PEP Rally

CLINID conference
Hunter Ratliff
04/17/2025

Ages, dates, and other identifying information may have been changed
I have no conflict of interest in relation to this presentation

Case #1

Case 1: HPI

A **50 y/o F** with PMH including hypothyroidism, ADHD p/w **a needle stick injury**

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A **50 y/o F** with PMH including hypothyroidism, ADHD p/w **a needle stick injury**

- Works in the at WVU, had injury while disposing of **18 gauge needle**
- Punctured the glove on her finger
- Developed bleeding after injury
- **Source patient** HIV (+)

Terms

- **Exposed patient** = healthcare worker with needlestick injury
- **Source patient** = patient whose blood the healthcare worker was exposed to

Case 1: Poll

1. Immediate next steps (right after the needle stick)?
2. What labs should be done on the **exposed patient**?
3. What do you want to know about the **source patient**?

A **50 y/o F** with PMH including hypothyroidism, ADHD p/w **a needle stick injury**

- 18 gauge needle to finger
- Immediate bleeding

Case 1: Immediate next steps

The **exposed patient** washed the injured area with soap and water

She was already in the ED (at time of needle stick), so labs were obtained

At time of needle stick, **source patient** had already left the ED

Home meds
- Levothyroxine
- Vyvanse
- Ozempic

Exposed pt	Result
HIV (4G)	Neg
HCV	Neg
Anti-HBs	**0.25**
HBsAg	Neg
Anti-HBc	Neg

Exposed pt	Result
CBC	Normal
Creatinine	0.8
Alk phos	114
AST	21
ALT	10
Bili	0.7
uPreg test	Neg

Case 1: Source patient

The **source patient** follows in our clinic

- Diagnosed 2005
- RF: MSM & substance use (sober for 8 years)
- No resistance
- Biktarvy since 2018

Date	HIV VL
-7 mo	TND
-1 yr	**39**
-1.5 yr	<20
-2 yr	<20
-2.5 yr	**49**
-3 yr	<20

Labs (2013)	Result
HCV	Neg
Anti-HBs	**>40**
HBsAg	Neg
Anti-HBc	Reactive

Case 1: Poll

1. Should she get PEP for HIV?
2. What should be done for PEP

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-3 yr	<20

Labs (2013)	Result
HCV	Neg
Anti-HBs	**>40**
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Source patient
- RF: MSM & IVDU (sober)
- On Biktarvy

A **50 y/o F** with PMH including hypothyroidism, ADHD p/w **a needle stick injury** from source patient with HIV

Exposed pt	Result
HIV (4G)	Neg
HCV	Neg
Anti-HBs	**0.25**
HBsAg	Neg
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Exposed pt	Result
CBC	Normal
Creatinine	0.8
LFTs	Normal
uPreg test	Neg

Questions for the group

1. Should she get PEP for HIV?
2. What should be done for PEP

Case 1: ED course

A **50 y/o F** with PMH including hypothyroidism, ADHD p/w **a needle stick injury** from source patient with HIV

- Started on Truvada & raltegravir the same day
- Same day started having nausea & fatigue
- Eventual GI upset with emesis

Source patient
Did not ever get labs on the patient before he left the ED

Case 1: Employee health follow up

A **50 y/o F** with PMH including hypothyroidism, ADHD p/w **a needle stick injury** from source patient with HIV. Was started on tenofovir/emtricitabine & raltegravir (DTF / FTC / RAL) within hours

- Two weeks after needle stick, **doing quite poorly** from a GI standpoint
- Employee health rechecks labs

Exposed pt	Day 0
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Exposed pt	Day 0	Day 14
CBC	Normal	Normal
Creatinine	0.8	Normal
Alk phos	114	**260**
AST	21	**93**
ALT	10	**223**
Bili	0.7	0.3

Case 1: Poll

A **50 y/o F** p/w **a needle stick injury** from source patient with HIV

- Started on tenofovir/emtricitabine & raltegravir (TDF / FTC / RAL) within hours
- Severe nausea & vomiting

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HCV	Neg
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- Started on tenofovir/emtricitabine & raltegravir (TDF / FTC / RAL) within hours
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What's going on?

- Why are the LFTs abnormal?
- Any change in management?

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Questions for the group

- Why are the LFTs abnormal?
- Any change in management?

Case 1: Follow up

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- **Stopped Truvada & raltegravir** until could be seen in ID clinic after the weekend
- Seen in ID clinic **on day 17** after exposure

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- **Stopped Truvada & raltegravir** until could be seen in ID clinic after the weekend
- Seen in ID clinic on day 17 after exposure
  - **Switched to Biktarvy** to finish remaining two week course
  - Checked viral hepatitis labs

Exposed pt	Day 0	Day 14	Day 17
CBC	Normal	Normal	Normal
Creatinine	0.8	Normal	Normal
Alk phos	114	**260**	**197**
AST	21	**93**	**93**
ALT	10	**223**	**104**
Bili	0.7	0.3	0.3

Exposed pt	Day 17
HCV PCR	Neg
HBV PCR	Neg

Case 1: Most recent follow up

A **50 y/o F** with PMH including hypothyroidism, ADHD p/w **a needle stick injury** from source patient with HIV. Was started on tenofovir/emtricitabine & raltegravir (TDF / FTC / RAL) within hours. Developed GI upset & hepatotoxicity (at 2 weeks) so stopped Truvada & raltegravir and switched to Biktarvy to finish additional 2 week course

- Still some GI upset on Biktarvy, but able to finish the course without further emesis

Exposed pt	Day 0	Day 14	Day 17	Day 33
CBC	Normal	Normal	Normal	Normal
Creatinine	0.8	Normal	Normal	Normal
Alk phos	114	**260**	**197**	118
AST	21	**93**	**93**	16
ALT	10	**223**	**104**	16
Bili	0.7	0.3	0.3	0.4

Case #2

Case 2: HPI

A **32 y/o G3P2** with PMH including gestational hypertension who p/w **a needle stick injury** during her pregnancy

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A **32 y/o G3P2** with PMH including gestational hypertension who p/w **a needle stick injury** during her pregnancy

- Currently pregnant (**at 38.5 weeks**)
- Works in a dental office, had needlestick 2.5 weeks ago
  - **Source patient** reportedly **HIV** & **HCV** positive
  - **Exposed patient** believes **source** was taking one pill once a day

Case 2: HPI

A **32 y/o G3P2** (@38w) with PMH including gestational hypertension who p/w **a needle stick injury** during her pregnancy from a reported HIV & HCV positive source

The **exposed patient** was seen in the ED:

- HIV & HCV screens: negative
  - HBsAg: negative
  - No anti-HBs was obtained
- BMP: normal
  - No LFTs obtained

Case 2: Poll

A **32 y/o G3P2** with PMH including gestational hypertension who p/w **a needle stick injury** during **36th week of pregnancy** from a reported HIV & HCV positive source

What's do you tell the MARS line?

- For HIV PEP?

Questions for the group

- What to do for HIV PEP?

Case 2: ED visit

A **32 y/o G3P2** (@38w) with PMH including gestational hypertension who p/w **a needle stick injury** during her pregnancy from a reported HIV & HCV positive source

- Discharged from ED on **Truvada** (FTC/TDF) & raltegravir (RAL)
- Was given **3 days supply** at the ED

Case 2: ED visit

A **32 y/o G3P2** (@38w) with PMH including gestational hypertension who p/w **a needle stick injury** during her pregnancy from a reported HIV & HCV positive source

- Discharged from ED on **Truvada** (FTC/TDF) & raltegravir (RAL)
- Was given **3 days supply** at the ED
- Out of pocket cost was **over $4000**
- Employer wouldn't pay for it
    - So only takes 3 days of PEP

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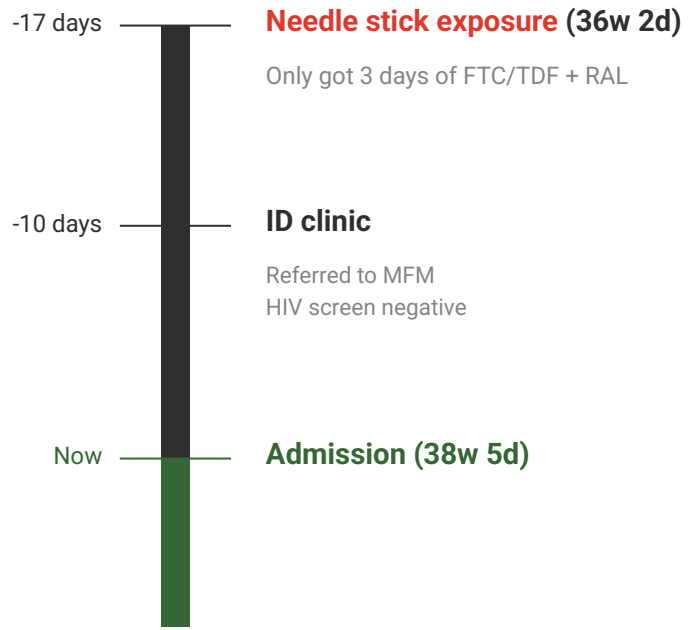
Seen by ID outpatient → referred to MFM → admit for in-house observation & possible delivery

Case 2: Summary

A **32 y/o G3P2** (@38w) with PMH including gestational hypertension who p/w **a needle stick injury** during her pregnancy from a reported HIV & HCV positive source. Only took **3 days** of **FTC/TDF + RAL** due to cost, so admitted for monitoring & possible delivery



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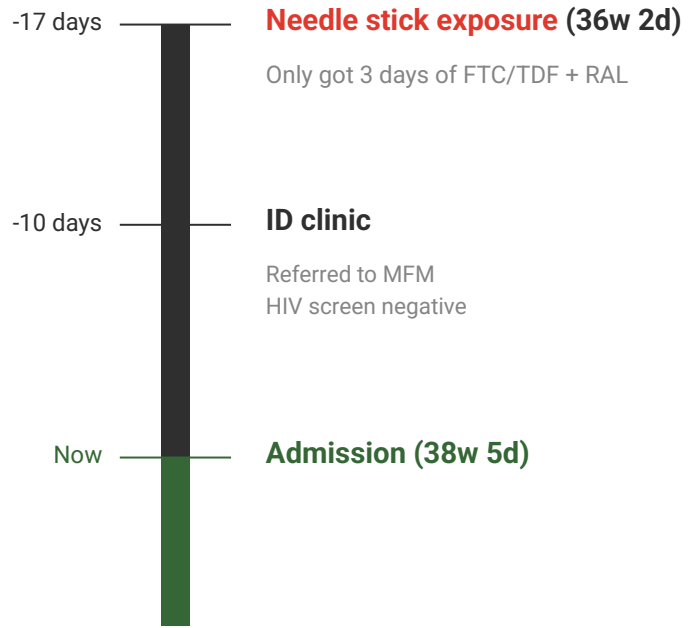
It's Friday afternoon...

- Work up to be sent?
- What to do if she goes into labor now?
- Empiric management?



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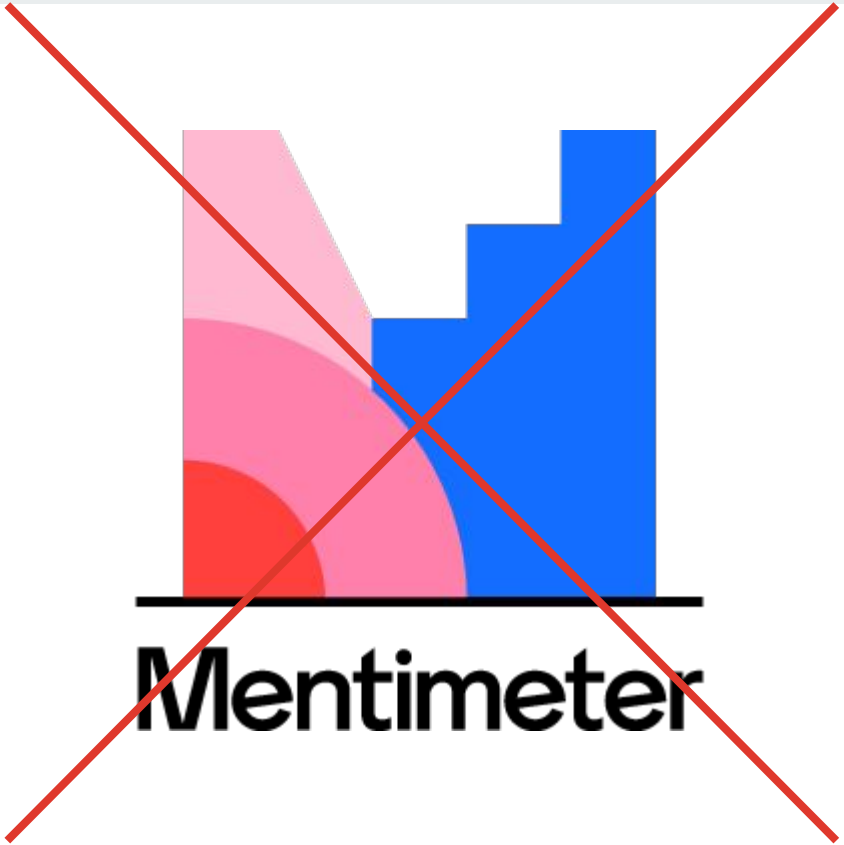

Case 2: Admission

A **32 y/o G3P2** (@38w) with PMH including gestational hypertension who p/w **a needle stick injury** during her pregnancy from a reported HIV & HCV positive source. Only took **3 days** of **FTC/TDF + RAL** due to cost, so admitted for monitoring & possible delivery

- Fourth gen HIV screen negative (now 17 days from exposure)
- HIV PCR pending
- Recommend avoiding labor until PCR comes back
- If positive or goes into labor:
    - Start IV zidovudine (AZT) 3 hours before c-section

Case 2: Hospital course

A **32 y/o G3P2** (@38w) with PMH including gestational hypertension who p/w **a needle stick injury** during her pregnancy from a reported HIV & HCV positive source. Only took **3 days** of **FTC/TDF + RAL** due to cost, so admitted for monitoring & possible delivery

- HIV PCR comes back negative (molecular lab runs it on a Sunday)
- Uncomplicated vaginal delivery

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Management of the newborn

- Work up to be sent?
- Do they need PPx?
- Breastfeeding?

Case 2: Hospital course

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- HIV PCR comes back negative (molecular lab runs it on a Sunday)
- Uncomplicated vaginal delivery

Pediatric ID consulted for the newborn

- They get in touch with **source patient's provider**, he has been undetectable, most recently 5 months ago
- **Post-delivery viral load** on **mother** is **negative**
- No testing of newborn needed; **okay to breastfeed**

Occupational post-exposure prophylaxis

Links to articles discussed here

Learning objectives

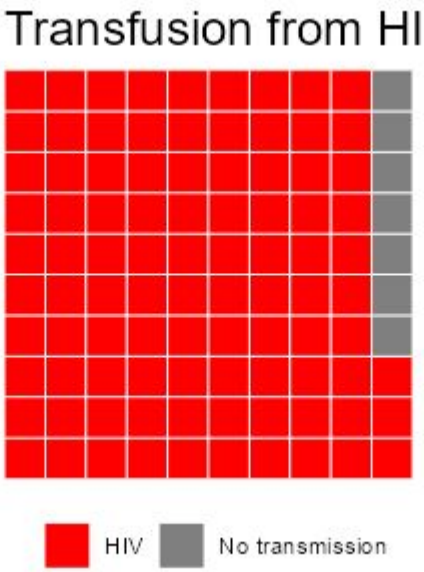
- Describe the **risk of HIV transmission** in occupational exposures
- Review the **immediate management** of occupational HIV exposures, including:
  - Suggested labs (from **source** & **exposed**)
  - Timeline of to start PEP
  - Situations that warrant PEP
- Discuss the **long-term management** of PEP
  - What agents to pick
  - Duration of PEP
  - Follow up testing
- Examine key differences of **PEP in pregnancy**
  - Risk of transmission
  - Which agents to use
  - Risk of breastfeeding
- Review the **intrapartum management** of HIV

Risk of HIV transmission

For transmission of HIV to occur, must have both

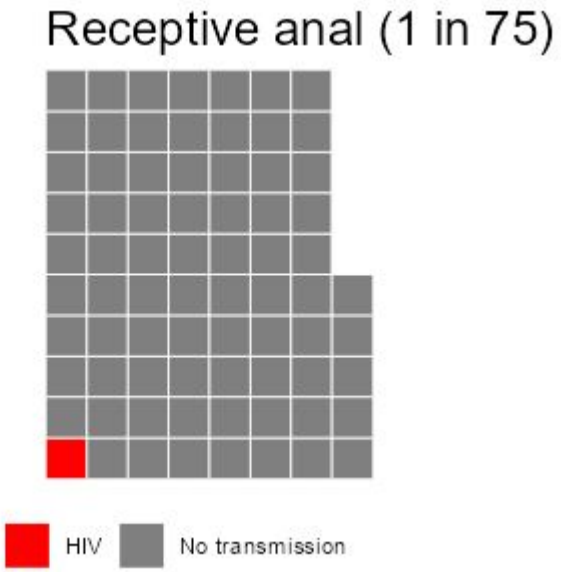
1. Infectious body fluid
    - Blood
    - Semen or vaginal fluid
    - Amniotic fluid
    - Breast milk
    - Not saliva!
2. Portal of entry
    - Percutaneous - Needle stick, IVDU
    - Mucous membranes - genitals, anal
    - Cutaneous (with non-intact skin)

Risk of HIV transmission [1]



Exposure	Risk
Blood transfusion, HIV (+)	92.5%
Receptive anal intercourse	1 in 75 (1.4%)
Shared needles (IVDU)	1 in 160 (0.63%)
Percutaneous (needle stick)	**1 in 450 (0.23%)**
Insertive anal intercourse	1 in 900 (0.11%)
Receptive penile-vaginal intercourse	1 in 1250 (0.08%)
Insertive penile-vaginal intercourse	1 in 2500 (0.04%)

Risk of HIV transmission [1]



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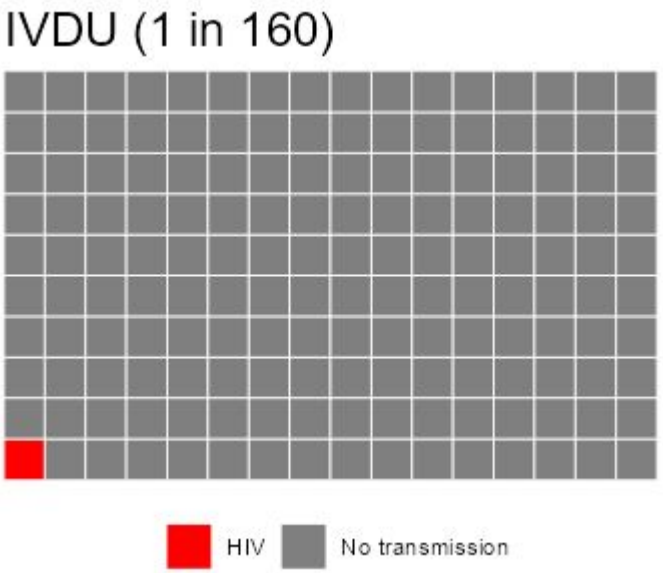

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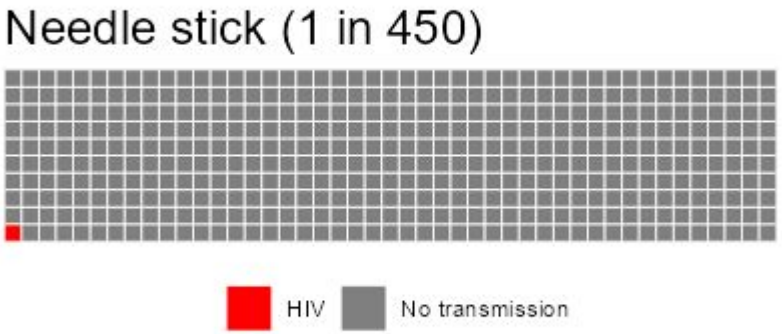

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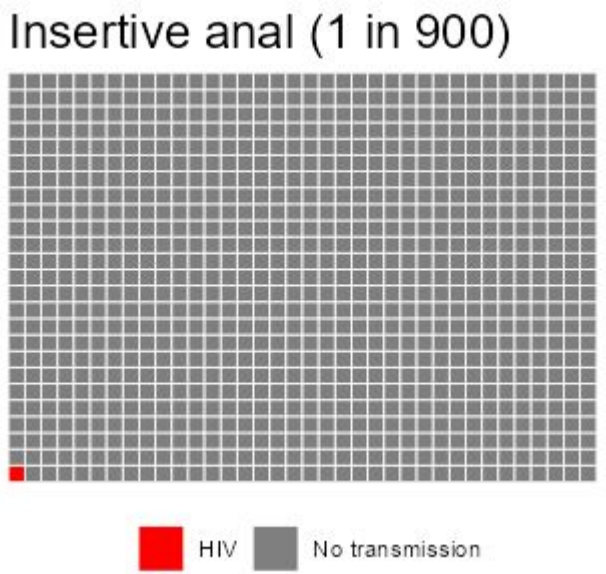

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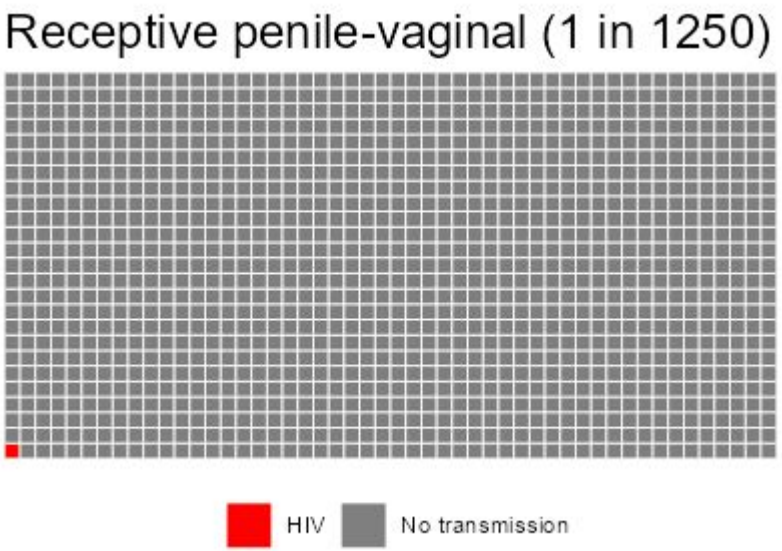

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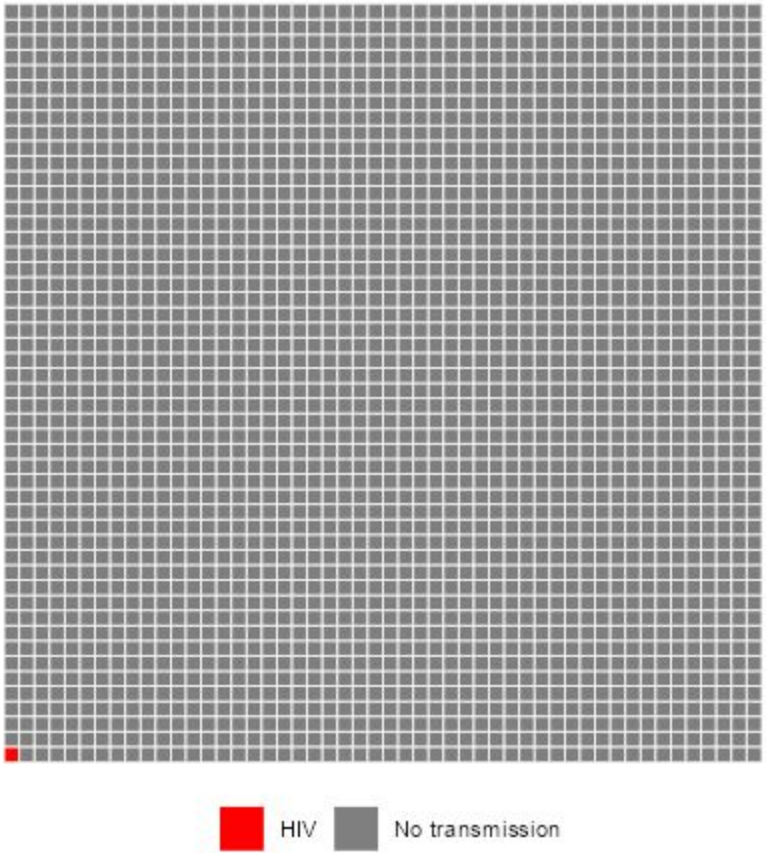
Insertive penile-vaginal (1 in 2500)



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Risk of HIV transmission: if source is on ART

Does the **source patient being on ART** reduce the likelihood of transmission?

- **Probably**

By how much?

- **We don’t know**

Risk of HIV transmission: if source is on ART

PARTNER study [2]

- Robust findings for **U=U**
- But only looked at **sexual transmission**

The 2020 SHEA guidelines [3]

- They appropriately highlight that needlestick is similar to single unprotected sexual encounter in terms of transmission risk
- **No cases** of healthcare workers (HCW) living with HIV transmitting to patients if HCW has VL < 1000
- But this is looking at **HCW → patient**, not patient → HCW transmission

Risk of HIV transmission: if source is on ART

Studies looking at PWID: Some observational studies [**4**] have implied that ART reduces HIV transmission among PWID

- Modeling estimates from Vancouver [**5**] project that **reduced transmission** **may be more related to** **reduced drug use** among PLHIV who are in treatment
- Given the large reduction attributable to reduced drug use, they did not find a large reduction **attributable to ART alone**

Immediate management of occupational HIV exposures

- Describe the **risk of HIV transmission** in occupational exposures
- Review the **immediate management** of occupational HIV exposures, including:
  - Suggested labs (from **source** & **exposed**)
  - Timeline of to start PEP
  - Situations that warrant PEP
- Discuss the **long-term management** of PEP
  - What agents to pick
  - Duration of PEP
  - Follow up testing
- Examine key differences of **PEP in pregnancy**
  - Risk of transmission
  - Which agents to use
  - Risk of breastfeeding
- Review the **intrapartum management** of HIV

Immediate management

1. Wash the area well
    - With soap & water
    - Other agents (alcohol, CHG) are virucidal to HIV
        - ➢ No evidence to support their use
2. Report it occupational health

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Makary et al (NEJM, 2007) [**6**]

Survey of 700 surgical residents

- By the end of residency:
    - **99%** had a needlestick
    - **53%** had a needlestick from a **high risk** patient
- Mean (PGY-5): **7.7 exposures**

Frequently not reported

- 51% did not report their most recent exposure
- 16% involved high risk patient

Who *do* the residents tell?

- Most common: attending (51%)
- Least: significant other (13%)

Immediate management: Source patient [7][8]

Source patient

- Ideally, source patient should be tested
- If source is known to be HIV (+), ask about:
  - Recent viral load
  - Treatment history
  - Any resistance

If source has *known HIV*, do not delay PEP while awaiting this info!

- Ideally, started within **1-2 hours of exposure**
- Cutoff: 72 hours
  - Exceptionally high risk: USPHS says can be up to a week (but likely very reduced effectiveness)

Immediate management: Exposed patient [8]

Baseline testing

- HIV, HCV, anti-HBs, HBsAg
- Baseline labs for PEP
- Pregnancy testing

Counseling the HCW

Discuss what their **risk of acquiring HIV**

- Many HCW may not know the *success of modern HIV treatment*, so they will have **understandable anxiety** about HIV/AIDS

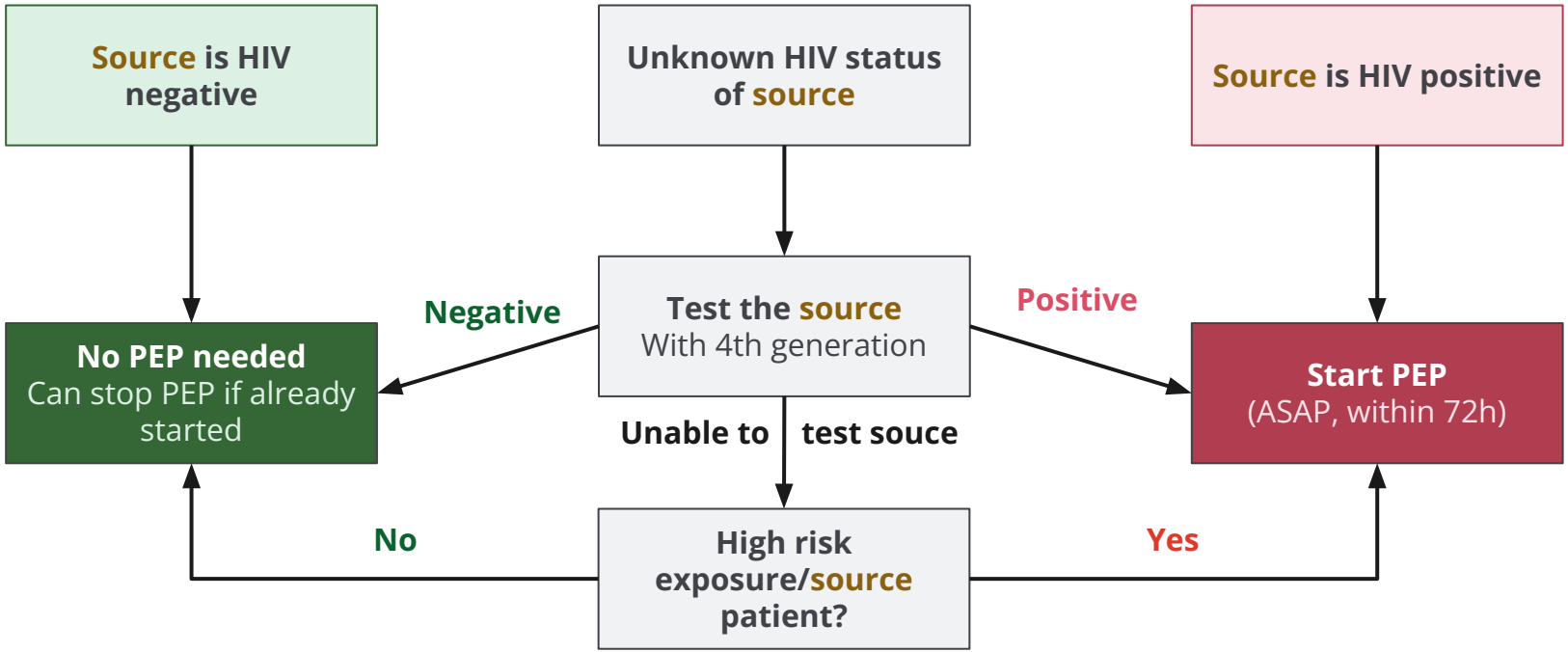
Discuss risk them (**exposed**) **transmitting HIV**

- Highest risk in first 6-12 weeks
- Need for condoms & not donating blood
- Watch out for **acute retroviral symptoms**

Discuss **side effects of PEP**

- One study showed only 60% adherence

When to start PEP? [8]



Management is different if the **source** is thought to potentially have **acute HIV** (beyond the scope of this talk)

Long-term management of PEP

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Suggested PEP: US Public Health Service [9]

Prefered HIV PEP regimen

TDF/FTC (daily)
Tenofovir /
Emtricitabine

+

RAL (BID)
Raltegravir

Notably, **not updated since 2013**

- This was right around when dolutegravir came to market

Suggested PEP: US Public Health Service [9]

Alternate HIV PEP regimens, in order of preference

One of the boxes below

- **RAL** (raltegravir)
- **DRV/r**
  Darunavir + ritonavir
- **ETR** (etravirine)
- **RPV** (rilpivirine)
- **ATV/r**
  Atazanavir + ritonavir
- **LPV/r**
  Lopinavir + ritonavir

-AND-

One of the boxes below

- **TDF/FTC** (Truvada)
  Tenofovir / emtricitabine
- **TDF + 3TC**
  Tenofovir + lamivudine
- **AZT/3TC** (Combivir)
  Zidovudine/lamivudine
- **AZT + FTC**
  Zidovudine + emtricitabine

Helpful in advanced CKD

Suggested PEP options: CDC & others [7][8][10]

2 NRTI + integrase inhibitor

TDF/FTC (daily)
Tenofovir / Emtricitabine

+

DTG (daily)
Dolutegravir

Suggested PEP options: CDC & others [7][8][10]

2 NRTI + integrase inhibitor

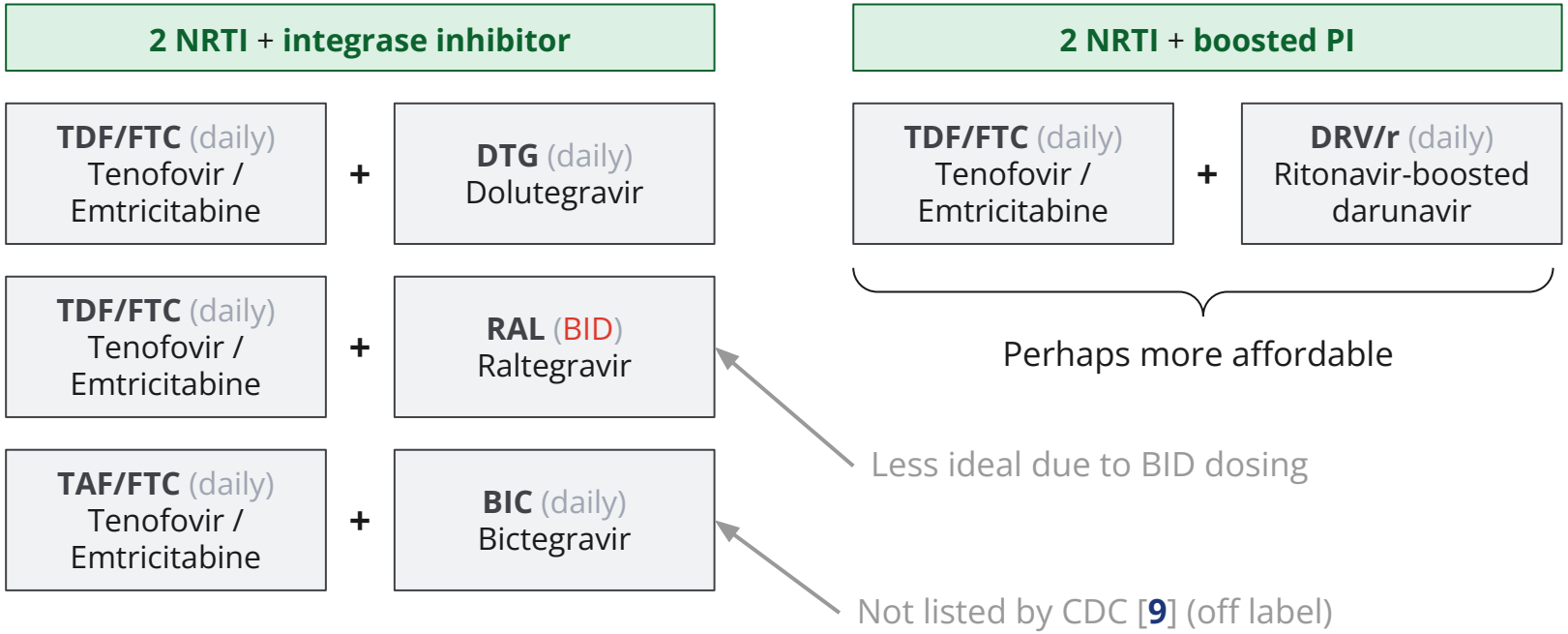
TDF/FTC (daily) Tenofovir / Emtricitabine	+	**DTG** (daily) Dolutegravir	
TDF/FTC (daily) Tenofovir / Emtricitabine	+	**RAL** (BID) Raltegravir	← Less ideal due to BID dosing

Suggested PEP options: ~~CDC~~ & others [7][8]

2 NRTI + integrase inhibitor

TDF/FTC (daily) Tenofovir / Emtricitabine	+	**DTG** (daily) Dolutegravir	
TDF/FTC (daily) Tenofovir / Emtricitabine	+	**RAL** (BID) Raltegravir	← Less ideal due to BID dosing
TAF/FTC (daily) Tenofovir / Emtricitabine	+	**BIC** (daily) Bictegravir	← Not listed by CDC [9] (off label)

Suggested PEP options: CDC & others [7][8][10]



Follow up: Duration of PEP & monitoring [8]

Duration of PEP: **28 days** from starting

Labs for PEP toxicity

- Monitor CBC, renal function, LFTs
- Obtain labs at **baseline** and **2 weeks**

Follow up: Duration of PEP & monitoring [8]

Duration of PEP: **28 days** from starting

Labs for PEP toxicity

- Monitor CBC, renal function, LFTs
- Obtain labs at **baseline** and **2 weeks**

Side effects of PEP

- Most common: GI (nausea, vomiting, and diarrhea)
  - Anti-emetics/diarrheals
- If severe, can switch to another regimen
- Watch out for **acute retroviral syndrome**

Follow up: HIV testing

For HIV testing:

- If **source patient** is HIV negative, no need for further testing of **exposed patient**
  - Unless worried that **source** had acute HIV
- USPHS (2013) [**9**]: Baseline, 6 weeks, 12 weeks, 6 months
  - This was before 4th gen screen became widely available
- Modern practice [**8**]: Baseline, 6 weeks, 3-4 months
- **Extended to 12 months** if **exposed** becomes **coinfected with HCV** [**8**][**9**]

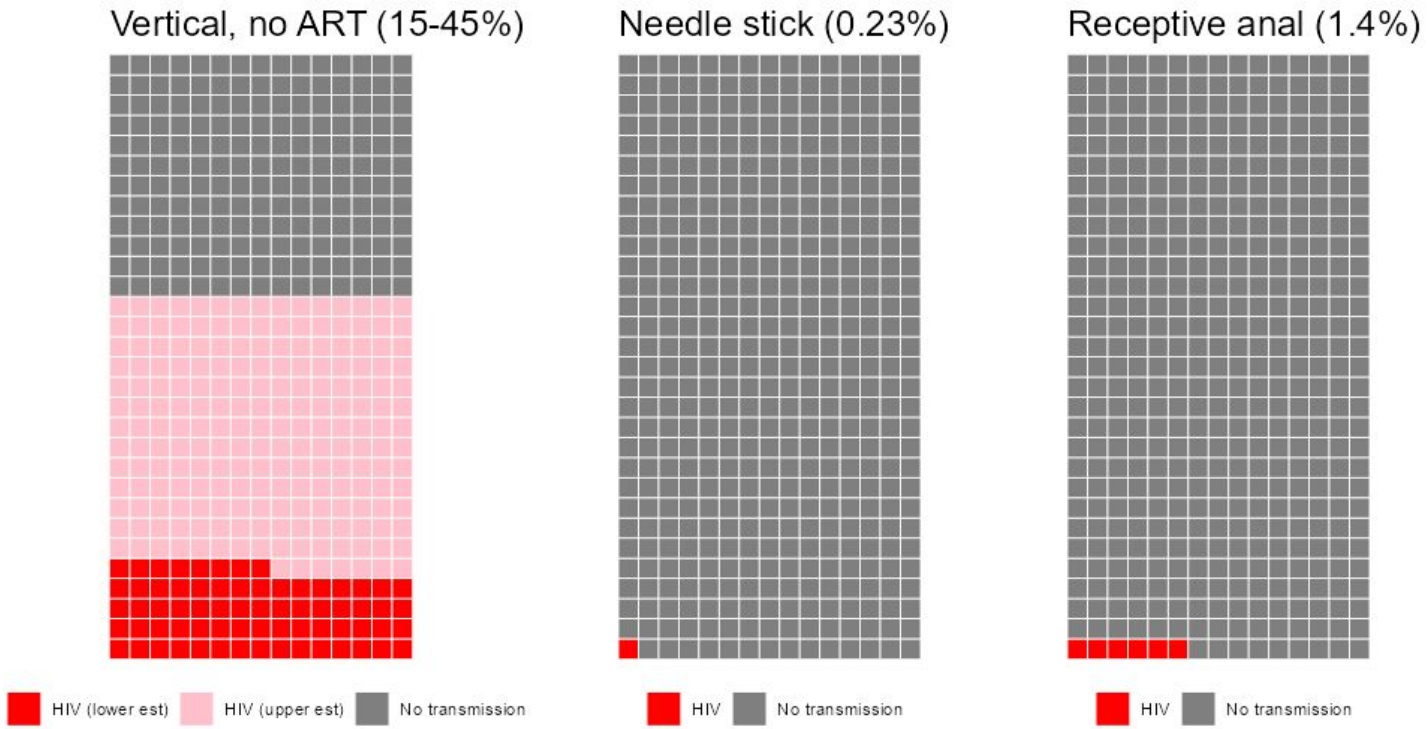
PEP in pregnancy

- Describe the **risk of HIV transmission** in occupational exposures
- Review the **immediate management** of occupational HIV exposures, including:
  - Suggested labs (from **source** & **exposed**)
  - Timeline of to start PEP
  - Situations that warrant PEP
- Discuss the **long-term management** of PEP
  - What agents to pick
  - Duration of PEP
  - Follow up testing
- Examine key differences of **PEP in pregnancy**
  - Risk of transmission
  - Which agents to use
  - Risk of breastfeeding
- Review the **intrapartum management** of HIV

Risk of vertical transmission

- Transmission rates of HIV (**without ART**) from mother to child range from **15-45%**, including from breastfeeding [**11**]

Risk of vertical transmission [11]



Risk of vertical transmission

- Transmission rates of HIV (**without ART**) from mother to child range from **15-45**%, including from breastfeeding [**11**]
- Without breastfeeding, it is estimated [**12**]
  - 30% of vertical transmissions occur in utero, the majority **during the 3rd trimester**
  - **70% occur during labor & delivery**
- Taking **ART during pregnancy** reduces the risk to **< 2%**
- If the mother has **acute HIV** during pregnancy, this **increases the risk by 2.3** [**13**]

PEP in pregnancy [7][8]

- Overall, **similar to HIV management in pregnancy** (& PEP in non-pregnant patients)
  - **Long term safety data is lacking**, most short term data is promising
  - Enroll patients in the **Antiretroviral Pregnancy Registry** (www.APRegistry.com)

PEP in pregnancy [7][8]

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  - **Long term safety data is lacking**, most short term data is promising
  - Enroll patients in the **Antiretroviral Pregnancy Registry** (www.APRegistry.com)

2 NRTI + integrase inhibitor

TDF/FTC (daily) Tenofovir / Emtricitabine	+	**DTG** (daily) Dolutegravir	← Originally thought to ↑ risk of neural tube defects, but later data showed no ↑ risk
TDF/FTC (daily) Tenofovir / Emtricitabine	+	**RAL** (BID) Raltegravir	
TAF/FTC (daily) Tenofovir / Emtricitabine	+	**BIC** (daily) Bictegravir	← Not enough safety data yet, so not recommended. Though early data is promising

PEP in pregnancy [7][8]

- Overall, **similar to HIV management in pregnancy** (& PEP in non-pregnant patients)
  - **Long term safety data is lacking**, most short term data is promising
  - Enroll patients in the **Antiretroviral Pregnancy Registry** (www.APRegistry.com)

2 NRTI + integrase inhibitor

TDF/FTC (daily) Tenofovir / Emtricitabine	+	**DTG** (daily) Dolutegravir
TDF/FTC (daily) Tenofovir / Emtricitabine	+	**RAL** (BID) Raltegravir
TAF/FTC (daily) Tenofovir / Emtricitabine	+	~~**BIC** (daily) Bictegravir~~

2 NRTI + boosted PI

TDF/FTC (daily) Tenofovir / Emtricitabine	+	**DRV/r** (daily) Ritonavir-boosted darunavir

Preferred option if needing PI

PEP in pregnancy [7][8][9]

2 NRTI backbone

- **TxF / xTC**
  Tenofovir / Emtricitabine
  Tenofovir / Lamivudine
- **AZT / 3TC**
  Zidovudine / Lamivudine

AND

Integrase inhibitor

- **DTG**
  Dolutegravir
- **RAL**
  Raltegravir

OR

PI

- **ATV/r**
  Atazanavir (boosted)
- **DRV/r**
  Darunavir (boosted)

OR

NNRTI

- **RPV**
  Rilpivirine

Must use ritonavir for boosting, as cobicistat boosted regimens have higher rates of virologic failure

Breastfeeding & PEP [8]

Breastfeeding is **not a contraindication for PEP**

- But should discuss infant's potential **risks of HIV transmission** & exposure to ART
- May consider "**pump & dump**" or storing breastmilk while awaiting results of **source patient's** HIV screen

	Risk of transmission in breastmilk
HIV	There is risk of transmission; the **highest risk** is during **acute HIV**
Tenofovir **Lamivudine** **Dolutegravir**	All three have been detected in breastmilk at **low levels** (subtherapeutic)
Raltegravir	Studies have been mixed

Perinatal HIV management

Biggest priority
Having mom on ART

- Describe the **risk of HIV transmission** in occupational exposures
- Review the **immediate management** of occupational HIV exposures, including:
  - Suggested labs (from **source** & **exposed**)
  - Timeline of to start PEP
  - Situations that warrant PEP
- Discuss the **long-term management** of PEP
  - What agents to pick
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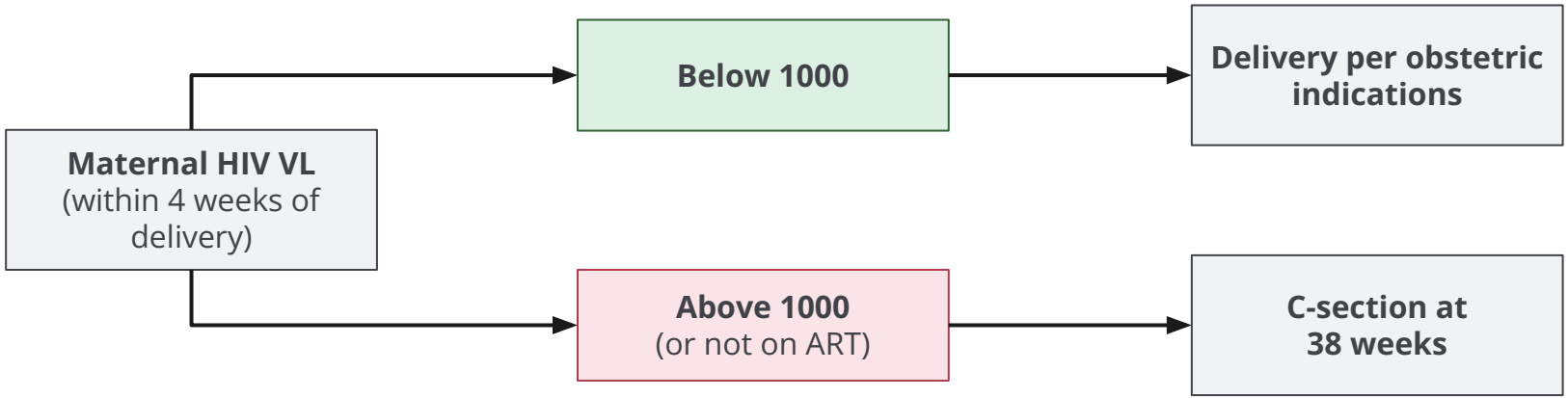
- Examine key differences of **PEP in pregnancy**
  - Risk of transmission
  - Which agents to use
  - Risk of breastfeeding
- Review the **intrapartum management** of HIV

Intrapartum HIV: Mode of delivery [14]

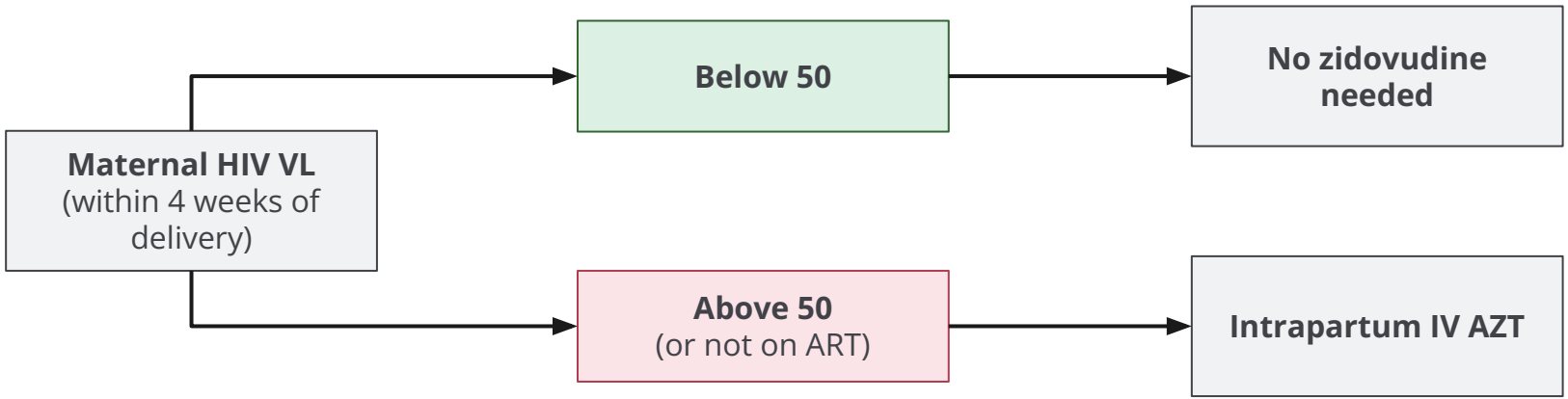
Historically, **C-sections** have been associated with **lower risk of mother to child transmission**

- Largely based off of data before widespread use of ART in pregnancy was common
- Now, mode of delivery is **largely informed by maternal viral load** (ideally within 4 weeks of delivery)



Intrapartum HIV: ART [14]

- Women should keep taking their ART before/during/after delivery
- Indications for **IV zidovudine** (ideally **started 3 hours before delivery**)
  - **VL below 50**: No benefit
  - **50 - 1000**: consider AZT
  - **>1000**: AZT (along with C-section)



Learning points & take aways

Learning points & take aways

- Risk to HIV transmission from occupation needle sticks are around 1 in 450, but likely lower if the source patient is on ART
- In the event of a needle stick, wash the area with soap & water and immediately report to occupational health or the ED to start PEP (ideally within 1-2 hours)
    - Ideally, obtain data on the source patient including HIV, HCV, and HBV status
    - For sources known to be HIV positive, recent viral load & treatment history is helpful
- HIV PEP is indicated when the source has HIV (or high risk source patient)
    - Suggested PEP: 28 days of TxF/xTC -plus- INSTI (DTG, RAL, ?BIC) or booster PI (DRV/r)
    - Monitor for toxicity (labs at baseline, 2 weeks) and side effects
    - Exposed patient should have HIV screen at baseline, 6 weeks, and 3-4 months (unless HCV+)
- PEP is similar in pregnancy (but perhaps more important given risk of transmission with acute HIV)
- At time of delivery, C-section & intrapartum AZT if VL is above 1000 &/or 50 (respectively)

Slides available on hunterratliff1.com/talk/; Citations available via QR code or via the "citations" button on the website