ashp MIDYEAR 2016
Clinical Meeting & Exhibition

PrEPping for Prevention…..Engaging Pharmacists in HIV Prevention Strategies

Melody L Berg, PharmD, MPH, BCPS-AQ ID, AAHIVP
Eric Farmer, PharmD, BCPS, AAHIVP

December 6, 2016

4:15-5:15pm

Disclosure

- The program chair and presenters for this continuing education activity have reported no relevant financial relationships.

Objectives

- Evaluate use of tenofovir/emtricitabine for Pre-exposure Prophylaxis (PrEP) for appropriate candidates and identify available resources to help patients with procurement of medication.
- Design an effective Post-Exposure Prophylaxis (PEP) regimen for your institution that includes an effective antiretroviral regimen that limits barriers to medication procurement and appropriate follow up care and testing.
- Justify guideline concordant intrapartum and postpartum antiretroviral regimens to prevent perinatal transmission of HIV from an HIV-infected mother to a fetus.

ashp® MIDYEAR 2016
Clinical Meeting & Exhibition

PrEPping us for the Future

Eric Farmer, PharmD, BCPS, AAHIVP
HIV Clinical Pharmacist
Indiana University Health, LifeCare Program

Objectives

- Identify eligible individuals for whom PrEP is indicated.
- Review current CDC recommendations for those eligible to receive PrEP.
- Discuss barriers and practical strategies to prescribing PrEP in your practice.

The Need for PrEP

- Approximately 1.2 million people are living with HIV/AIDS in the United States
  - Approx 1 in 6 (15.8%) are undiagnosed
  - Approx 50,000 new HIV infections annually in US
- Incidence of HIV is increasing or highest in:
  - Men who have sex with men (MSM)
  - Black/African Americans
  - Ages 13-14yo, 20-29yo
  - South, Midwest
- Approx 24.7% of MSM, 18.5% IV drug users, and 0.4% heterosexually active adults are estimated to have substantial risks for aquiring HIV consistent with a PrEP indication.
- Medical cost savings of averting 1 HIV infection: $229,800

CDC. HIV Surveillance Report, 2011; vol. 23 CDC. HIV Surveillance Report. 2012; vol. 24 (published 11/2014) MMWR Vol 64 (46) Nov 2015. Schackman R, et al. CROI 2015. Abstract 1104

Estimated Lifetime Risk of HIV Diagnosis

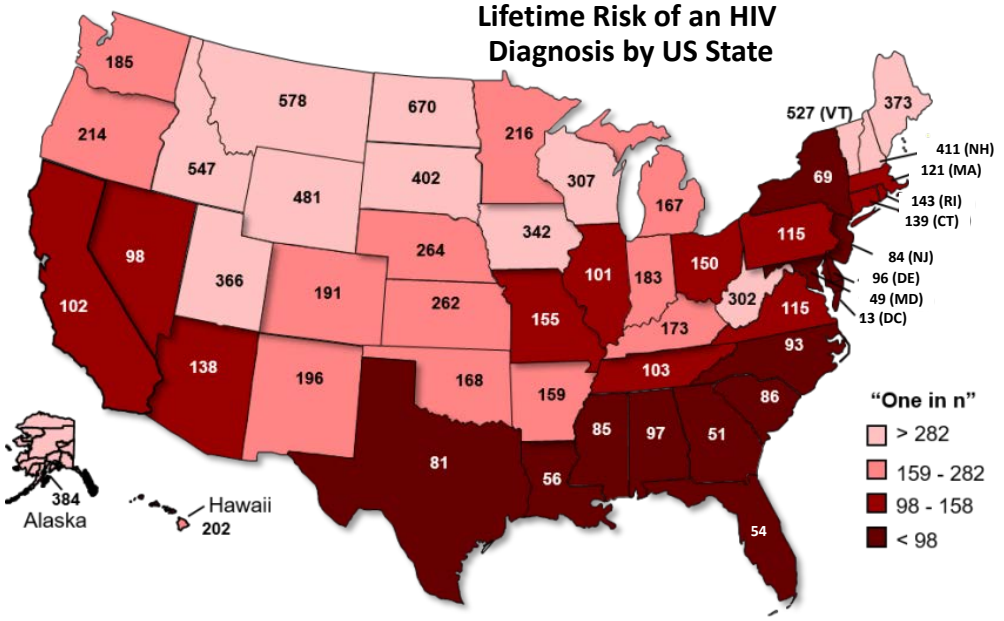
Mortality Data from National Center for Health Statistics (2009-2013, US census data)

Methods:

- HIV diagnoses and non-HIV deaths used to calculate the probability of HIV diagnosis at a given age
- Lifetime risk = cumulative probability of HIV diagnosis from birth (results presented as 1 in N)

Results: Lifetime Risk of Acquiring HIV

- Overall in USA: 1 in 99
- Black MSM: 1 in 2
- Hispanic MSM: 1 in 4
- White MSM: 1 in 11

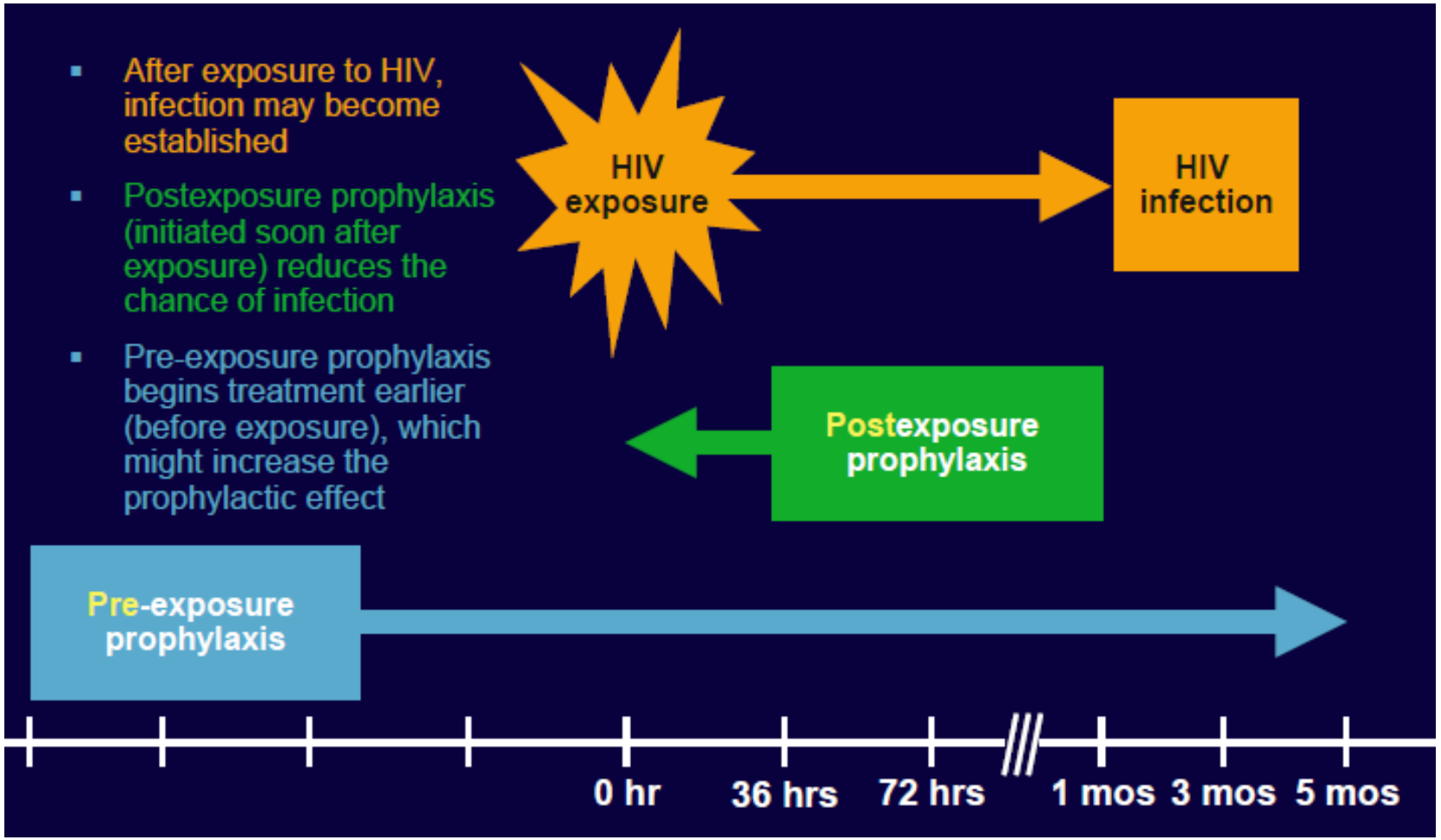


HIV Risk Group	Relative Risk	Lifetime Risk
Male vs female	4X for male	1 in 62 (2%) vs 1 in 221 (0.5%)
Male: black vs white	7X for black male	1 in 20 (5%) vs 1 in 132 (1%)
Female: black vs white	19X for black female	1 in 48 (2%) vs 1 in 880 (0.1%)
Male: IDU vs heterosexual	13X for PWID	1 in 36 (3%) vs 1 in 473 (0.2%)
MSM vs heterosexual male	79X for MSM	1 in 6 (17%) vs 1 in 473 (0.2%)

Lifetime risk may be a useful tool to more effectively communicate the risk of HIV to the general public and can help to highlight severe disparities

Hess K. et al. CROI 2016. Boston, MA. Oral 52

Pre- vs. Post- Exposure Prophylaxis



www.clinicalcareoptions.com/HIV

HIV Testing Recommendations

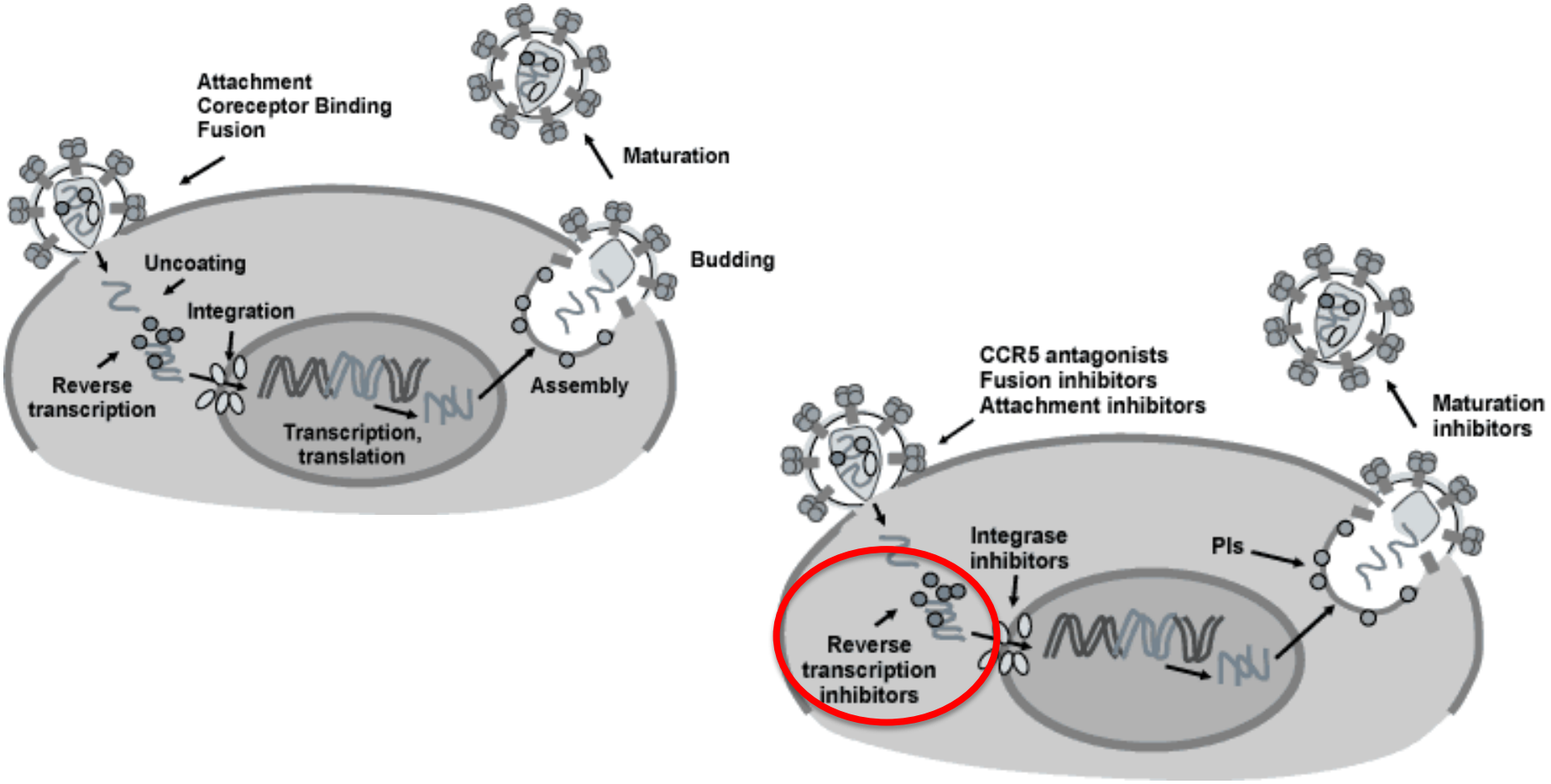
Routine for ALL patients aged 13-64 years of age in ALL healthcare settings.

Repeat testing at least annually for high risk patients.

	MSM	Heterosexual Women and Men	Injection Drug Users
Potential indicators of substantial risk of acquiring HIV infection	▪ HIV-positive sexual partner ▪ Recent bacterial STI ▪ High number of sex partners ▪ History of inconsistent or no condom use ▪ Commercial sex work	▪ HIV-positive sexual partner ▪ Recent bacterial STI ▪ High number of sex partners ▪ History of inconsistent or no condom use ▪ Commercial sex work ▪ In high-prevalence area or network	▪ HIV-positive injecting partner ▪ Sharing injection equipment ▪ Recent drug treatment (but currently injecting)

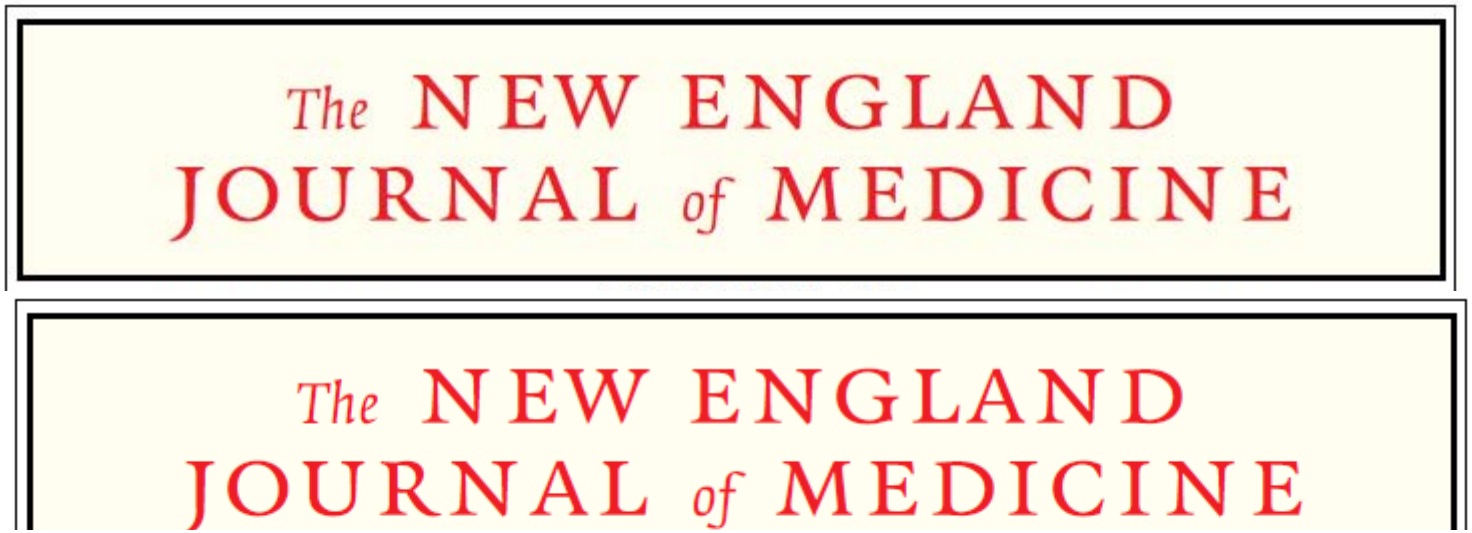
www.clinicalcareoptions.com/HIV CDC. PrEP Guidelines, 2014

How PrEP Works



www.clinicalcareoptions.com/HIV

Eligible PrEP Patients



Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial

Kachit Choopanya, Michael Martin, Pravan Suntharasamai, Udomsak Sangkum, Philip A Mock, Manoj Leethochawalit, Sithisat Chiamwongpaet, Praphan Kitisin, Pitinan Natrujirote, Somyot Kittimunkong, Rutt Chuachoowong, Roman J Gvetadze, Janet M McNicholl, Lynn A Paxton, Marcel E Curlin, Craig W Hendrix, Suphak Vanichseni, for the Bangkok Tenofovir Study Group

Grant RM, et al. *N Engl J Med*. 2010;363: 2587-2599
Baeten JM, et al. *N Engl J Med*. 2012;367:399-410
Choopanya K, et al. *Lancet*. 2013;381:2083-2090

PrEP Efficacy

Trial	Population/Setting	Intervention	Reduction in HIV Infection Rate, %
CAPRISA[1] (N = 899)	High-risk women in South Africa	▪ Coitally applied vaginal TFV gel	39
iPrEX[2] (N = 2499)	High-risk MSM 11 sites in US, South America, Africa, Thailand	▪ Daily oral TDF/FTC	44
Partners PrEP[3] (N = 4747)	Serodiscordant heterosexual couples in Africa	▪ Daily oral TDF ▪ Daily oral TDF/FTC	▪ Women: 71; men: 63 ▪ Women: 66; men: 84
TDF2[4] (N = 1219)	Heterosexual males and females in Botswana	▪ Daily oral TDF/FTC	62*
FEM-PrEP[5] (N = 2120)	High-risk women in Africa	▪ Daily oral TDF/FTC	▪ Equal numbers of infections in active and control arms ▪ Study stopped for lack of efficacy
Thai IDU[6] (N= 2413)	Volunteers from 17 Thai treatment centers	▪ Daily oral TDF	49

1. Abdool Karim Q, et al. Science. 2010;329:1168-1174. 2. Grant RM, et al. N Engl J Med. 2010;363: 2587-2599. 3. Baeten JM, et al. N Engl J Med. 2012;367:399-410. 4. Thigpen MC, et al. N Engl J Med. 2012;367:423-434. 5. Van Damme L, et al. N Engl J Med. 2012;367:411-422. 6. Choopanya K, et al. Lancet. 2013;381:2083-2090

www.clinicalcareoptions.com/HIV

Clinical Eligibility for PrEP

Prior to Prescribing PrEP	
Document negative HIV test results within 1 week of Rx	Do not accept patient-reported results
Check for normal renal function, UA	Not recommended for CrCl <60mL/min
Check for HBV infection	Consider vaccinating if not immune
Document pregnancy test if appropriate	Additional counseling on risks
Screen for STIs	Every visit
Screen for acute HIV infection symptoms	Every visit

Signs & Symptoms of Acute HIV Infection	
Fever	Myalgia
Rash	Headache
Pharyngitis	Diarrhea
Lymphadenopathy	Arthralgia

CDC. PrEP Guidelines 2014, www.clinicalcareoptions.com/HIV

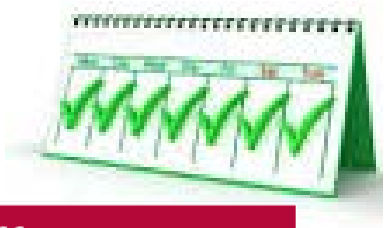
Celebration of Learning Question #1

Which of the following patient populations has the least evidence to support an indication for PrEP?

A. MSM
B. IVDU
C. HIV neg male in monogomous relationship with HIV pos female
D. Adolescents
E. HIV neg female with 3 regular sexual partners and 100% condom use for all sexual activity

PrEP Rx

- Emtricitabine/tenofovir DF 200/300mg 1 tablet daily
- Provide 3 month Rx
- Taken ***every day*** without regard to food



Common Side Effects
Nausea
Abdominal Discomfort
Diarrhea
Headache

Serious Side Effects
Rash
Renal Complications
Decreased BMD
Risk of Resistance

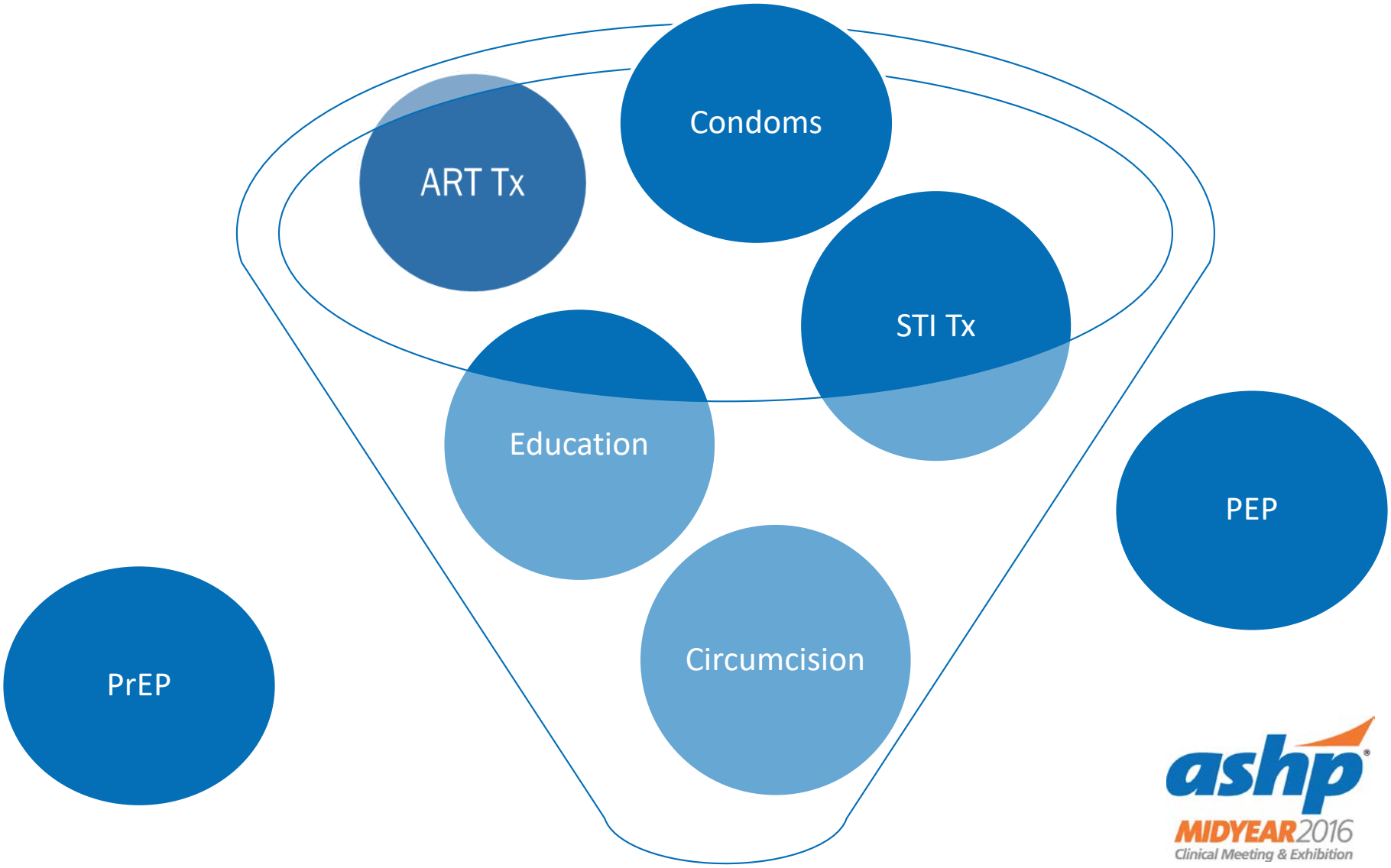
Time to Achieve "Therapeutic Protection"	
Site of Exposure	Time to Protection
Blood	20 days
Rectal Tissue	7 days
Vaginal Tissue	20 days

Follow up & Monitoring

Follow-up	At Least Every 3 Mos	After 3 Mos and at Least Every 6 Mos Thereafter	At Least Every 6 Mos	At Least Every 12 Mos
All patients	▪ HIV test ▪ Medication adherence counseling ▪ Behavioral risk reduction support ▪ Adverse event assessment ▪ STI symptom assessment	▪ Assess renal function 	▪ Test for bacterial STIs	▪ Evaluate need to continue PrEP
Women	▪ Pregnancy test (where appropriate)			
HBsAg+			▪ HBV DNA by quantitative assay*	

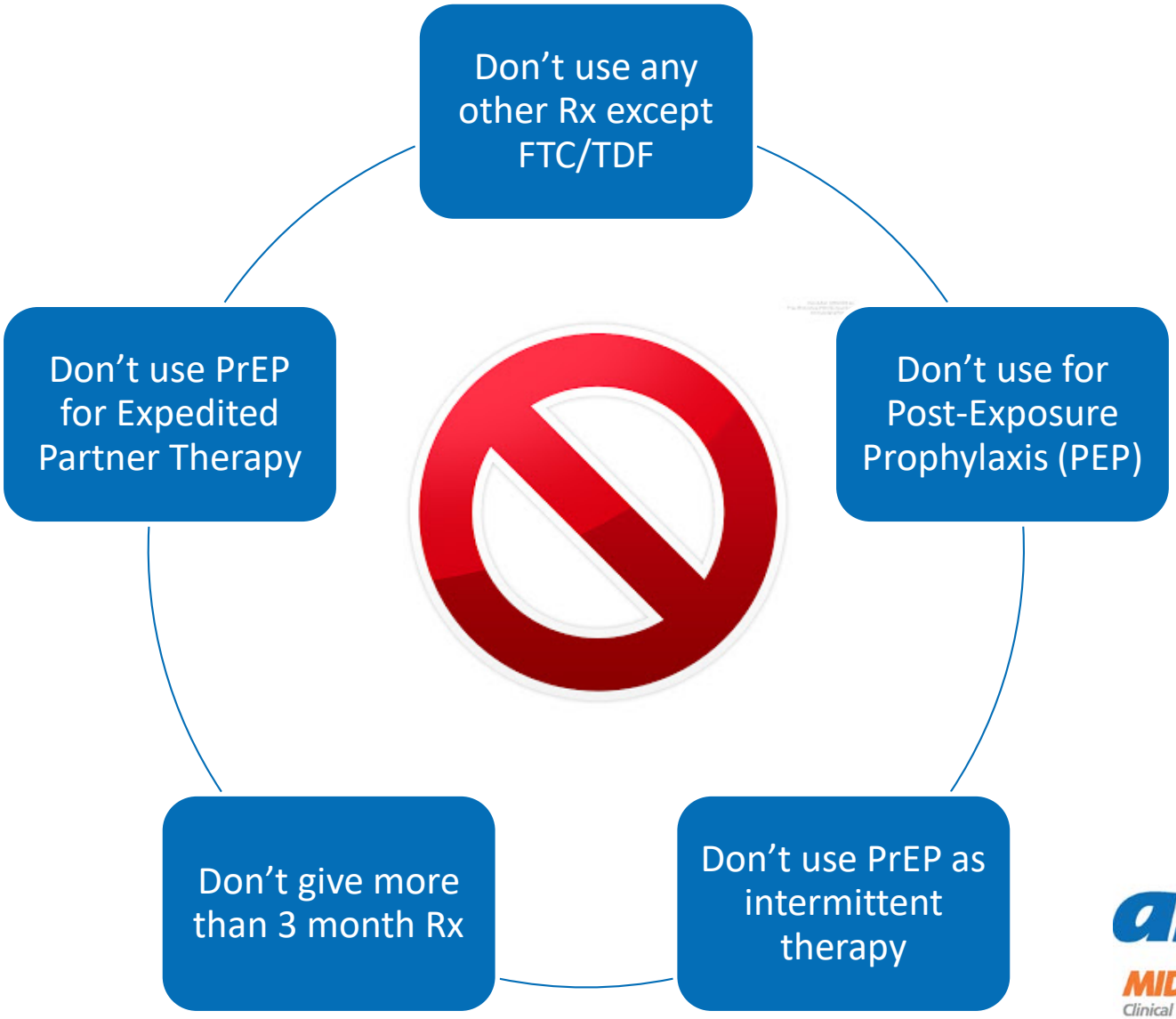
www.clinicalcareoptions.com/HIV CDC. PrEP Guidelines, 2014

Comprehensive Prevention Plan



Dos of PrEP

Don’ts of PrEP



Pearls of PrEP

- PrEP is NOT a cure or vaccine for HIV
- PrEP is NOT a “morning-after pill”
- Extra PrEP pills ≠ extra protection
- PrEP does NOT prevent pregnancy
- PrEP does NOT protect against other STIs
- PrEP is only for HIV-negative individuals
- PrEP works best when taken every day with other risk reduction strategies
- Every dose matters

Paying for PrEP

- Private insurance
  - Annual deductible
  - Copays & Coinsurance
- Gilead Copay Assistance Card
  http://www.gileadadvancingaccess.com/copay-coupon-card
- Truvada for PrEP Medication Assistance Program:
  1.855.330.5479 http://start.truvada.com

Celebration of Learning Question #2

Which of the following is NOT important to check at each PrEP follow up visit?

A. Urine drug screen
B. Adherence to medication
C. Screen for STIs
D. HIV test
E. Pregnancy test (if female)

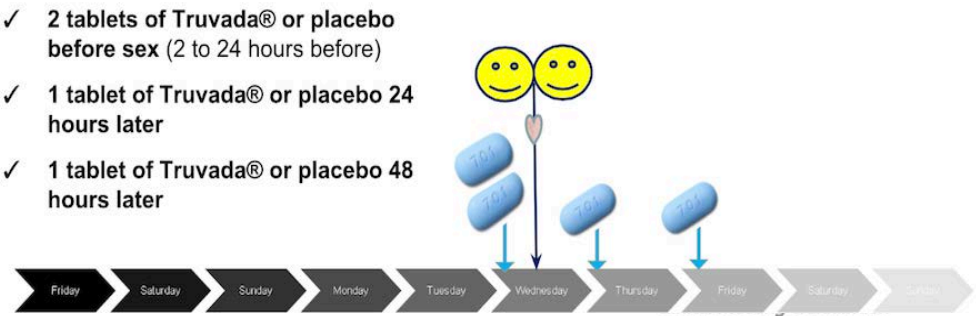
PrEP Resources

- http://www.cdc.gov/hiv/basics/prep.html
- http://nccc.ucsf.edu/clinical-resources/pep-resources/prep/
  PrEPline, 855-448-7737 11am-6pm EST
- http://whatisprep.org
- http://www.truvadapreprems.com/
- http://www.hivinsite.com/
- http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/
- https://aidsetc.org/
- http://www.clinicaloptions.com/HIV.aspx
- http://www.thebody.com

The Future of PrEP

- Cabotegravir: novel INSTI packaged in nanoparticles permitting monthly or quarterly IM dosing[1]
- Carbotegravir/rilpivirine long acting IM formulation allowing for Q4- or Q8-week dosing[2]
- Availability of new tenofovir formulation: tenofovir alafenamide (TAF) → less renal and bone adverse effects[3]
- Microbicides – vaginal gels, rings, etc.[4]
- PrEP "On-Demand"[5]

Ipergay : Event-Driven iPrEP



1. Andrews C, et al. CROI 2013 Abstract 24LB
2. Margolis DA, et al. CROI 2016 Abstract 31LB (LATTE 2)
3. Descovy Prescribing Information, Gilead Sciences, 2016.
4. Smith J, et al. CROI 2013 Abstract 25LB
5. Molina JM, et al. CROI 2015 Abstract 23LB (IPERGAY)

Celebration of Learning Question #3

For which of the following individuals is PrEP NOT indicated?

A. 18yo hispanic bisexual male, 4 male and female sexual partners over past year

B. 24yo white female, IV drug abuser, last use 3 years ago, has HCV infection

C. 40yo black male, MSM, monogamous relationship with HIV positive partner

D. 65yo white male, heterosexual, history of syphilis x3 in past year

E. 26yo white female, commercial sex worker, reports 100% condom use and no history of STIs

F. 30yo white homosexual male, denies sexual activity in past 18 months, denies IVDA, wishes to start PrEP

PrEP Key Takeaways

- PrEP is one prevention strategy, that may reduce the risk of HIV acquisition when used in combination with other risk reduction strategies.

- Evidence supports use of PrEP in MSM, heterosexual individuals, and IVDU engaged in high-risk behavior.

- Adherence to PrEP is crucial for success. Every dose matters.

ashp® MIDYEAR 2016
Clinical Meeting & Exhibition

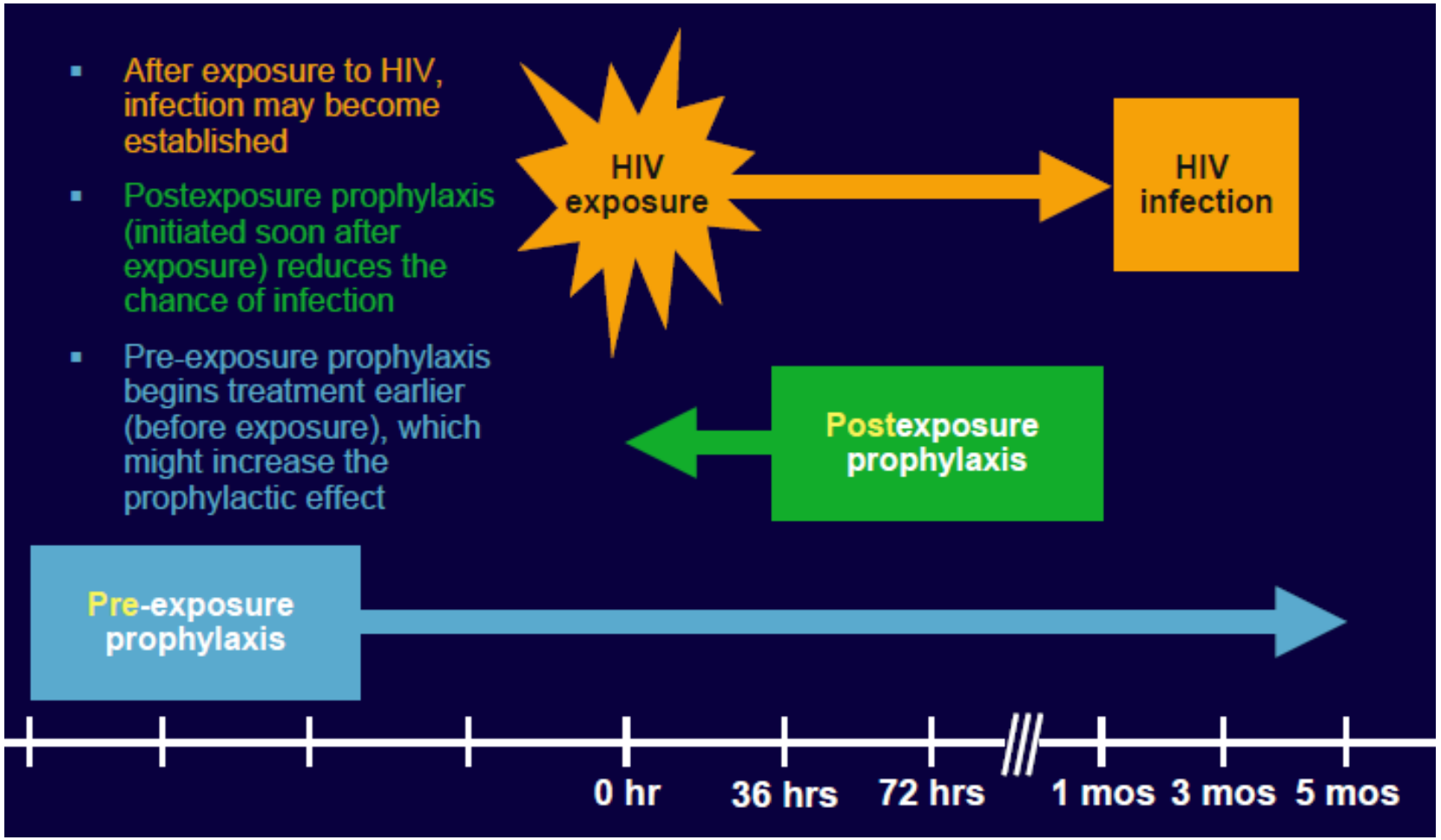
Keeping up with PEP

Eric Farmer, PharmD, BCPS, AAHIVP
HIV Clinical Pharmacist
Indiana University Health, LifeCare Program

Objectives

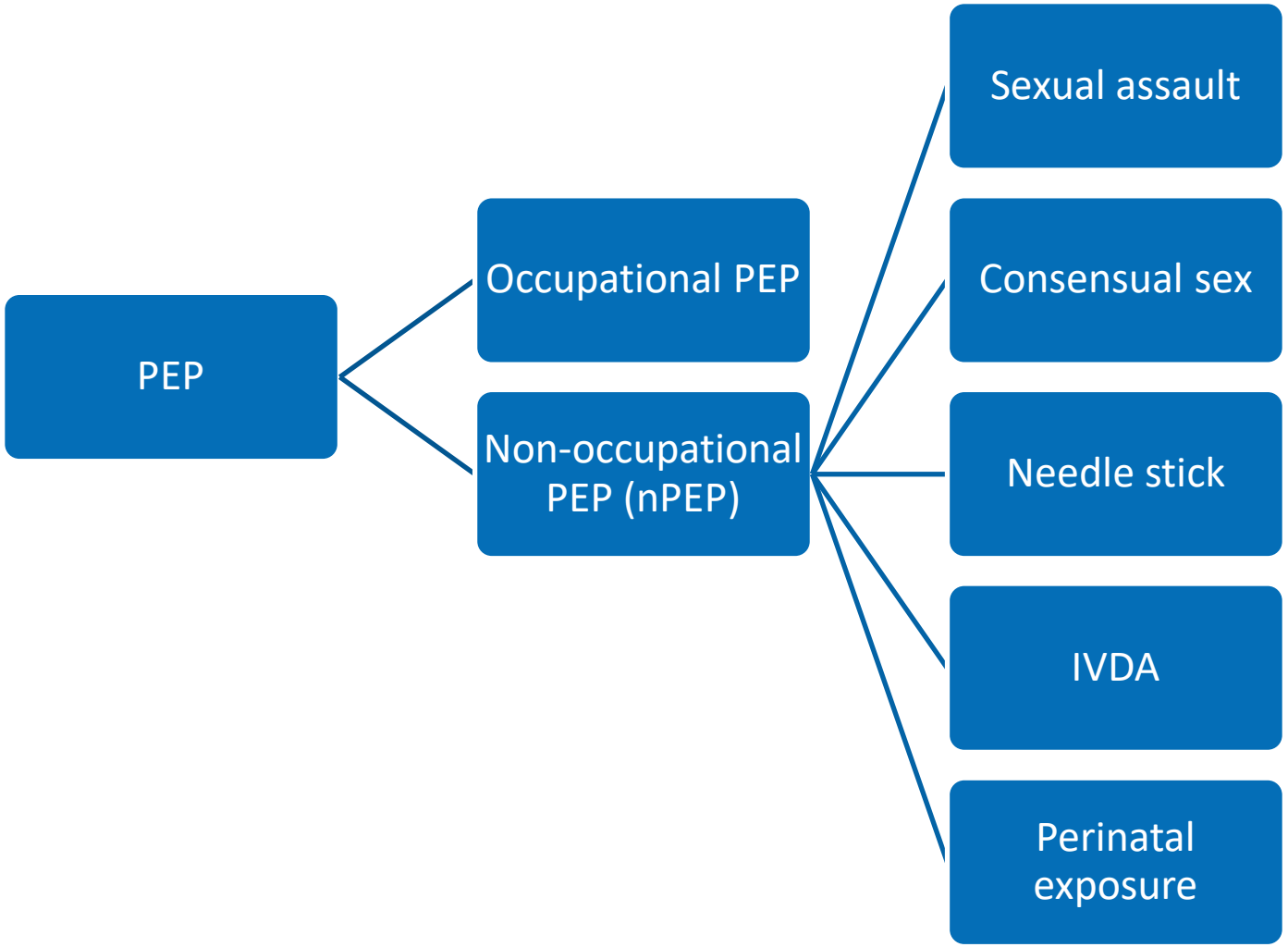
- Identify eligible individuals for whom PEP is indicated.
- List treatment recommendations for patients eligible to receive PEP.
- Review risk reduction counseling for patients receiving PEP.

Pre- vs. Post- Exposure Prophylaxis



www.clinicalcareoptions.com/HIV

Types of PEP

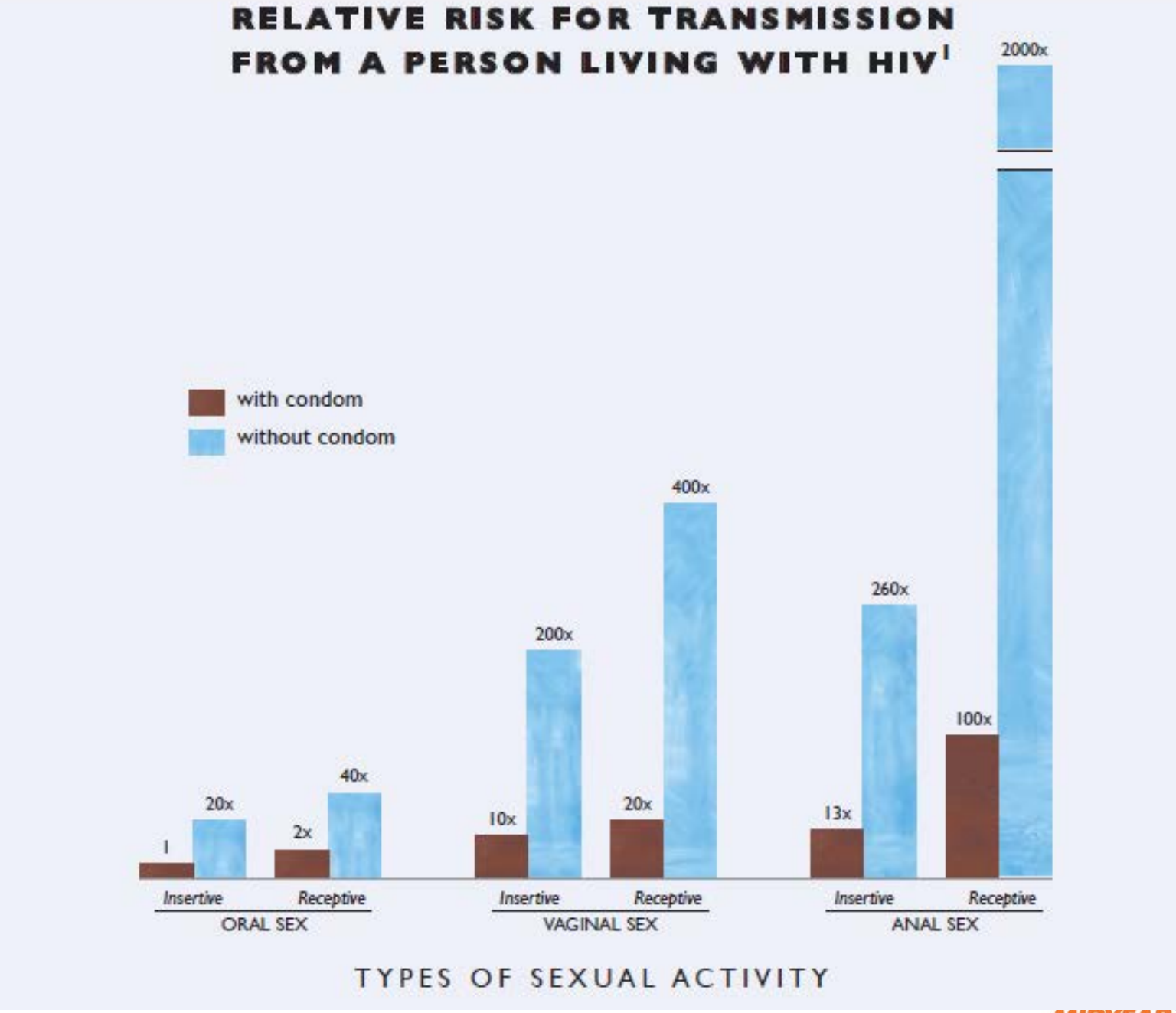

PEP
Occupational PEP
Non-occupational PEP (nPEP)
Sexual assault
Consensual sex
Needle stick
IVDA
Perinatal exposure

HIV Transmission

- Transmission modalities
  - Bodily fluids: blood, semen, vaginal fluid, breast milk
  - Mother to child (MTCT) “Vertical Transmission”
  - Intravenous drug use
  - Transfusions
- Transmission risk:

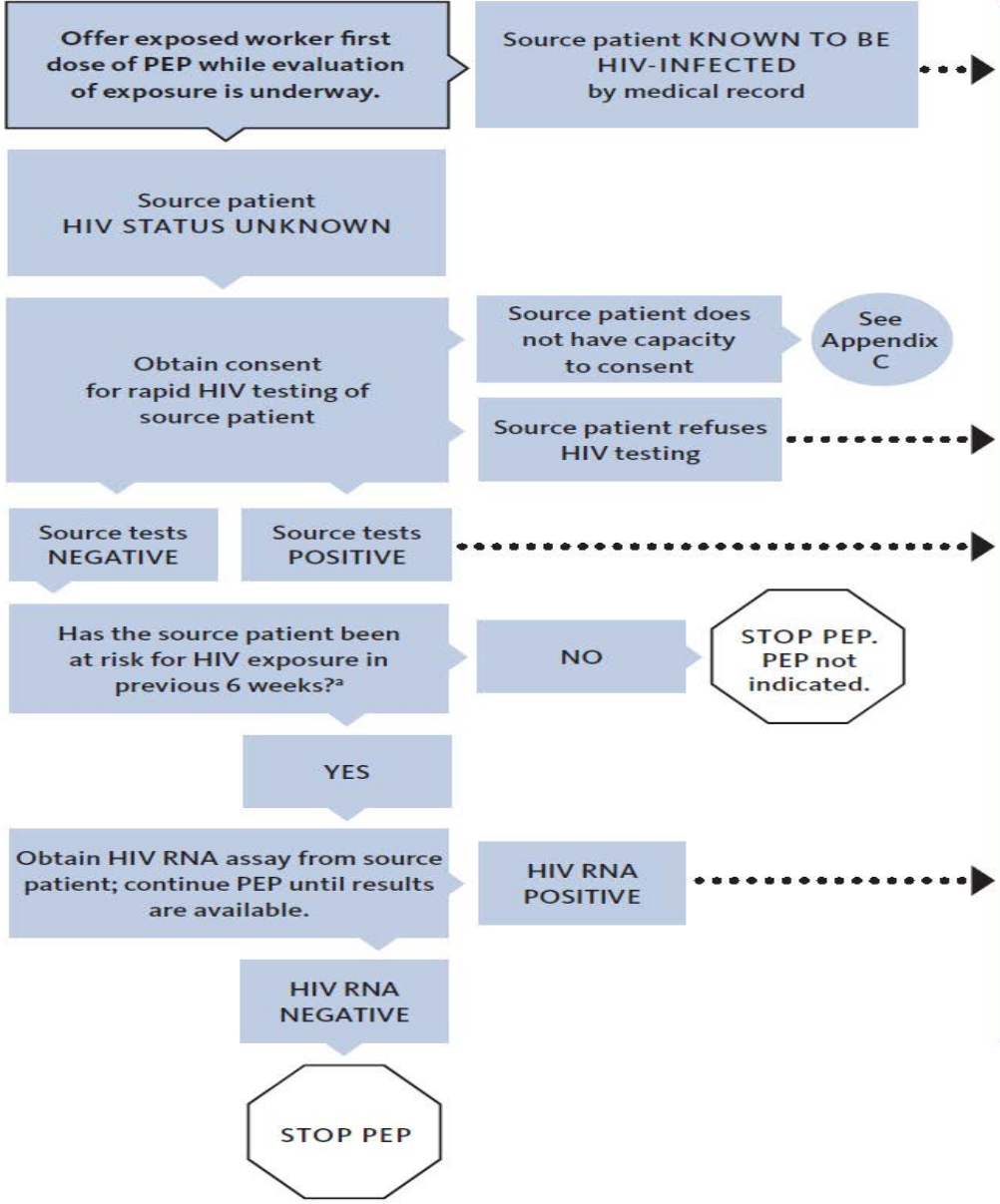
Blood transfusion	90%
Perinatal – no ART	25%
IVDA Needle sharing	0.67%
Receptive anal intercourse	0.5%
Percutaneous needle stick	0.3%
Receptive vaginal intercourse	0.1%
Receptive oral intercourse	0.01%

MMWR 54, Jan 2005



MMWR. 2003;52(RR1-12):9

PEP



COMPLETE 28-DAY REGIMEN:

Recommended PEP Regimen[b,c]

Tenofovir 300 mg PO qd
+
Emtricitabine[d] 200 mg PO qd

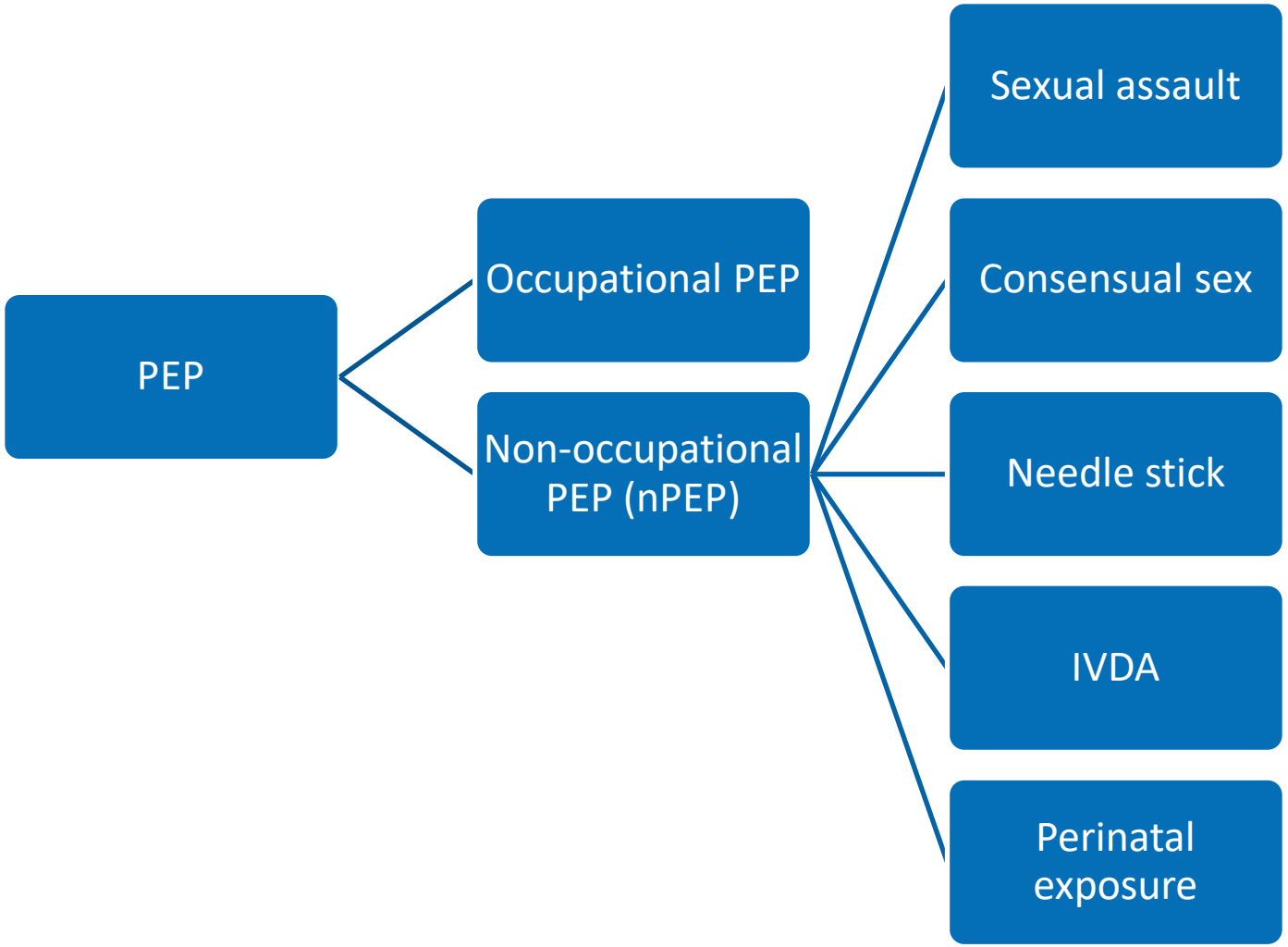
PLUS

Raltegravir[e] 400 mg PO bid
or
Dolutegravir[e] 50 mg PO qd

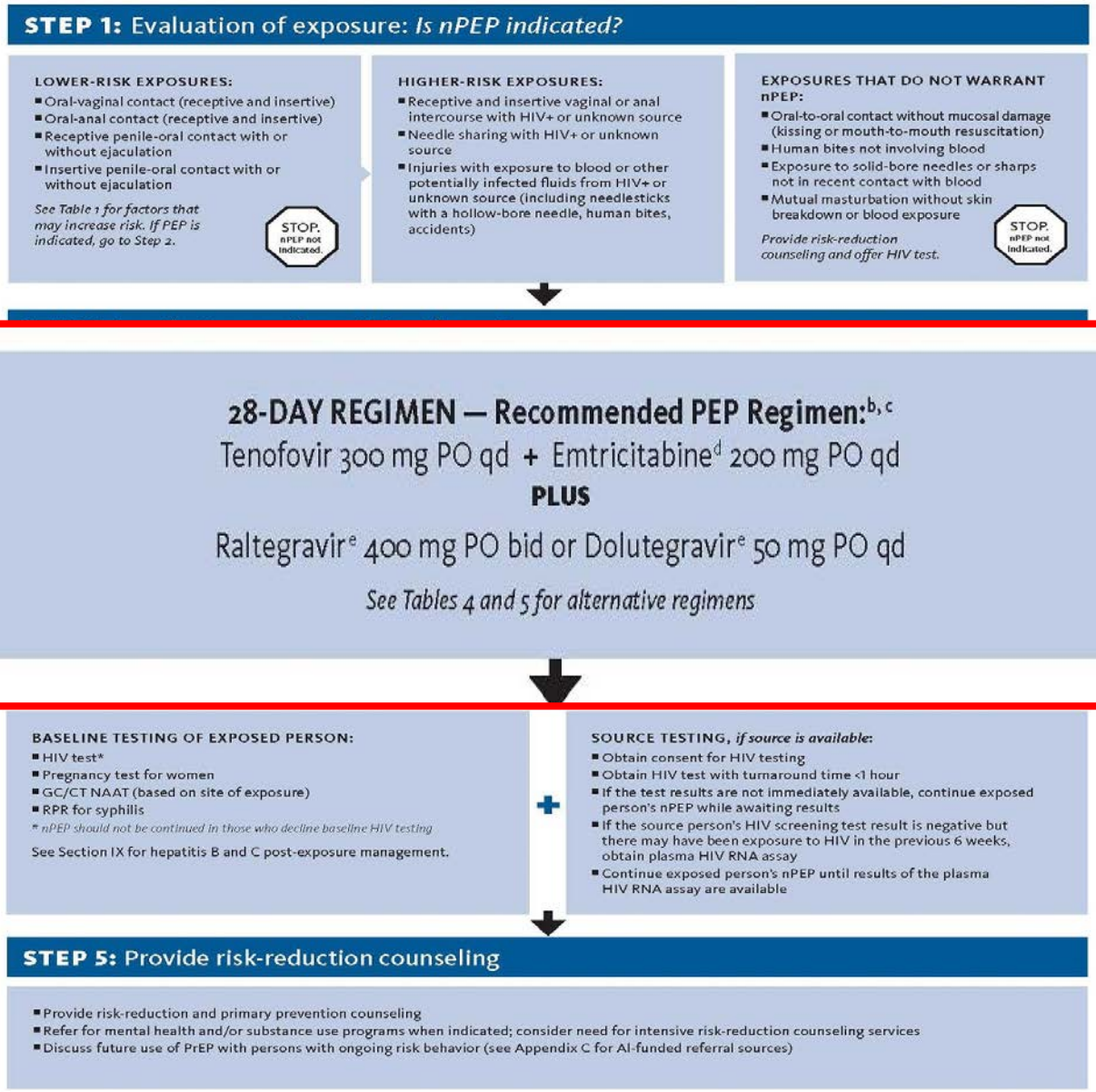
- Perform baseline confidential HIV testing of the exposed worker and refer to experienced clinician within 3 days of initiating PEP.
- See Tables 4 and 5 for alternative regimens.

http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-occupational-exposure

Types of PEP


PEP
Occupational PEP
Non-occupational PEP (nPEP)
Sexual assault
Consensual sex
Needle stick
IVDA
Perinatal exposure

nPEP



http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/

PEP Monitoring

Monitoring Recommendations						
	Baseline	Week 1	Week 2	Week 3	Week 4	Week 12
Clinic Visit	X	X or phone	X or phone	X or phone	X	
Pregnancy Test	X					
BMP, LFTs, CBC	X		X		X	
HIV Test	X				X	X

http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-occupational-exposure/

Celebration of Learning Question #4

Which of the following ART regimens is most appropriate to recommend for occupational PEP after a needle stick injury?

A. Lopinavir/ritonavir + lamivudine/zidovudine x28 days
B. Isentress + emtricitabine/tenofovir x14 days
C. Emtricitabine/tenofovir/efavirenz x28 days
D. Emtricitabine/tenofovir/elvitegravir/cobicistat x14 days
E. Dolutegravir + emtricitabine/tenofovir x28 days

Risk Reduction Counseling

- Avoid blood, plasma, organ, tissue, semen, or egg donations
- Avoid breastfeeding or pregnancy for 6-12 weeks
- Use contraceptive barrier (condom) for sexual intercourse
- No special precautions at work or change in patient care responsibilities
- Adherence to antiretroviral regimen for full course
- HIV transmission and disease education

Case 1: The Unlucky Shopper

- 24yowm presents to ED requesting PEP
- Shopping at TJ Maxx for jeans. While trying on a pair, he put his hands into the pockets and claims he was stuck on palm of R hand by hypodermic needle.
- Immediately left store; did not bring needle with him
- Did not report to store
- To PEP or Not to PEP?

The Unlucky Shopper

- PMH: Depression, Recent cocaine abuse
- Rx: No meds
- NKDA
- SH: Sexually active with multiple female partners; inconsistent condom use

- PLAN: PEP x28 days would be recommended despite improbability of his story

Case 2: The Frequent Flyer

- 49yobm presents to ED requesting PEP
- Engaged in unprotected vaginal sex with HIV-positive girlfriend yesterday
- Has received PEP due to similar incidents twice in past year
- To PEP or Not to PEP?

The Frequent Flyer

- PMH: Hypertension, Gout
- Rx: Lisinopril
- NKDA
- SH: 1/2ppd tobacco x30 years, reports “100%” condom use for all sexual activity; has private insurance
- GF has history of several resistance mutations

- PLAN: PEP x28 days given. Prescribed same Rxs as wife due to concerns for possible transmitted resistance. Discussed risk reduction strategies and referred to local clinic for PrEP

Case 3: The Worried Well

- 24yowf researcher in lab processing blood samples for cancer treatment study
- Accidentally touched a piece of paper with a smear of dried blood specimen on it with pad of R index finger
- No open wounds and no blood transferred to patient's finger
- Source patient HIV status unknown
- Has almost healed paper cut on L index finger and worried about exposure after vigorously washing injury
- To PEP or Not to PEP?

The Worried Well

- PMH: Migraines
- Rx: oral contraceptive
- Allergy: Sulfa
- SH: In a monogamous relationship with HIV neg male; private insurance

- PLAN: PEP not recommended. Provide supportive listening and review HIV transmission risks

PEP Key Takeaways

- Be familiar with your institution's PEP protocols and verify the protocols are reviewed and updated regularly.
- PEP is recommended if the patient presents within 72h of the exposure and treatment should last 28 days.
- Assess each PEP situation and provide appropriate referrals (i.e. PrEP) and risk reduction counseling.

ashp® MIDYEAR 2016
Clinical Meeting & Exhibition

Towards an HIV-Free Generation: Understanding Methods to Prevent Perinatal HIV Transmission

Melody L. Berg, PharmD, MPH, BCPS-AQ ID, AAHIVP
Senior Clinical Content Specialist
Wolters Kluwer Health

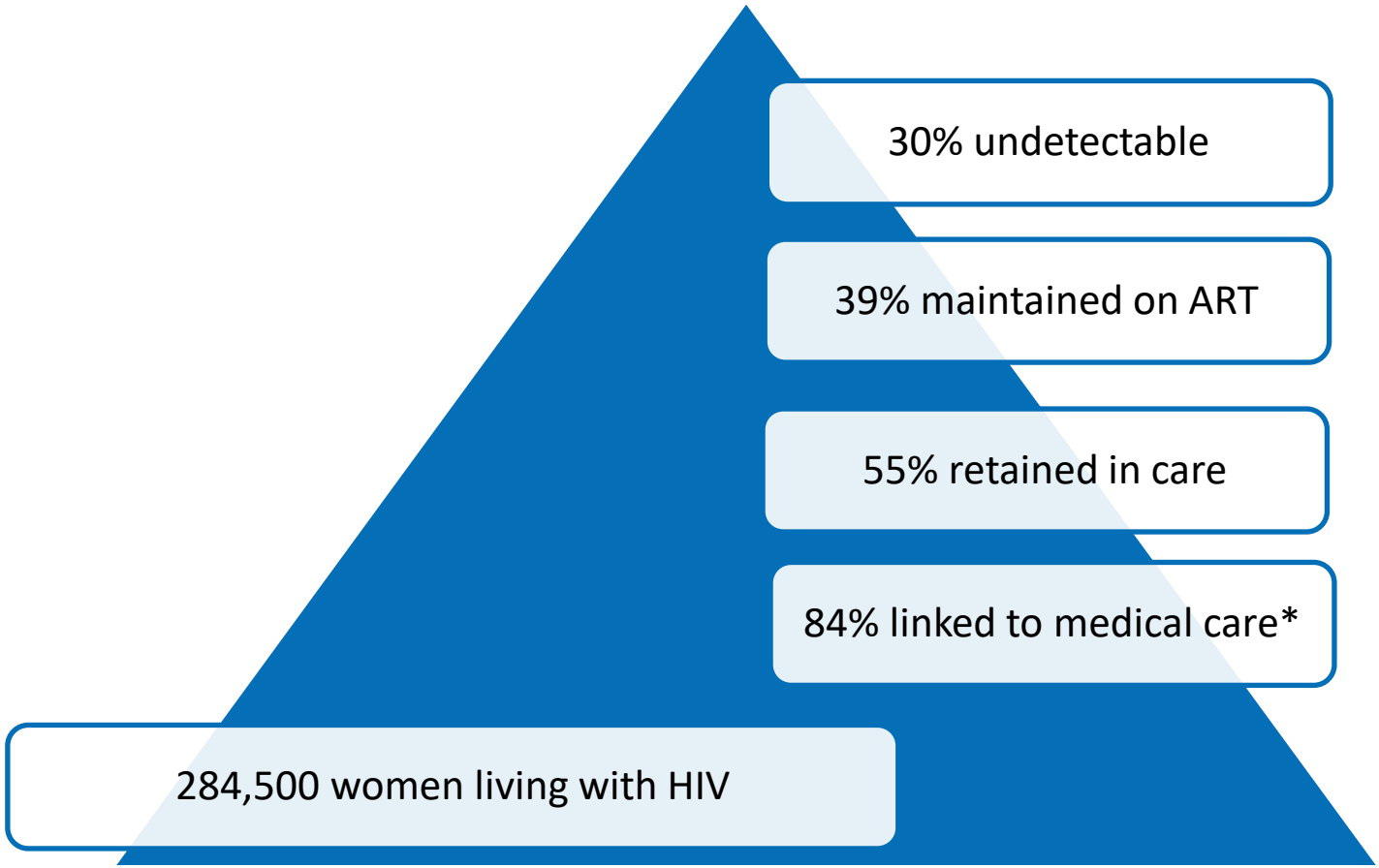
Objectives

- Identify areas for intervention to prevent perinatal HIV transmission
- Discuss pros and cons of PrEP use in a pregnant woman
- Formulate an effective intrapartum protocol to prevent perinatal HIV transmission for your institution
- Select an appropriate infant antiretroviral prophylaxis regimen

Case

JK is a 28-year-old woman with no significant past medical history who presents to her obstetrician reporting recent positive home pregnancy test. Her last menstrual period was 6 weeks prior. She takes no medicines and denies any history of allergies to medicines. She denies tobacco and illicit substance use but admits to 6-7 alcoholic beverages per week. She is currently in a monogamous relationship and is employed as a preschool teacher. She reports 3 lifetime sexual partners including her current partner.

Women and HIV



*within first 3 months

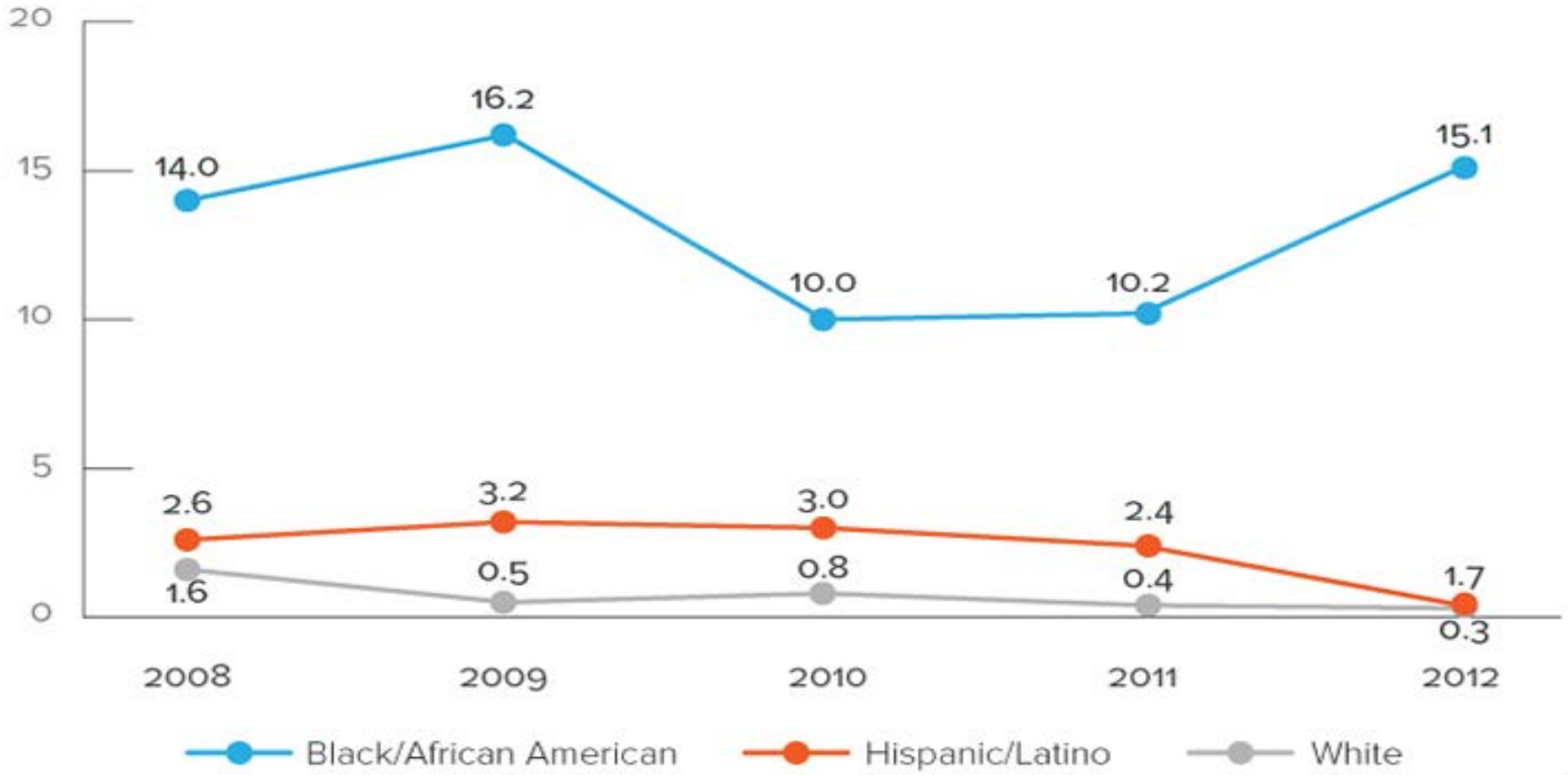
http://www.cdc.gov/hiv/group/gender/women/index.html. Accessed 9/13/16.

HIV and Children

- 174 children diagnosed with HIV in 2014, 73% via perinatal transmission
- 1,999 children living with perinatally-acquired HIV in 2013; 9,131 adolescents living with perinatally-acquired HIV in 2013
- 4,998 children diagnosed with AIDS have died since beginning of epidemic through 2013, 91% were perinatally-acquired

http://www.cdc.gov/hiv/group/gender/pregnantwomen/. Accessed 9/13/16.

Rates (per 100,000 live births) of perinatally-acquired HIV infections by year of birth and mother's race/ethnicity, 2008–2012



http://www.cdc.gov/hiv/group/gender/pregnantwomen/. Accessed 9.13.16.

Case Question #1

- Would you recommend HIV testing for JK?
- What if this was her first partner?

Modes of Transmission

- Antepartum
- Intrapartum
- Postpartum

Antepartum Prophylaxis

Known HIV Infection

- Preconception counseling
- Appropriate ART treatment and follow-up
- Birth Plan

Unknown HIV Infection

- Test, Test, Test
- PrEP candidate?
- Appropriate ART treatment, if necessary

Case Question #2

- JK tests positive for HIV. Her CD4 is currently 574 cells/mcl. Her HIV RNA is 22,000 copies/ml. All other labs are within normal limits. Her HIV genotype test did not reveal any antiretroviral resistance. What regimen would you recommend for JK?
  - Zidovudine/lamivudine + lopinavir/ritonavir
  - Tenofovir DF/emtricitabine/efavirenz
  - Abacavir/lamivudine + atazanavir + ritonavir
  - Zidovudine/lamivudine + raltegravir

Antepartum Antiretroviral Therapy for ART-Naive

2-NRTI Backbone		Preferred PI regimen		Preferred NNRTI regimen		Preferred INSTI Regimen
Abacavir/ Lamivudine	PLUS	Atazanavir/ ritonavir	OR	Efavirenz	OR	Raltegravir
Tenofovir DF/ Emtricitabine		Darunavir/ ritonavir				
Zidovudine/ Lamivudine						

https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/180/intrapartum-antiretroviral-therapy-prophylaxis. Accessed 9/13/16.

Revisiting Case Question #2

- Zidovudine/lamivudine + lopinavir/ritonavir
- Tenofovir DF/emtricitabine/efavirenz
- Abacavir/lamivudine + atazanavir + ritonavir
- Zidovudine/lamivudine + raltegravir

Lopinavir/ritonavir versus Efavirenz for Antepartum Prophylaxis

Methods

- Open-label, randomized study
- December 2009-March 2013 in Uganda
- 12-28 weeks gestation, no ART in preceding 24 months, all with zidovudine/lamivudine backbone

Results

- 391 enrolled
  - 173 women received efavirenz
  - 175 women received lopinavir/ritonavir
- 97.6% with UD VL at delivery in efavirenz arm vs. 86% in lopinavir/ritonavir arm
- 2 infants infected with HIV (both in lopinavir/ritonavir arm)
- No differences between groups in adverse events

Cohan D et al. *AIDS*. 29(2); 2015. 183-191.

Panel's Recommendations for Intrapartum Antiretroviral Therapy/Prophylaxis

Panel's Recommendations
• Women should continue their antepartum combination antiretroviral therapy (cART) drug regimen on schedule as much as possible during labor and before scheduled cesarean delivery **(AIII)**. • Intravenous (IV) zidovudine should be administered to HIV-infected women with HIV RNA >1,000 copies/mL (or unknown HIV RNA) near delivery **(AI)**, but is not required for HIV-infected women receiving cART regimens who have HIV RNA ≤1,000 copies/mL during late pregnancy and near delivery and no concerns regarding adherence to the cART regimen **(BII)**. Scheduled cesarean delivery at 38 weeks' gestation (compared to 39 weeks for most indications) is recommended for women who have HIV RNA >1,000 copies/mL near delivery (see Transmission and Mode of Delivery) **(AI)**. • Women who present in labor with unknown HIV status should undergo expedited HIV testing **(AII)**. If the results are positive, a confirmatory HIV test should be done as soon as possible and maternal (IV zidovudine)/infant (combination antiretroviral [ARV] prophylaxis) ARV drugs should be initiated pending results of the confirmatory test **(AII)**. If the maternal confirmatory HIV test is positive, infant ARV drugs should be managed as discussed in the Infant Antiretroviral Prophylaxis section **(AI)**; if the maternal confirmatory HIV test is negative, the maternal and infant ARV drugs should be stopped.

https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/180/intrapartum-antiretroviral-therapy-prophylaxis. Accessed 9/13/16.

To AZT or not to AZT: That Is the Question?

Methods

- French Perinatal Cohort
- January 1997-December 2010
- Women who received ART during pregnancy and didn't breastfeed were included
- Compared those who received IV AZT to those who didn't

Results

- 11,538 women included
  - 10,984 received AZT
  - 554 did not receive AZT
- VL ≥ 1000 copies/ml at delivery
  - MTCT: 7.5% without IV AZT
  - MTCT: 2.9% with IV AZT
- VL ≤ 400 copies/ml at delivery
  - **MTCT 0% with IV AZT**
  - MTCT 0.6% without IV AZT
- No significant differences in hematological malignancies

Briand N et al. *CID*. 57. 2013. 903-14.

Case Question #3

JK presents to the hospital at 37 weeks in labor. She was most recently seen by her HIV provider at 34 weeks where her viral load was 545 copies/ml. Would you recommend she receive IV zidovudine?

- Should she have a c-section?

Postpartum Prophylaxis

- Infant antiretroviral prophylaxis
  - Oral zidovudine x 6 weeks (4 weeks can be considered)
  - High risk: Oral zidovudine x 6 weeks + oral nevirapine (birth, 48h, 96h)
  - Dosing based on neonatal age
- Infant testing (birth?, 14-21 days, 1-2 months, 4-6 months)
- Treatment for mom
- Breast is best?

https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/187/infant-antiretroviral-prophylaxis. Accessed 9/13/16
https://aidsinfo.nih.gov/guidelines/html/2/pediatric-arv-guidelines/121/zidovudine. Accessed 9/13/16.

Do we have to do Zidovudine for 6 weeks?

Methods

- Retrospective, cohort
- HIV-exposed children between January 2000-December 2010
- Zidovudine duration (2-6 weeks), and nevirapine addition, stratified based on transmission risk

Results

- 114 infants (79 low-risk, 28 high-risk, 11 very high-risk)
- Transmission risk = 1.8% (0.9% when protocol followed)
- 2-week zidovudine group = 1.4%
- No significant differences in hematologic parameters based on zidovudine duration

Neubert J et al. BMC Pregnancy and Childbirth. 13(22). 2013.

1, 2 or 3? Evaluating Postpartum Prophylaxis Regimens

Methods

- Prospective, randomized, cohort study
- 3 study groups:
  - zidovudine alone x 6 weeks
  - zidovudine x 6 weeks + nevirapine x 3 doses
  - zidovudine x 6 weeks + nelfinavir x 2 weeks + lamivudine x 2 weeks

Results

- 1684 infants (566 single-drug, 562 two-drug, 556 in three-drug)
- Transmission rate 5.7% at 3 months:
  - 4.8% in single-drug
  - 2.2% in two-drug regimen
  - 2.4% in three-drug
- Neutropenia occurred most frequently in 3-drug regimen group

Nielsen-Saines K et al. N Engl J Med. 366(25): 2368-79. 2012.

Case Question #4

JK delivered a healthy baby boy via c-section and received IV zidovudine. Which of the following would you recommend for Baby Boy?

- Zidovudine orally x 6 weeks
- Zidovudine orally x 4 weeks
- Zidovudine orally x 6 weeks + nevirapine orally x 3 doses
- Initiate a 3-drug antiretroviral regimen immediately as baby is likely infected

But What About the Mississippi Baby?

SCIENTIFIC AMERICAN

HIV Detected in "Cured" Mississippi Baby, Creating Huge AIDS Therapy Setback

The infant was placed back on medication but the clinical trial to replicate virus suppression is still expected to proceed

The Washington Post

To Your Health

False hope from 'cure' of Mississippi baby with HIV leads to resurgence of virus in second child

Key Takeaways

- Testing and identification of infection early is key to prevention

- HIV-negative pregnant women at high risk for HIV acquisition should be considered PrEP candidates

- Intrapartum intravenous zidovudine and neonatal antiretroviral prophylaxis can be tailored based on risk stratification