HIV prevention strategies: TasP, PEP & PrEP

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MNCLHD

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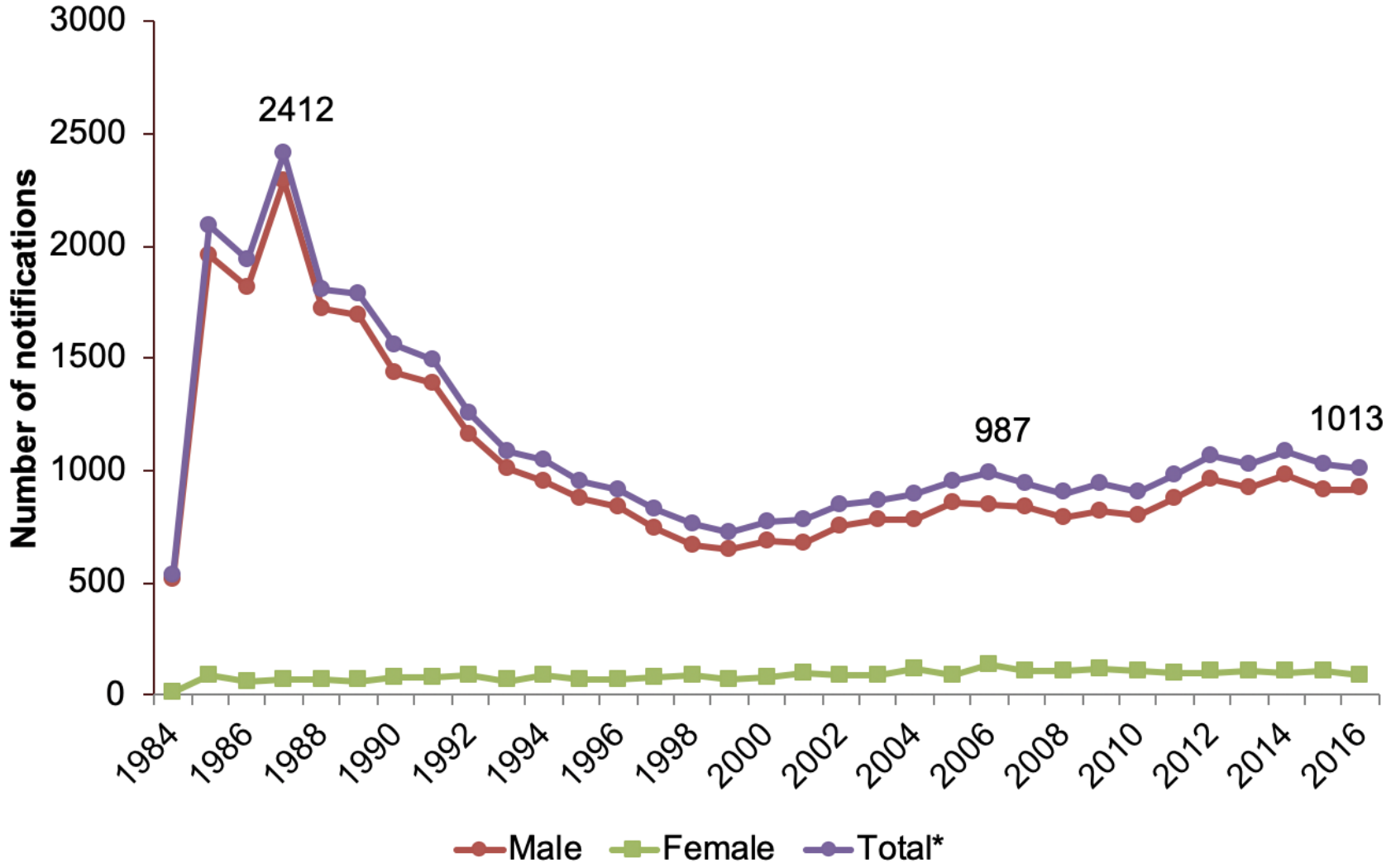
Learning Objectives

- Describe HIV prevention strategies including Pre-exposure prophylaxis (PrEP), Post Exposure prophylaxis (PEP) and Treatment as Prevention (TasP)
- Introduce PEP guideline, indications and options for local access.
- Introduce concept of determining risk
- How to initiate PrEP using ashm: decision making in prep use card
- How to monitor PrEP

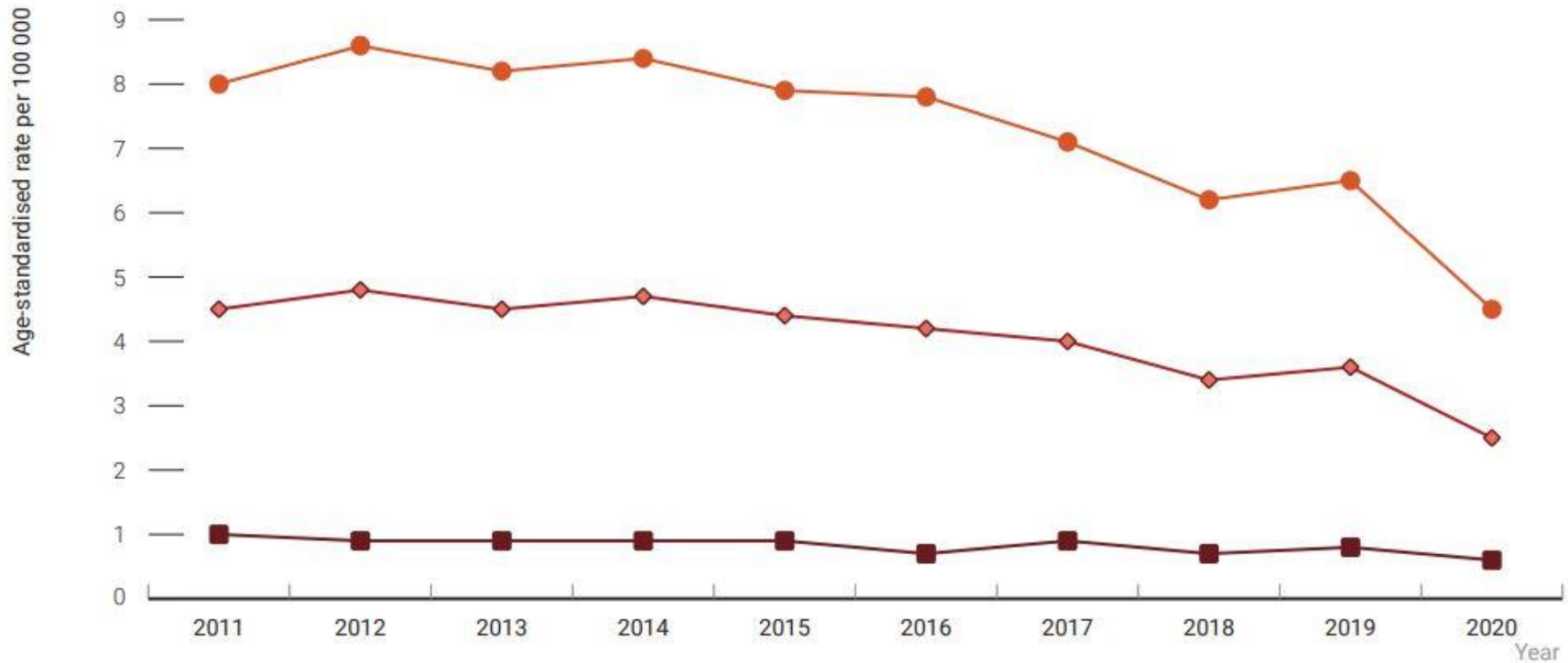
Newly diagnosed HIV infection in Australia by year



Source: 2017 HIV, Viral Hepatitis and Sexually Transmitted Infections in Australia Annual Surveillance Report

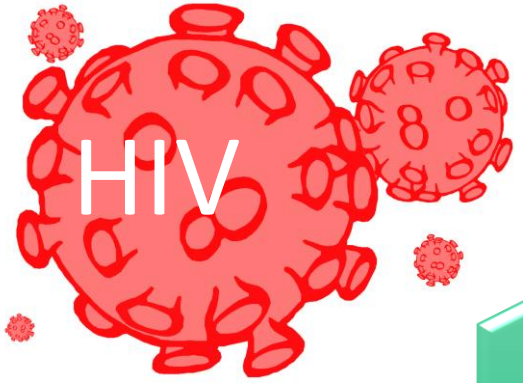
ashm

Figure 1 HIV notification rate per 100 000 population, 2011–2020, by gender



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Men	8.0	8.6	8.2	8.4	7.9	7.8	7.1	6.2	6.5	4.5
Women	1.0	0.9	0.9	0.9	0.9	0.7	0.9	0.7	0.8	0.6
Total	4.5	4.8	4.5	4.7	4.4	4.2	4.0	3.4	3.6	2.5

Source: State and territory health authorities; see Methodology for detail.



Safe sex practices

Condoms & Lube

Education

Testing

PEP

?future

Safe injecting practices

ARV

TasP

NSP

PrEP

ashm

Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine

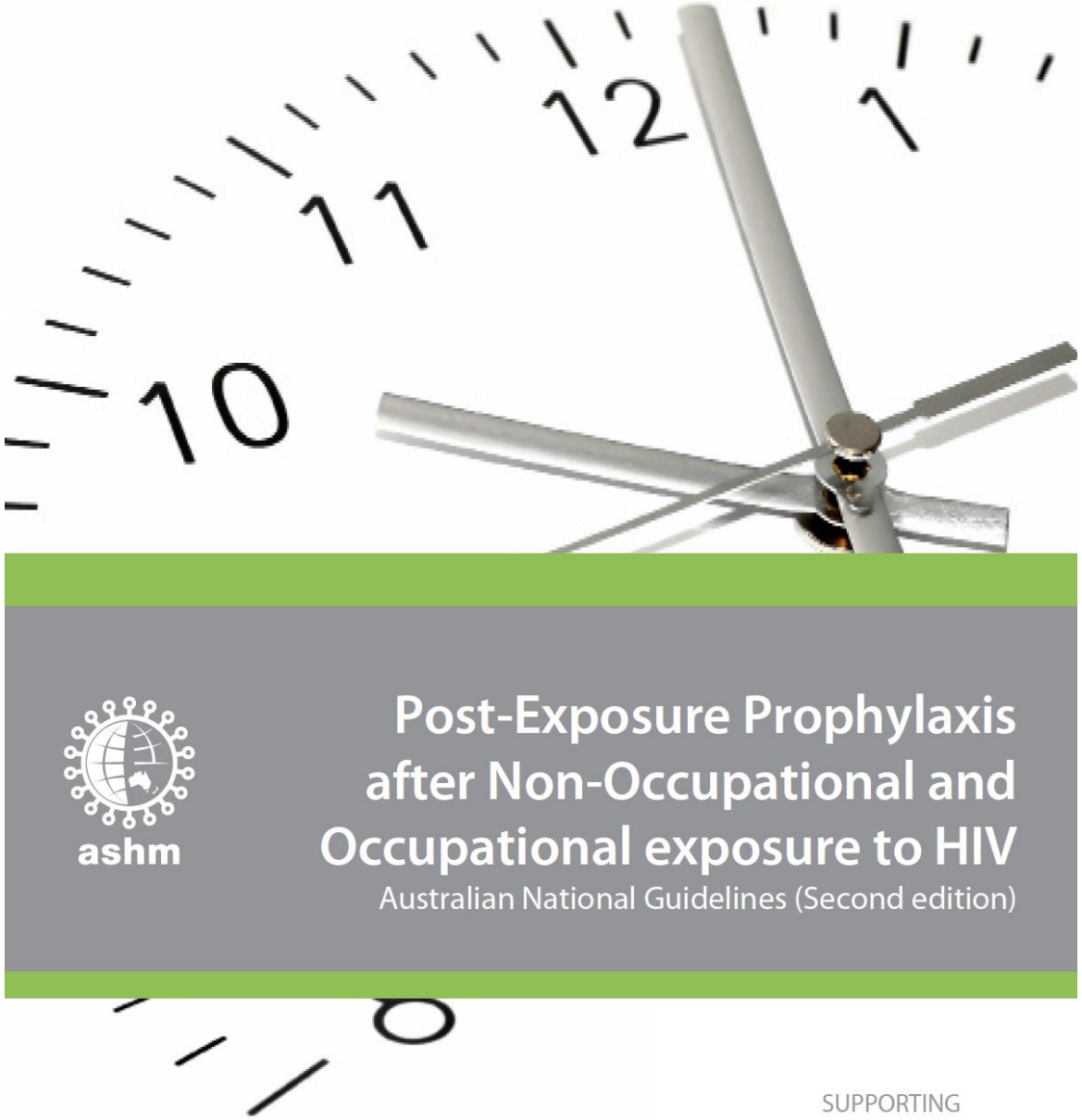
A guide for clinicians to discuss

U=U

UNDETECTABLE = UNTRANSMITTABLE

TasP: treatment as prevention

PEP:
Post Exposure Prophylaxis



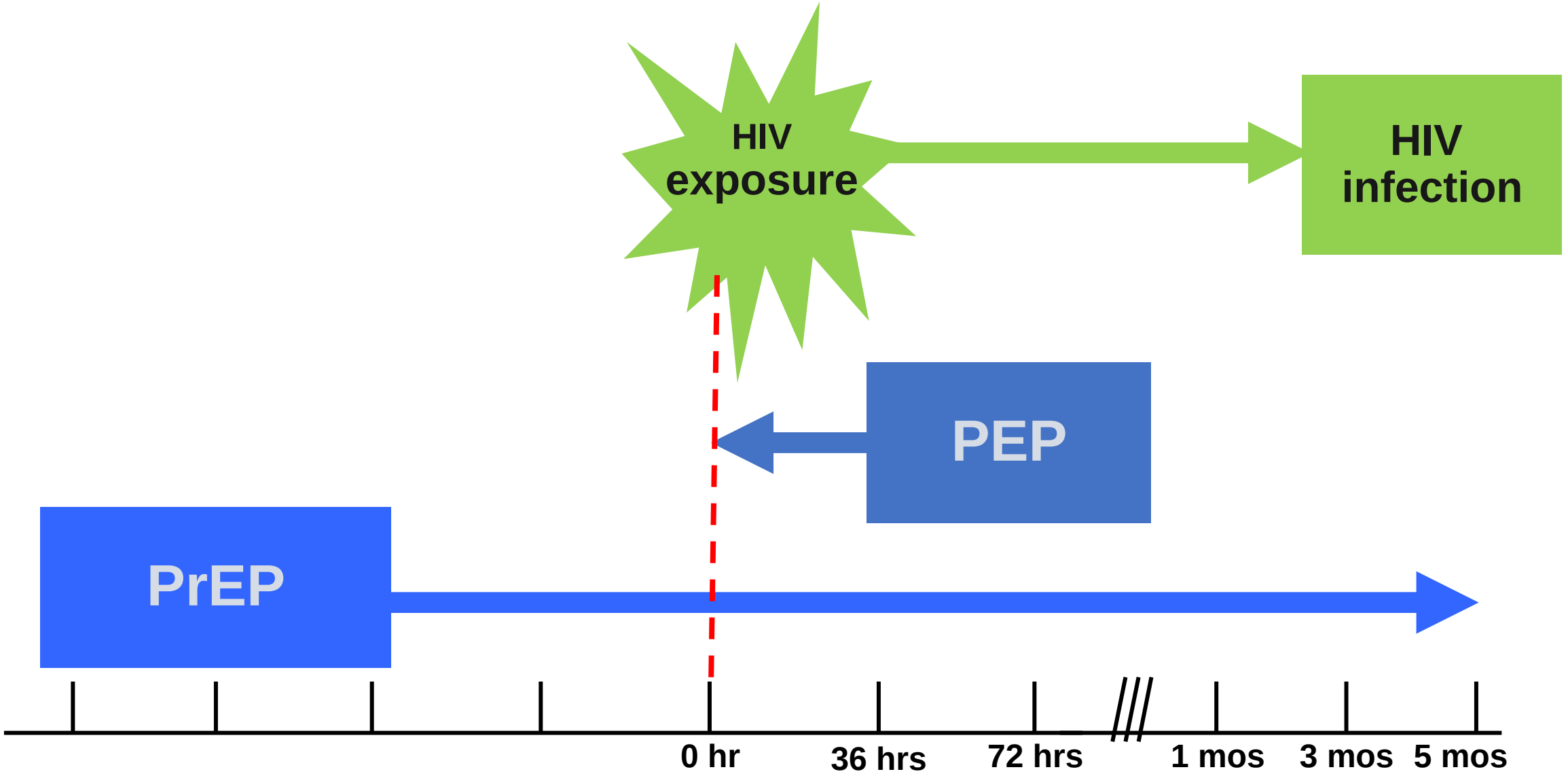
SUPPORTING THE HIV, VIRAL HEPATITIS AND SEXUAL HEALTH WORKFORCE

PEP – Post exposure prophylaxis

- Antiretroviral medication to reduce likelihood of HIV infection
- Taken within **72 hours** of HIV exposure
- 2-3 drugs for 28 days
- Low level of Evidence
- **Any hospital Emergency Department or any s100 prescriber**

- Ashm guideline
- NSW PEP Hotline 1800 PEP NOW (1800 737 669)
- Victorian NPEP Service 1800 889 887

PEP: Post exposure prophylaxis

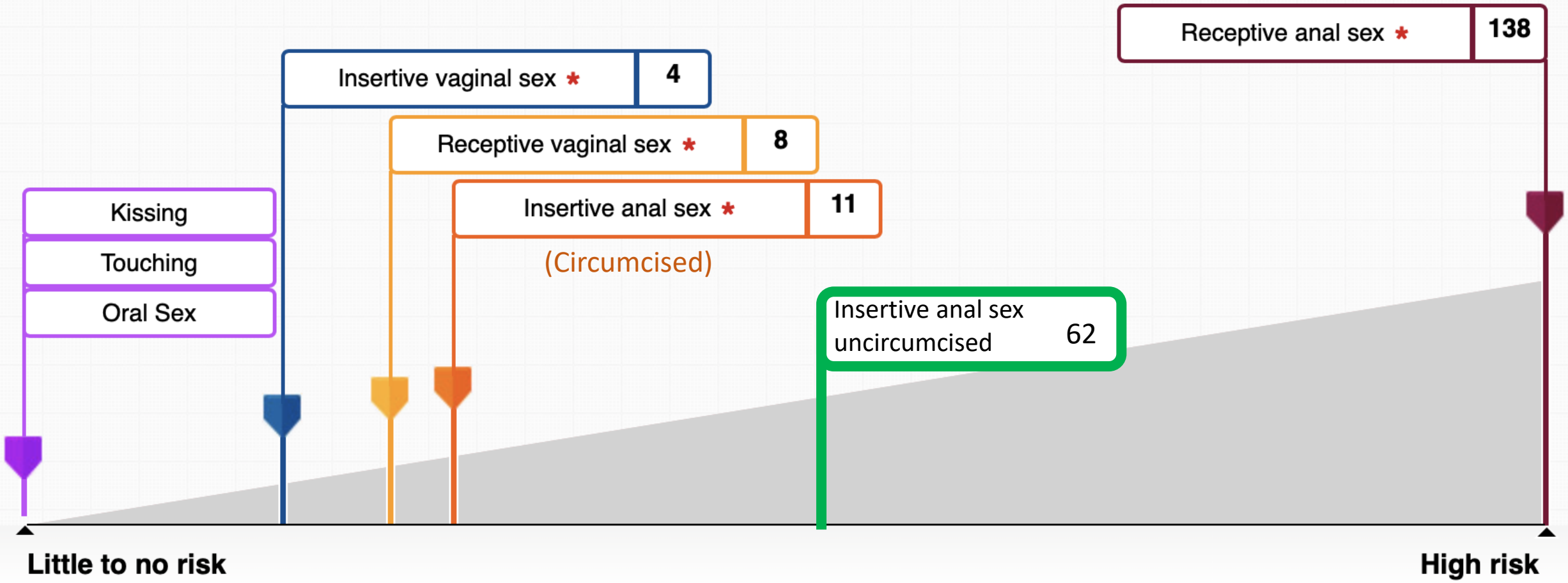


Assessment of the risk of HIV transmission

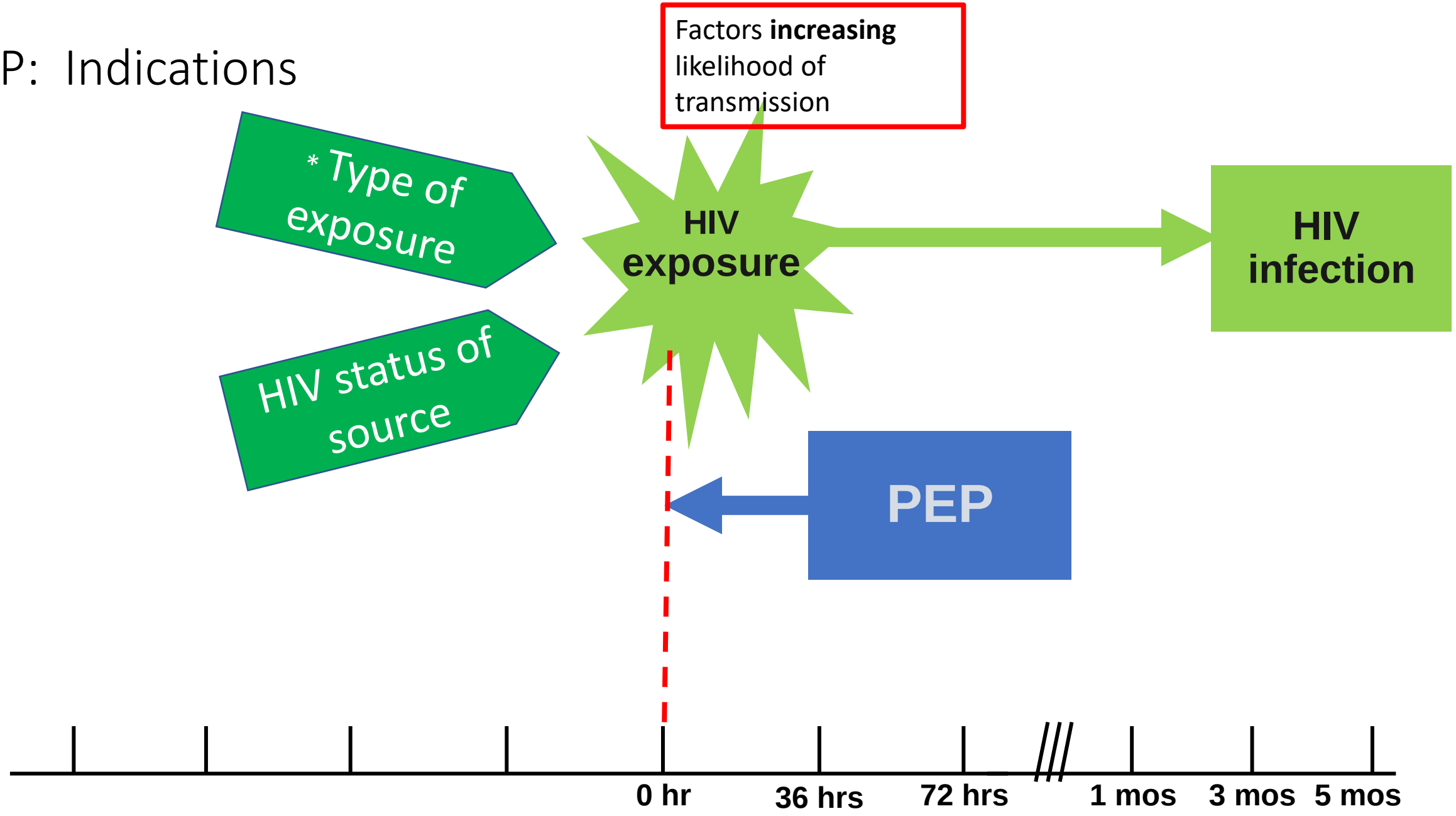
Risk of transmission =
risk per exposure
x
risk of source being HIV positive

Know the HIV Risk

Learn the HIV risk of different sexual activities when one partner is HIV positive and one partner is HIV negative (a discordant partnership)



PEP: Indications



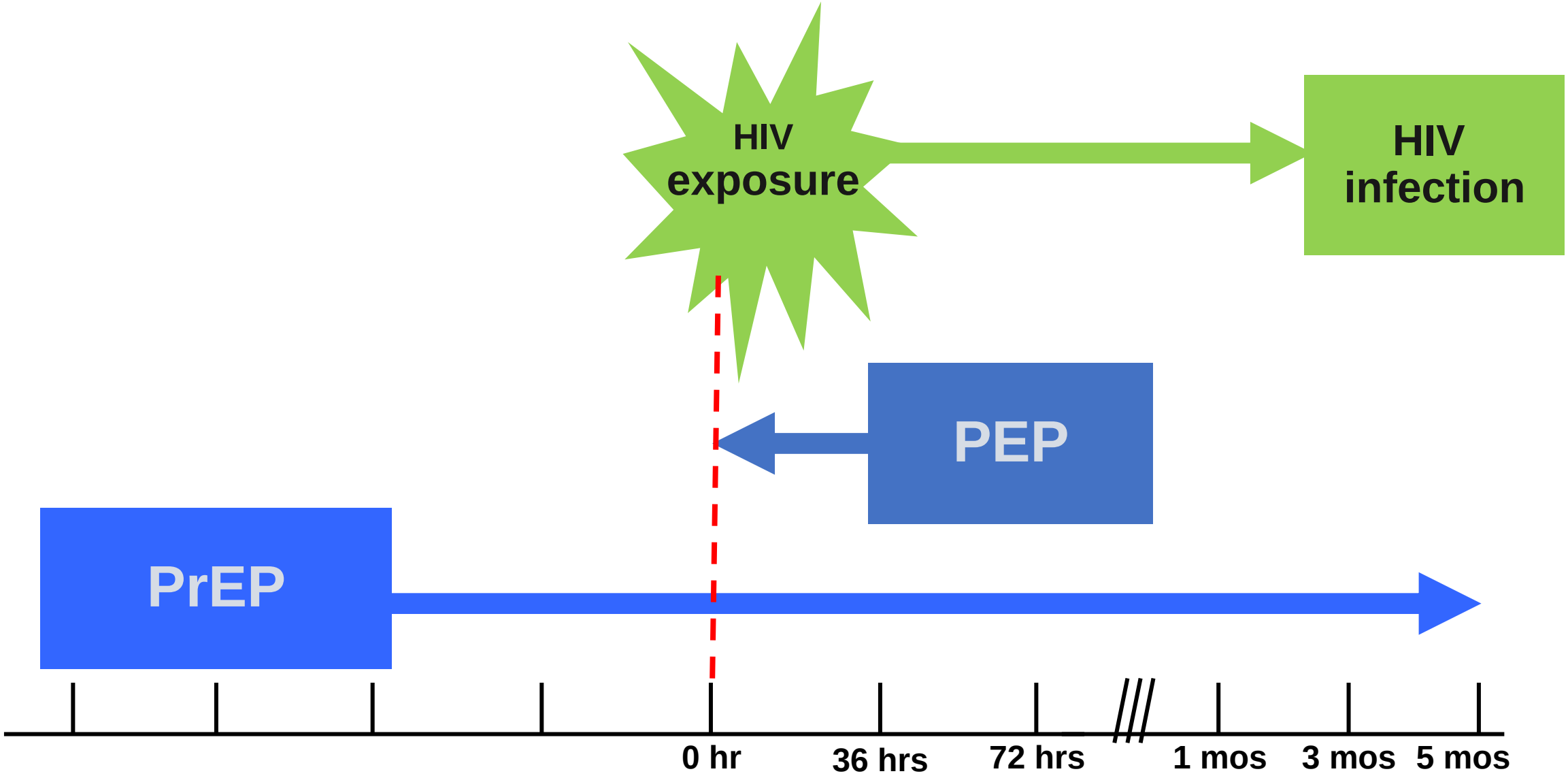
What is Pre-exposure prophylaxis (PrEP)?

- PrEP involves the use of **antiretroviral drugs (ARVs)** by HIV uninfected individuals to **reduce HIV acquisition risk**.

- The efficacy of ARVs as continuous daily PrEP has been established in clinical trials among various risk groups including:
  - men who have sex with men (iPrEx, Proud studies),
  - heterosexual adults (Partners PrEP and TDF2), and
  - injecting drug users (Bangkok Tenofovir study)

- Transgendered people have not been well represented in PrEP studies.

PrEP: pre-exposure prophylaxis

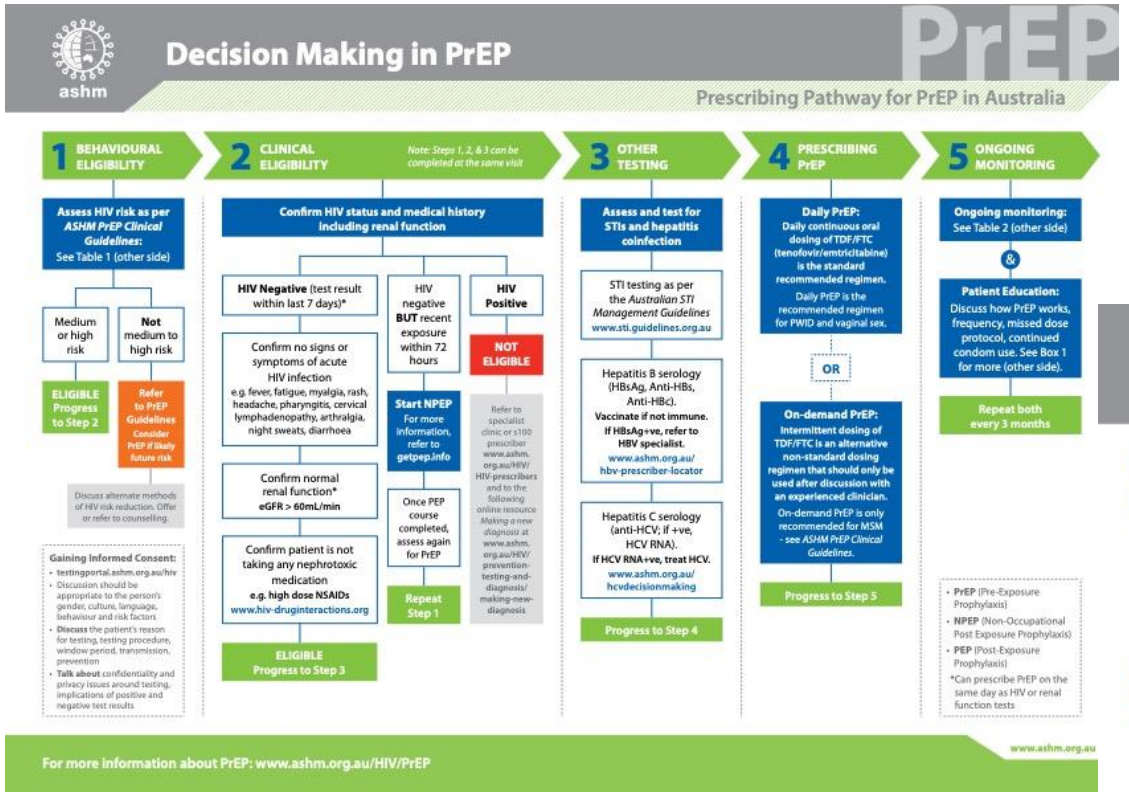


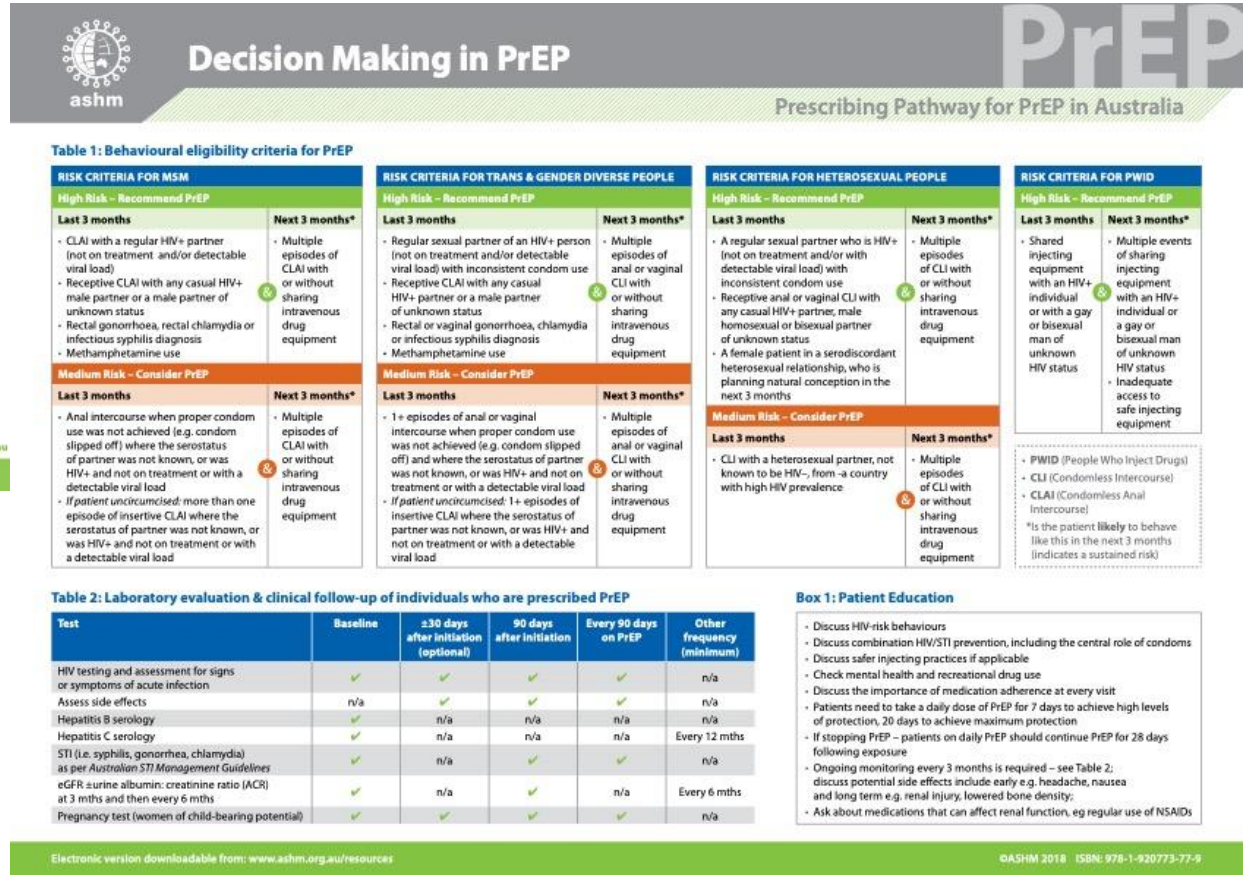
Case study #1: Mark

- 34 yo man identifies as gay
- Heard about PrEP from friends
- Regularly ‘bottoms’ with casual partners he meets on Grindr
- ‘Pretty good’ at using condoms most of the time but has had some ‘slip ups’
- Wants to ‘bareback’

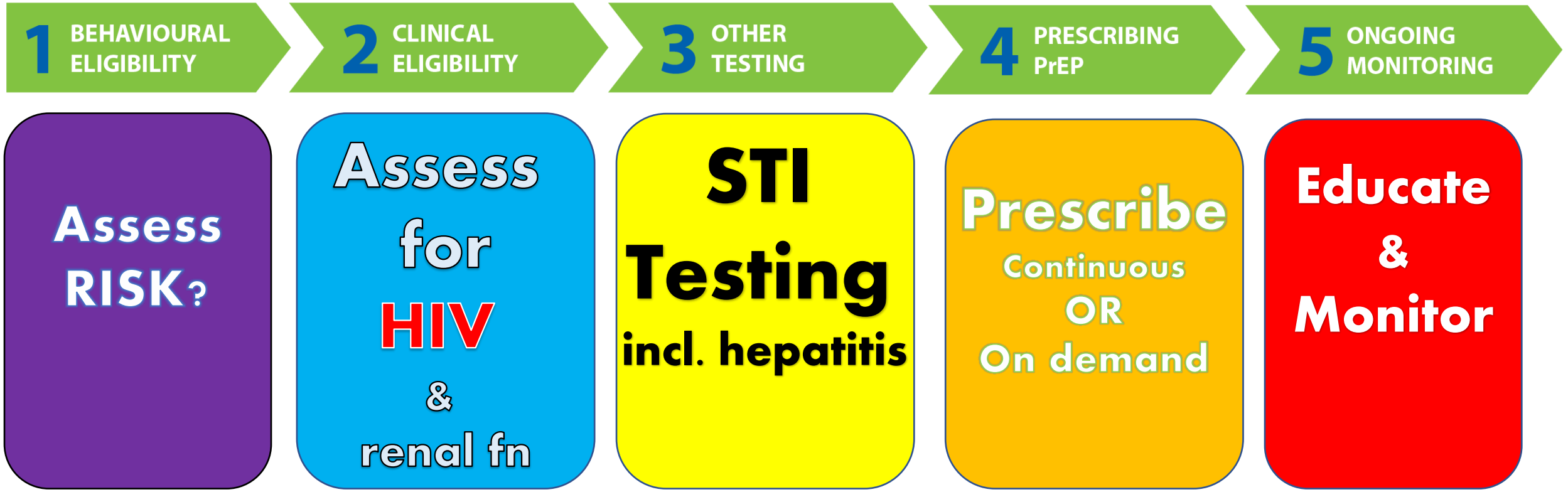
ASHM Decision Making in PrEP Tool

https://www.ashm.org.au/products/product/3000100092





The steps in prescribing PrEP



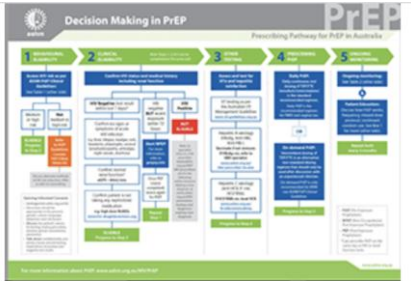
- https://www.ashm.org.au/products/product/3000100092

1 BEHAVIOURAL ELIGIBILITY

Assess RISK?

Assess Risk:
Are they Medium or High risk?

1 BEHAVIOURAL ELIGIBILITY



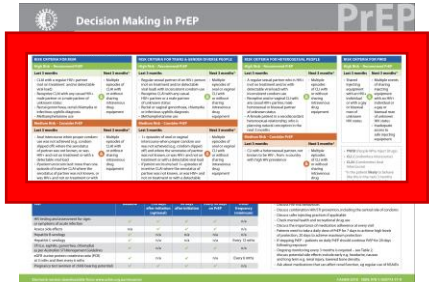


Table 1: Behavioural eligibility criteria for PrEP

RISK CRITERIA FOR MSM

High Risk – Recommend PrEP

Last 3 months	Next 3 months*
• CLAI with a regular HIV+ partner (not on treatment and/or detectable viral load) • Receptive CLAI with any casual HIV+ male partner or a male partner of unknown status • Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis • Methamphetamine use	& • Multiple episodes of CLAI with or without sharing intravenous drug equipment

Medium Risk – Consider PrEP

Last 3 months	Next 3 months*
• Anal intercourse when proper condom use was not achieved (e.g. condom slipped off) where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load • *If patient uncircumcised:* more than one episode of insertive CLAI where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load	& • Multiple episodes of CLAI with or without sharing intravenous drug equipment

RISK CRITERIA FOR TRANS & GENDER DIVERSE PEOPLE

High Risk – Recommend PrEP

Last 3 months	Next 3 months*
• Regular sexual partner of an HIV+ person (not on treatment and/or detectable viral load) with inconsistent condom use • Receptive CLAI with any casual HIV+ partner or a male partner of unknown status • Rectal or vaginal gonorrhoea, chlamydia or infectious syphilis diagnosis • Methamphetamine use	& • Multiple episodes of anal or vaginal CLI with or without sharing intravenous drug equipment

Medium Risk – Consider PrEP

Last 3 months	Next 3 months*
• 1+ episodes of anal or vaginal intercourse when proper condom use was not achieved (e.g. condom slipped off) and where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load • *If patient uncircumcised:* 1+ episodes of insertive CLAI where the serostatus of partner was not known, or was HIV+ and not on treatment or with a detectable viral load	& • Multiple episodes of anal or vaginal CLI with or without sharing intravenous drug equipment

RISK CRITERIA FOR HETEROSEXUAL PEOPLE

High Risk – Recommend PrEP

Last 3 months	Next 3 months*
• A regular sexual partner who is HIV+ (not on treatment and/or with detectable viral load) with inconsistent condom use • Receptive anal or vaginal CLI with any casual HIV+ partner, male homosexual or bisexual partner of unknown status • A female patient in a serodiscordant heterosexual relationship, who is planning natural conception in the next 3 months	& • Multiple episodes of CLI with or without sharing intravenous drug equipment

Medium Risk – Consider PrEP

Last 3 months	Next 3 months*
• CLI with a heterosexual partner, not known to be HIV–, from -a country with high HIV prevalence	& • Multiple episodes of CLI with or without sharing intravenous drug equipment

RISK CRITERIA FOR PWID

High Risk – Recommend PrEP

Last 3 months	Next 3 months*
• Shared injecting equipment with an HIV+ individual or with a gay or bisexual man of unknown HIV status	& • Multiple events of sharing injecting equipment with an HIV+ individual or a gay or bisexual man of unknown HIV status • Inadequate access to safe injecting equipment

- **PWID** (People Who Inject Drugs)
- **CLI** (Condomless Intercourse)
- **CLAI** (Condomless Anal Intercourse)

*Is the patient **likely** to behave like this in the next 3 months (indicates a sustained risk)

MSM Trans (gender diverse) Heterosexual PWID

1 BEHAVIOURAL ELIGIBILITY

Who to encourage to use prep

MSM	Trans gender Gender diverse	Heterosexual	PWID
Receptive anal sex without condoms with a casual sexual partner or HIV-positive (without an undetectable viral load) regular partner in last 3 months Syphilis, or rectal gonorrhoea/chlamydia in the last 3 months Methamphetamine use in the last 3 months Consider if uncircumcised and one episode of insertive anal sex without condoms in last 3 months	Regular partner who is HIV-positive (not on treatment and/or detectable viral load) and condoms not consistently used in last 3 months for vaginal or anal sex. 1+ episode of receptive condomless intercourse (CLI) with any casual HIV+ partner or a male partner of unknown status Rectal or vaginal gonorrhoea, rectal or vaginal chlamydia or infectious syphilis diagnosis (during the last 3 months or at screening for PrEP) Methamphetamine use, which may increase the risk of HIV acquisition	Regular partner who is HIV-positive (without an undetectable viral load) and condoms not consistently used in last 3 months for vaginal or anal sex. Consider if planning natural conception	Sharing equipment with a HIV-positive person or with a MSM in the last 3 months

(1) Are they eligible for Prep?

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1 BEHAVIOURAL ELIGIBILITY

•*Answer **yes** or **no** to the following example:*

•Receptive condomless anal intercourse (CLAI) with a male partner of unknown status

•&

•Multiple episodes of CLAI in the next three months

Answer (1)

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1 BEHAVIOURAL ELIGIBILITY

- *Answer **yes** or **no** to the following example:*

Shared injecting equipment with a gay or bisexual man of unknown status

&

Multiple events of sharing with a gay or bisexual man of unknown status over the next 3 months

Answer (2)

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(3) Are they eligible for Prep?

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1 BEHAVIOURAL ELIGIBILITY

- *Answer **yes** or **no** to the following example:*

Condomless intercourse with a heterosexual partner, not known to be HIV –ve, from a country with high HIV prevalence

&

Multiple episodes with condomless intercourse over the next three months

Answer (3)

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(4) Are they eligible for Prep?

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1 BEHAVIOURAL ELIGIBILITY

•*Answer **yes** or **no** to the following example:*

•Male having protected intercourse with a sex worker in Australia

•&

•Multiple episodes of condomless oral sex with a sex worker in Australia

Answer (4)

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(5) Are they eligible for Prep?

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1 BEHAVIOURAL ELIGIBILITY

- *Answer **yes** or **no** to the following example:*

- Male having condomless sex with a HIV positive man who has a sustained undetectable viral load

Answer (5)

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(6) Are they eligible for Prep? Mark:

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1 BEHAVIOURAL ELIGIBILITY

•*Answer **yes** or **no** to the following example:*

•Male having anal receptive sex with casual partners from Grindr

•Usually uses condoms

•&

•Wants to bareback in next 3 months

Answer: Mark

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1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

Assess for HIV & renal fn

Assess for HIV

- Recent exposure
- Testing last 7/7
- Acute HIV symptoms

Assess renal function

1 BEHAVIOURAL ELIGIBILITY → **2 CLINICAL ELIGIBILITY**

If HIV +ve

↓

Not eligible for PrEP!

HIV test

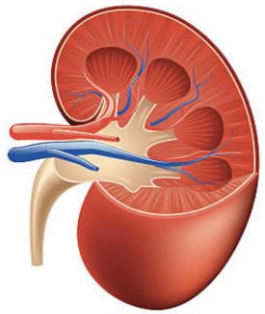
Renal fn

?HIV

Acute HIV

?PEP

- eGFR >60ml/min
- (microalbumin)
- Nephrotoxic medications



Any symptoms?

When was the last at risk episode?

If <72 hrs → PEP

Mark

- No recent exposure
- No symptoms of acute HIV
- No history of kidney problems
- Takes ibuprofen for headaches and pantoprazole for GORD

Need to order HIV Ag/Ab + eGFR and ACR

1 BEHAVIOURAL ELIGIBILITY

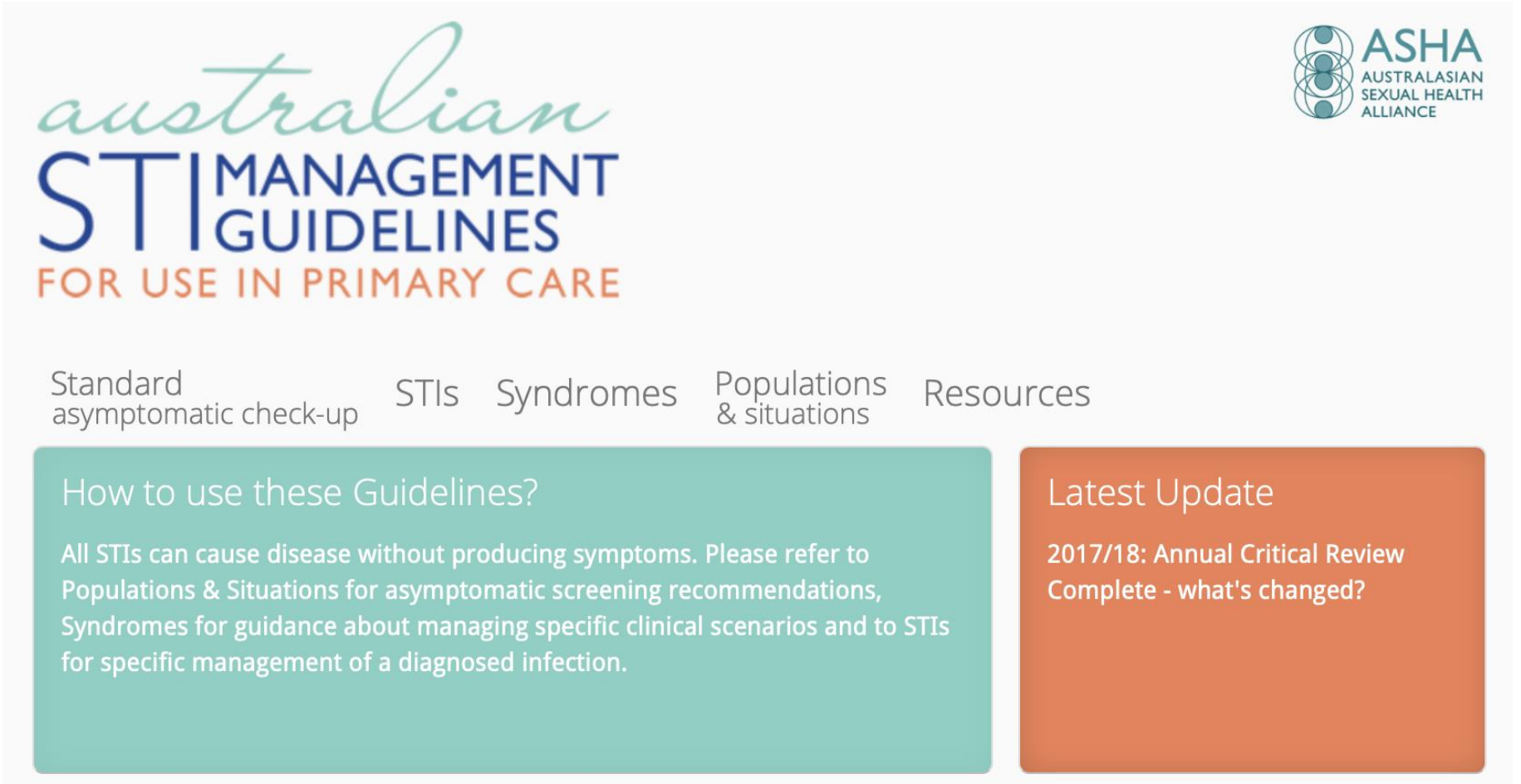
2 CLINICAL ELIGIBILITY

3 OTHER TESTING

STI Testing incl. hepatitis

1 BEHAVIOURAL ELIGIBILITY | 2 CLINICAL ELIGIBILITY | 3 OTHER TESTING

Other testing: STI



POPULATIONS & SITUATIONS

- Aboriginal and Torres Strait Islander People
- Adult Sexual Assault
- MSM - Men who have sex with men
- People in correctional facilities
- PLWHIV - People living with HIV
- Pregnant women
- PWID - People who inject drugs
- Refugees (and newly arrived migrants from similar settings)
- Regional & remote
- Sex workers
- Transgender
- WSW - Women who have sex with women
- Young people

AUSTRALIAN SEXUALLY TRANSMITTED INFECTION & HIV TESTING GUIDELINES 2014

FOR ASYMPTOMATIC MEN WHO HAVE SEX WITH MEN

Men who have sex with men (MSM) in Australia are disproportionately and increasingly affected by sexually transmissible infections (STIs) including HIV. This has been attributed, in part, to changes in sexual behaviour such as reduction in condom use for anal intercourse in recent years. Many STIs do not lead to symptomatic presentations, therefore regular STI testing will identify a large number of infections which would otherwise remain undiagnosed and untreated. The term "men who have sex with men" is simply a behavioural descriptor and is not considered a sexual identity, although most MSM in Australia identify as gay.

These guidelines have been developed to encourage regular STI screening of MSM, including those with HIV, who do not have symptoms of STIs. The recommendations include STI testing at anatomical sites other than the location of any symptoms which may have prompted a clinical consultation.

After behavioural risk assessment and appropriate pre test discussion, **all of the STI tests** listed should be offered to:

All men who have had any type of sex with another man in the previous year → **At least once a year**

All MSM who fall into one or more categories listed below:

- any unprotected anal sex
- more than 10 sexual partners in six months
- participate in group sex
- use recreational drugs during sex
- are HIV-positive:
  - *syphilis serology:* at each occasion of CD4/VL[a] monitoring;
  - *chlamydia/gonorrhoea* testing: consider at each occasion of CD4/VL[a] monitoring)

→ **Up to 4 times a year**[b]

SITE SPECIMEN	STI	TECHNOLOGY	COMMENT
Pharyngeal swab	Chlamydia & gonorrhoea	NAAT[c]	Self-collected or clinician-collected
Anorectal swab	Chlamydia & gonorrhoea	NAAT[c]	Self-collected or clinician-collected
First void urine[d]	Chlamydia	NAAT[c]	Alternative: self-collected or clinician-collected penile meatal swab
Serology	Syphilis	EIA[e]	
	HIV	EIA[e]	If HIV negative
	Hepatitis A	HAV IgG EIA[e]	Test if not vaccinated. Vaccinate if antibody negative
	Hepatitis B	HBV core antibody, surface Antigen EIA[e]	Test if not vaccinated. Vaccinate if no history or documentation of full vaccination course
	Hepatitis C	HCV IgG EIA[e]	Only in HIV-positive or if history of injecting drug use

a VL = HIV viral load

b Except viral hepatitis tests

c NAAT- nucleic acid amplification test eg Transcription-Mediated Amplification (TMA), Strand Displacement Amplification (SDA), Polymerase Chain Reaction (PCR)

d First void urine = initial part of the urine stream. Not first urine of the day and not mid stream urine. Collect specimen at least 20 minutes after last passing urine.

e EIA = Enzymeimmunoassay

STIs in Gay Men Action Group

PrEP and Hepatitis B, Hepatitis C

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1 BEHAVIOURAL ELIGIBILITY → 2 CLINICAL ELIGIBILITY → 3 OTHER TESTING

Test for Hepatitis B:

HbsAg, anti HbS, anti HbC

If positive HbSAg

Involvement of someone who manages Hep B is recommended.

Vaccination status- Hep A, Hep B

Test for Hepatitis C

anti HCV

If positive or previous hep C

HCV RNA

If positive → treat with DAA

Mark

- Order pathology
  - HIV Ag/Ab
  - eGFR and urine ACR

What STI testing do we need?

- HBV/HCV/Syphilis serology/HAV
- Gonorrhoea & Chlamydia PCR
- throat
- anus
- Urine

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

3 OTHER TESTING

4 PRESCRIBING PrEP

Prescribe

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What to prescribe?

Truvada

- Tenofovir disoproxil fumarate (TDF) 300mg
- Emtricitabine (FTC) 200mg

Both are used with another agent (triple therapy) as a treatment regime for HIV.

- PrEP on PBS as of 1st April 2018
- Streamlined Authority→ Restricted Benefit

Reverse transcriptase inhibitors prevent HIV replication through blocking viral RNA incorporation into host DNA

PrEP regimens

How to take prep
www.iwantprepnow.co.uk/how-to-take-prep/

Daily [recommended]

- Daily PrEP should be recommended to people who have ongoing high or medium risk
- In Australia, TDF/FTC has been registered for use as a daily medication.

On-demand PrEP - only for anal sex 2-1-1

- If exposure happens only for relatively short periods of time (e.g. during travel)
  - Holiday prep
- Irregular event-based exposure
- those who have adverse events with use of daily PrEP
- Only for MSM and Transwomen
- Less effective than daily PrEP (Ipergay trial reported 86% efficacy)
- Adherence can vary
- Four or more doses per week may be sufficient (iPrEx Study)

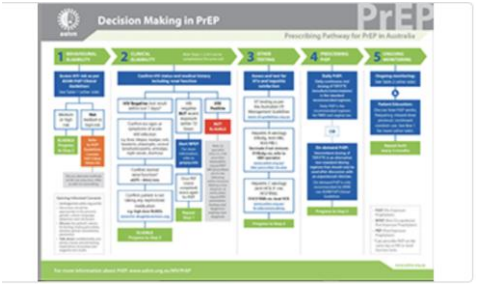
Mark

- You give mark a prescription for 3 months of TD/FTC (Truvada) and ask him not to start the medication until your have notified him of his results. We ask him to use paracetamol in the future for his headaches

- You receive his pathology results the next day – HIV negative, eGFR>90ml/min, no microglobulinaemia, HBV/HCV/Syphilis serology negative and STI PCR negative.

Educate & Monitor

5 ONGOING MONITORING



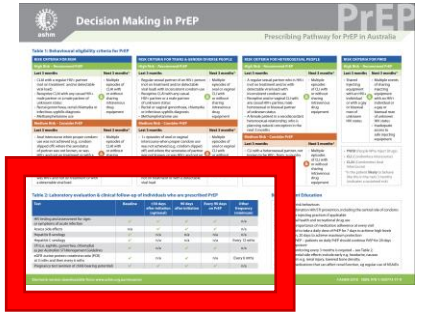
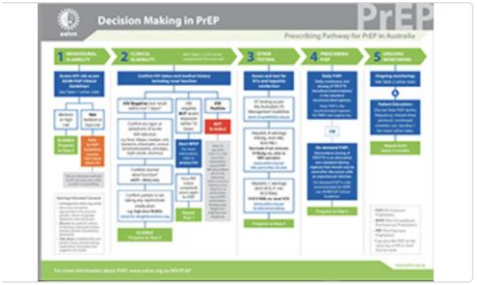
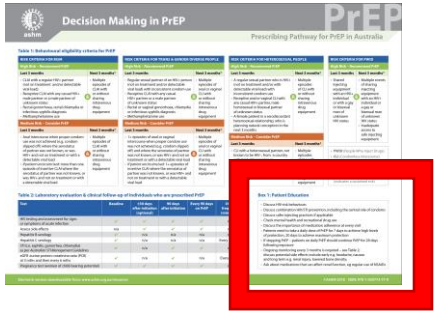


Table 2: Laboratory evaluation & clinical follow-up of individuals who are prescribed PrEP

Test	Baseline	±30 days after initiation (optional)	90 days after initiation	Every 90 days on PrEP	Other frequency (minimum)
HIV testing and assessment for signs or symptoms of acute infection	✔	✔	✔	✔	n/a
Assess side effects	n/a	✔	✔	✔	n/a
Hepatitis B serology	✔	n/a	n/a	n/a	n/a
Hepatitis C serology	✔	n/a	n/a	n/a	Every 12 mths
STI (i.e. syphilis, gonorrhea, chlamydia) as per *Australian STI Management Guidelines*	✔	n/a	✔	✔	n/a
eGFR ±urine protein: creatinine ratio (PCR) at 3 mths and then every 6 mths	✔	n/a	✔	n/a	Every 6 mths
Pregnancy test (women of child-bearing potential)	✔	✔	✔	✔	n/a

5 ONGOING MONITORING





Box 1: Patient Education

- Discuss HIV-risk behaviours
- Discuss combination HIV/STI prevention, including the central role of condoms
- Discuss safer injecting practices if applicable
- Check mental health and recreational drug use
- Discuss the importance of medication adherence at every visit
- Patients need to take a daily dose of PrEP for 7 days to achieve high levels of protection, 20 days to achieve maximum protection
- If stopping PrEP – patients on daily PrEP should continue PrEP for 28 days following exposure
- Ongoing monitoring every 3 months is required – see Table 2; discuss potential side effects include early e.g. headache, nausea and long term e.g. renal injury, lowered bone density;
- Ask about medications that can affect renal function, eg regular use of NSAIDs

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Side effects & Interactions

- Reports 10-30% of patients
- Limited to first month generally
  - Nausea
  - Diarrhoea
  - Headache
  - Fatigue
  - Flatulence
- Supportive measures to progress through period

- Liverpool App:

  www.hiv-druginteractions.org.au
- Concern is cumulative effects of nephrotoxic agents
- **Most common issues revolve around NSAIDS, protein powders and gym supplements.**

Having trouble viewing the interactions? Click here for the Interaction Checker Lite.

HIV Drugs

Truvada

A-Z | Class | Trade

- [x] Emtricitabine/Tenofovir-DF (FTC/TDF, PrEP)

- [x] Emtricitabine/Tenofovir-DF (FTC/TDF, PrEP)

Co-medications

soma

A-Z | Class | Trade

- [x] Pantoprazole

- [x] Pantoprazole

Drug Interactions

Check HIV/ HIV drug interactions

Switch to table view

Reset Checker

No Interaction Expected

Emtricitabine/Tenofovir-DF (FTC/TDF, PrEP)

Pantoprazole

More Info

HIV Drug Interactions

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Having trouble viewing the interactions? Click here for the Interaction Checker Lite.

HIV Drugs	Co-medications	Drug Interactions
Truvada	ibuprofen	Check HIV/ HIV drug interactions
A-Z Class Trade	A-Z Class Trade	Switch to table view
Emtricitabine/Tenofovir-DF (FTC/TDF, PrEP)	Ibuprofen	Reset Checker
Emtricitabine/Tenofovir-DF (FTC/TDF, PrEP)	Ibuprofen	Potential Interaction
		Emtricitabine/Tenofovir-DF (FTC/TDF, PrEP)
		Ibuprofen
		Look for alternatives
		More Info

Drug Interactions

Check HIV/ HIV drug interactions

Switch to table view

Reset Checker

Potential Interaction

Emtricitabine/Tenofovir-DF (FTC/TDF, PrEP)

Ibuprofen

Look for alternatives

More Info

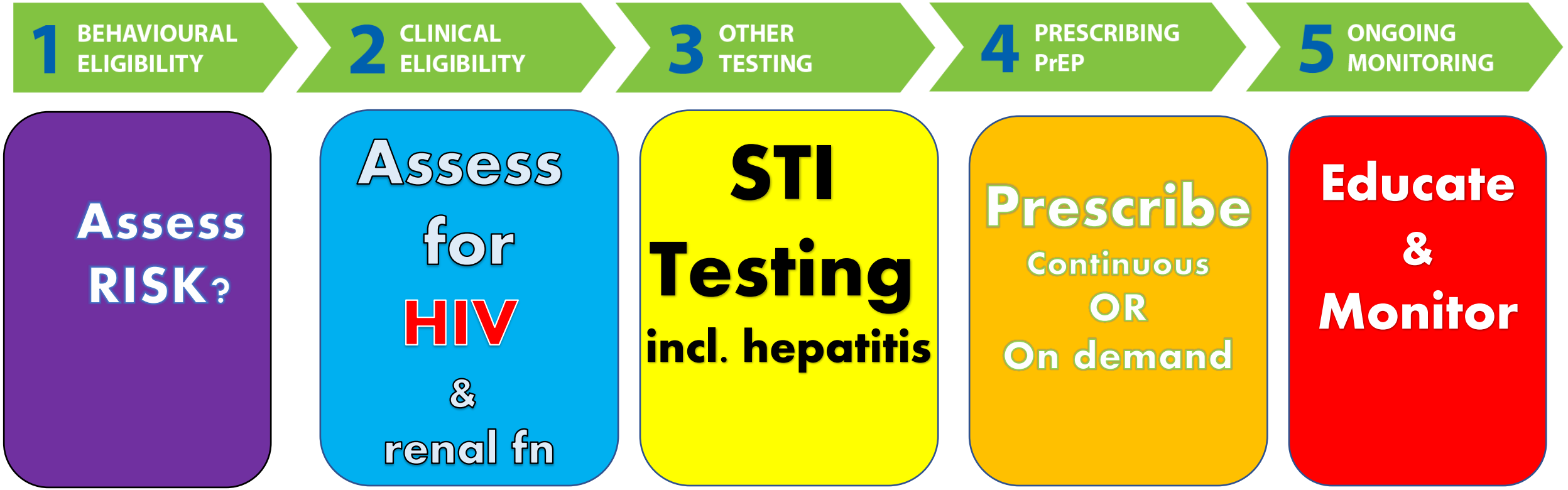
Quality of Evidence: Very Low

Summary:

Coadministration has not been studied but based on metabolism and clearance a pharmacokinetic interaction is unlikely. Ibuprofen is metabolised mainly by CYP2C9 and to a less extent by CYP2C8 and direct glucuronidation. However, coadministration could potentially result in increased risk of nephrotoxicity. Cases of acute renal failure after initiation of high dose or multiple NSAIDs have been reported in patients treated with tenofovir-DF and with risk factors for renal dysfunction. The risk is increased if an NSAID is used for a long duration, if the patient has a pre-existing renal

Mark

- You see Mark 3 months after commencing PrEP
- Mild headache for a few days after starting and no current STI symptoms
- You discuss HIV-risk behavior, STI prevention, recreational drug use, adherence, stopping protocol and nephrotoxic medications.
- You prescribe 3 months of daily Truvada (TDF/FTC)
- You order routine tests
  - HIV Ag/Ab
  - eGFR
  - STI testing


1 BEHAVIOURAL ELIGIBILITY
2 CLINICAL ELIGIBILITY
3 OTHER TESTING
4 PRESCRIBING PrEP
5 ONGOING MONITORING
Assess RISK?
Assess for HIV & renal fn
STI Testing incl. hepatitis
Prescribe Continuous OR On demand
Educate & Monitor