Immediately, do NOT wait for confirmatory PCR!

Basic Virology & Med Classes

Take out a **pencil** & paper!



NNRTI Non-nucleoside Reverse Transcriptase Inhibitor

NRTI Nucleoside Reverse Transcriptase Inhibitor

INSTI Integrase Strand Transfer Inhibitor

PI Protease Inhibitor

ART Regimen: Building Blocks

3 meds

- **2** fully active
- **PI** needs a **ritonavir** "booster"

Inhibits CYP 450-3A4

↓

↑ concentration of PI

Core		Backbone		
INSTI	+	NRTI	+	NRTI
PI	+	NRTI	+	NRTI
NNRTI	+	NRTI	+	NRTI

Nucleoside Reverse Transcriptase Inhibitor NRTI

Tenofovir [TDF]
- Need for HIV-HBV co-infxn [alternative = entecavir]
- Dose reduction for CrCl <50

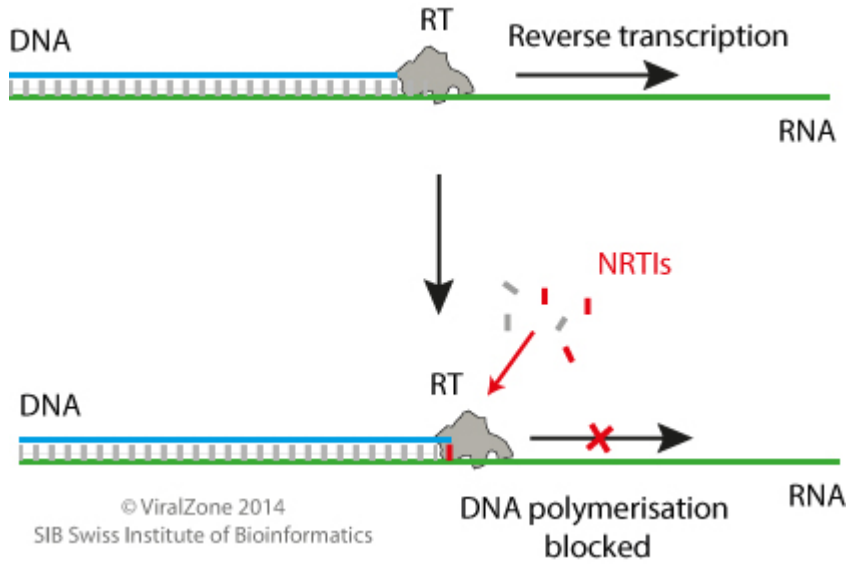
Lamivudine [3TC]
- Well, tolerated
- in all 1st & 2nd line regimens

Abacavir [ABC]
- Hypersensitivity reaction = absolute contraindication

Zidovudine [AZT]
- Q12hr dosing
- NOT if hgb <8
- Watch for anemia

Available Combo Pills
- ABC/3TC
- TDF/3TC
- AZT/3TC

Core		Backbone		
?	+	NRTI	+	NRTI



Non-Nucleoside Reverse Transcriptase Inhibitor NNRTI

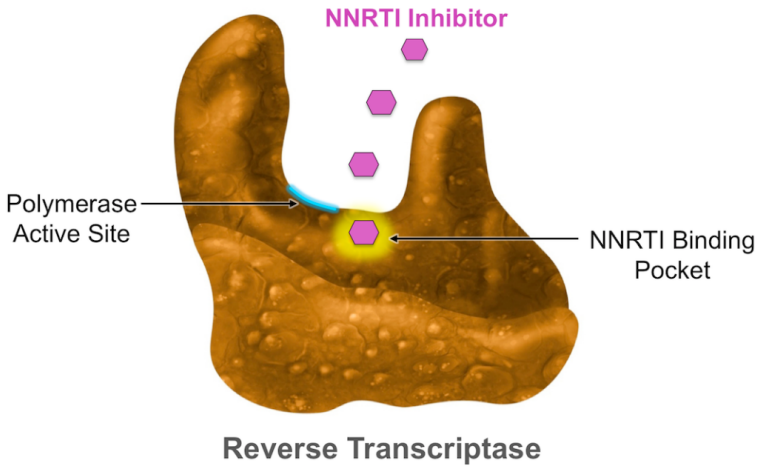
Nevirapine [NVP]
- **1st line**, but not for ART start
- SE: hypersensitivity reaction, rash, hepatitis

Efavirenz [EFV]
- **1st line**, but not for ART start
- SE: neuropsych, insomnia, nightmares, dizziness, gynecomastia

Available Single Tablet Regimen
- AZT / 3TC / NVP
- TDF / 3TC / EFV – "**B+**"
  - Very similar to "Atripla"

Core + Backbone

NNRTI + NRTI + NRTI



Protease Inhibitor
PI

Lopinavir / ritonavir [LPV/r – Kaletra]
- 2nd line
- diarrhea

Atazanavir / ritonavir [ATV/r]
- 2nd line
- Do NOT use with rifampicin for MTB tx
- Benign hyperbili/jaundice

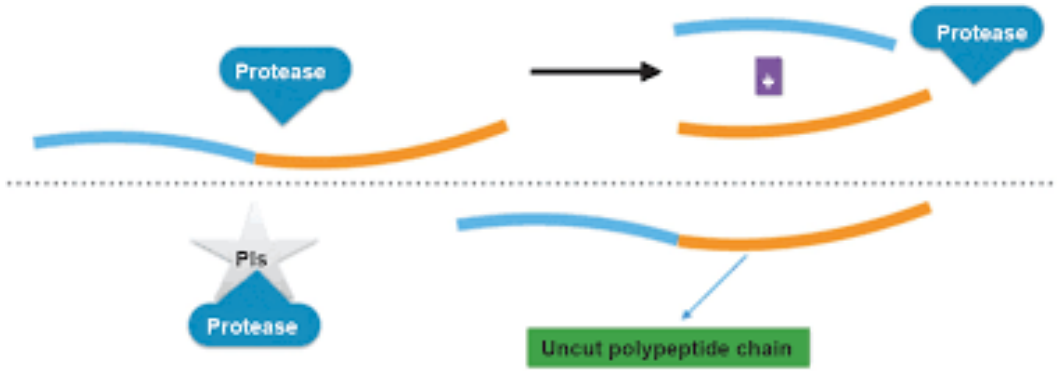
Darunavir / ritonavir [DRV + r]
- 3rd line
- Must take separately

Not Available in Single Tablet Regimen

Core + Backbone

PI + NRTI + NRTI

booster



Integrase Strand Transfer Inhibitor INSTI

Dolutegravir [DTG]

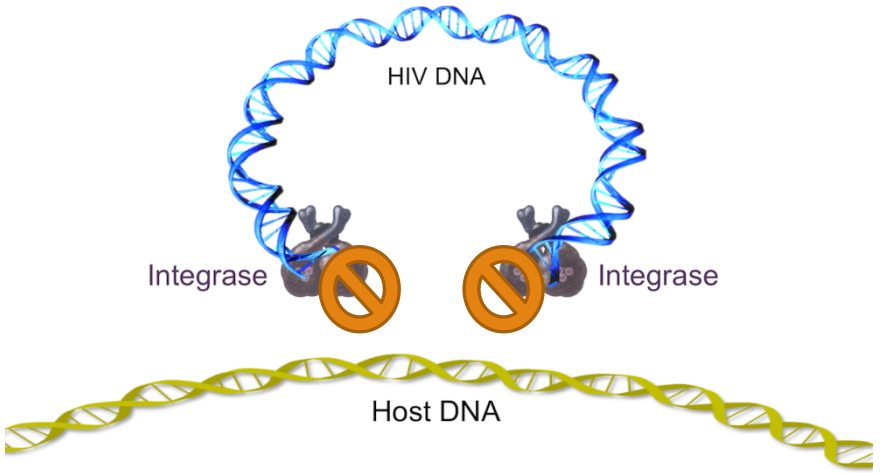
- **1st line** for patients 30kg + without childbearing potential
- WHO: 1st line treatment for pregnant women
- SE mild: HA, insomnia, nausea
  - Check LFTs before/after initiation if known liver disease
- BID with rifapentine for MTB treatment

Available Single Tablet Regimen

- TDF / 3TC / DTG

Core | Backbone

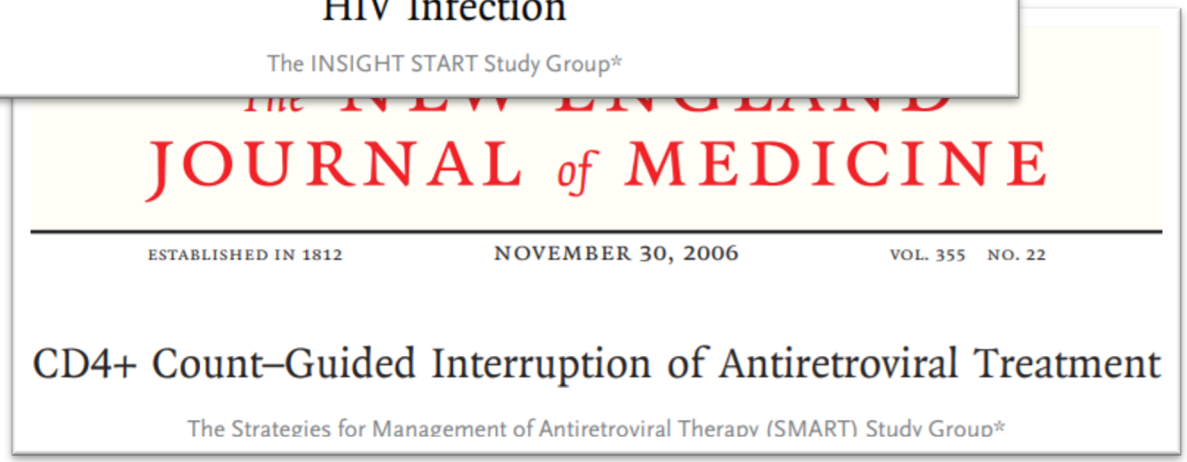
INSTI + NRTI + NRTI

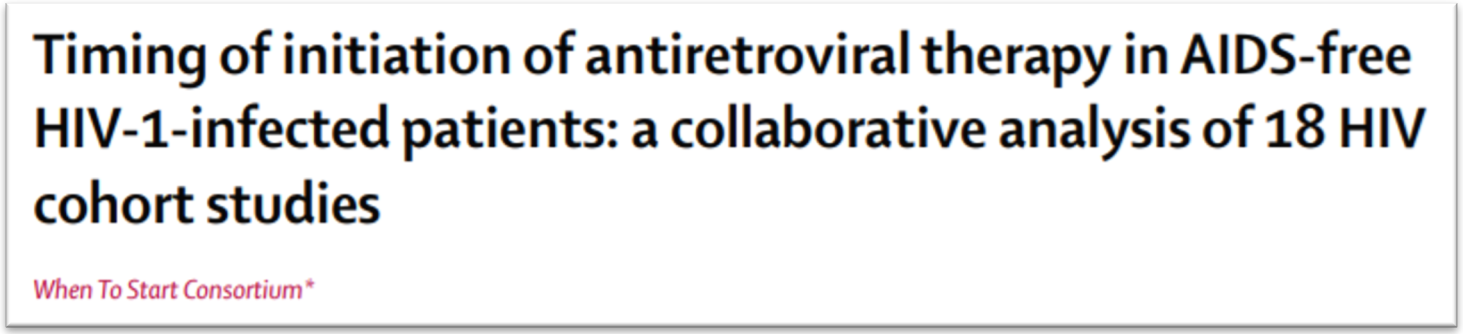


ART for all

Strategy of WHO & Liberia

- Established personal benefit
  - Decreased all-cause & AIDS-specific morbidity & mortality
- Likely population benefit
  - treatment as prevention



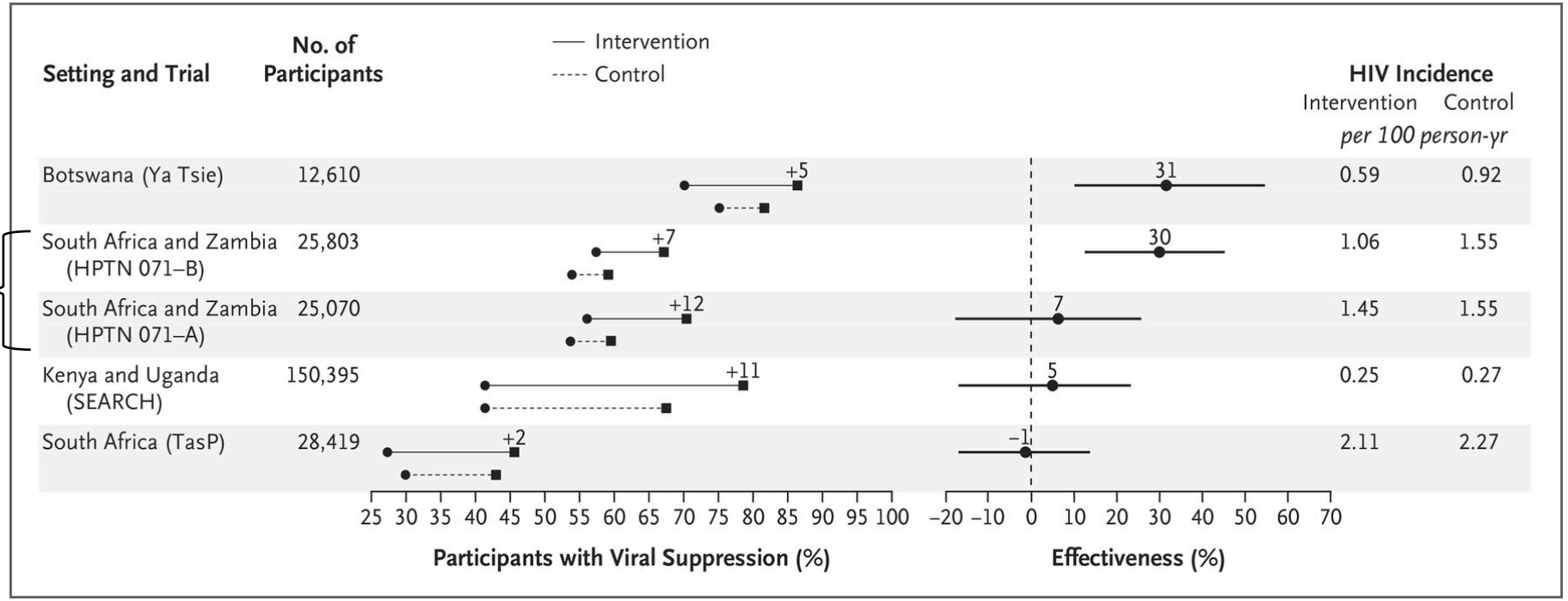


ART Start – Test and Treat

4 major trials: Ya Tsie, PopART (HPTN), SEARCH, TasP

- 3.5 / 4 had a *nonsignificant* impact on population incidence
- Many ecological confounders, protocol changes

PopART



START 2015; Karim 2019

Preparing for ART start

CONFIRM diagnosis

Social Support
- Especially for vulnerable patients

Clinical Evaluation
- WHO Staging
- Opportunistic Infections
  - MTB
- Chronic Conditions – HTN, DM

Baseline labs
- NOT required prior to ART start
- WHO Stage 3/4, inpatient ART start
  - routine urine LAM & serum CrAg

Counseling
- Lifelong treatment
- Individual counseling

First Line ART for Initiation (“start”)

	Core		Backbone			
Men 30kg Women 45yo +	DTG	/	TDF	/	3TC	
Women of childbearing potential	EFV	/	TDF	/	3TC	“B+”
Patients < 30kg	NVP	/	AZT	/	3TC	

HIV-2 ART considerations

Active ART

- NRTIs
- INSTIs
- LPV/r
- DRV/r

Inactive ART

- All NNRTIs
- ATV/r

Case

32 year old female

- Weight loss and diarrhea for 6 months
- BMI now 18
- HIV diagnosed by rapid testing 1 month ago

How do you counsel?

What is your next step?

Monitoring Schedule

Appointments

- Monthly for first 6 months
- Space up to q 3 month appointments if virally suppressed & adherent
- In stable patients, 6 or even 12 months of ART may be dispensed for exceptional circumstances (ie, travel)

Viral Load

- 6 months after ARV start
- 12 monthly thereafter

Monitoring Treatment

Adherence
- Determine pill count & doses missed by last fill date

Nutritional Status
- Weight loss
  - Flattening of pediatric growth curve
  - BMI <17 in adult = malnutrition => Therapeutic Feeding
  - MUAC <22cm in pregnancy = malnutrition => Therapeutic Feeding
- Weight should normalize within 6-12mo on ART

Viral Load
- Dried Blood Spot (DBS) = RNA PCR

CD4
- Baseline if available
- Treatment failure suspect
  - CD4 < 200 = urine LAM & serum CrAg
  - CD4 > 200 = no action
- *may be falsely elevated in acute illness

Symptoms

Appearance:	Weight loss / failure to thrive
	Body shape change / breast swelling (men)
	Swollen glands
Headache / confusion / dizziness	
Jaundice, Scleral icterus	
Mouth sores	
Cough	
Shortness of breath	
Fever / night sweats	
Vomiting / abdominal pain	
Diarrhoea	
Leg pain / numbness / weakness	
Rash on arms, legs or trunk	

Case (cont)

1 months later you see her in clinic

- Reports full adherence
- Diarrhea has stopped, weight is same as on start
- Notes that she has been feeling depressed

What do you review?

What are your next steps?

Case (cont)

She returns for 2nd month review

- Nightmares developed
- She has stopped her ART for the past 2 weeks entirely

What is your next step?

Case (cont)

You have switched your patient to a DTG-based regimen. Her 6 month viral load returns **detectable** but < 1,000.

What is your next step?

Case (cont)

She discloses that her husband is a truck driver who travels a 3-day route each week. She has not disclosed to him for fear of his reaction and therefore does not take ART on days when he is home to avoid inadvertent disclosure.

How do you respond?

Goal: >95% adherence

Adherence

"What challenges have you had taking your ARV?"

"What days / times are you most likely to forget your ARV?"

"Everyone has difficulty taking meds every day. When was the last time you were not able to take your ARV, and how many times in the past week, month were you unable?"

Goal: to help the patient
- No policing
- Encourage transparency

Root cause: there is *always* a reason (or reasons)
- Stigma & disclosure
- Socio-economic barrier
- Transportation & Work
- Psychological
- Misunderstanding
- Side effects

Practical Strategies
- Join with daily routines (meal, cleaning)
- Cell phone alarm
- Take meds with another person
- Keep a med diary

Intensive Adherence Counseling (IAC)

for *any* sign of poor adherence

for any detectable Viral Load (even is <1k)

Patient & Treatment Supporter

Education on ART, adherence, monitoring, failure, & resistance

<u>Indentify Specifics</u>

- Travel, Work, Education
- Stigma, Privacy, Domestic Difficulties
- Substance Use
- Mental Health / Depression

<u>Action Plan</u>

- Specific
- Written on Patient Card
- Monthly appointments
  - Pill Counts
  - Action Plan review
- Viral Load in 3mo

Disclosure

An **individual** process based on **trust**

Pediatric Disclosure – a *gradual & transparent process*

Age 5-7

- ARV keeps their body strong to keep a germ "asleep"

Age 8-10

- Full disclosure may begin
- Physician may or may not assist

Age 11-13

- Full knowledge of HIV status
- Understand safe activities (hugging, kissing, sharing food, etc) and precautions (needles/razors)

Adolescence

- Dialogue on stigma, peer relationships, sexuality
- Family Planning, condoms
- ARV fatigue
- *ART Teen Club*

Primary Care of PLWHA

Family Planning

- Preventing Mother to Child Transmission (PMTCT)
- Assume all patients >14yo are sexually active
  - Offer condoms to all
  - Contraceptive Counseling
    - Long Acting Reversible Contraceptives: DPMA (Depo-Provera), hormonal implant, Copper IUD
    - Patient autonomy in decision making

Diabetes

Hypertension

Cardiovascular Risk

Malignancy

- Cervical Cancer

Preventive Treatment

Cotrimoxazole Preventive Therapy (CPT)

- HIV exposed and infected children for age > 6 weeks
  - Stop if confirm negative after breastfeeding
- HIV+ adults for life
- Contraindication: jaundice, renal failure, sulfa allergy

TB Preventive Treatment (TPT)

- All HIV+ children and adults at time of ART start
  - Rule out active TB: no cough, weight loss (or failure to thrive in children), fever, night sweat
- Isoniazid (INH) x 6 months (6H)
  - With pyridoxine
  - Visits: start & 1, 3, & 6 months
- Isoniazid (INH) + Rifapentine (RFP) weekly for 3 months (3HP)
- Poor adherence = less effective but **will not cause drug-resistant TB**

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Cases (cont)

35yoM with newly diagnosed HIV ready to start treatment

- What are you next steps, recommendations
- Then your follow-up?
- What might be available to start in the “real world” in clinic?

6yoF newly diagnosed HIV

- What are your next steps?
- Then follow-up?

32yoF with history poor adherence who has failed efavirenz. What are your next steps?