BioMedical Prevention of HIV

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Nurse Practitioner / Epidemiologist

Overview Objective

- Epidemiological Control of STIs / HIV
- Biomedical Prevention of HIV
  - **T**reatment **as** **P**revention (TasP)
  - **P**ost **E**xposure **P**rophylaxis (PEP)
  - **Pr**e **E**xposure **P**rophylaxis (PrEP)
- Nurse Practitioner Prescribing
  - S100 and S85
  - Gaps to access S100 prescribers

Epidemiological Control of Sexually transmissible Infections

$$Ro = \beta cD$$ E.g. Reduce Ro for HIV by

- Probability of Tx **(β)**
  - Co factors (gonorrhoea, Chlamydia)
  - Viral load
  - Condom use (use, desire, availability)
  - change type of sex (anal sex, chem sex, non-sober sex)
- Rate of partner change **(c)**
  - !!! Good Luck !!!

Duration of infection (D) –

- **Most important = Access / barriers to access**

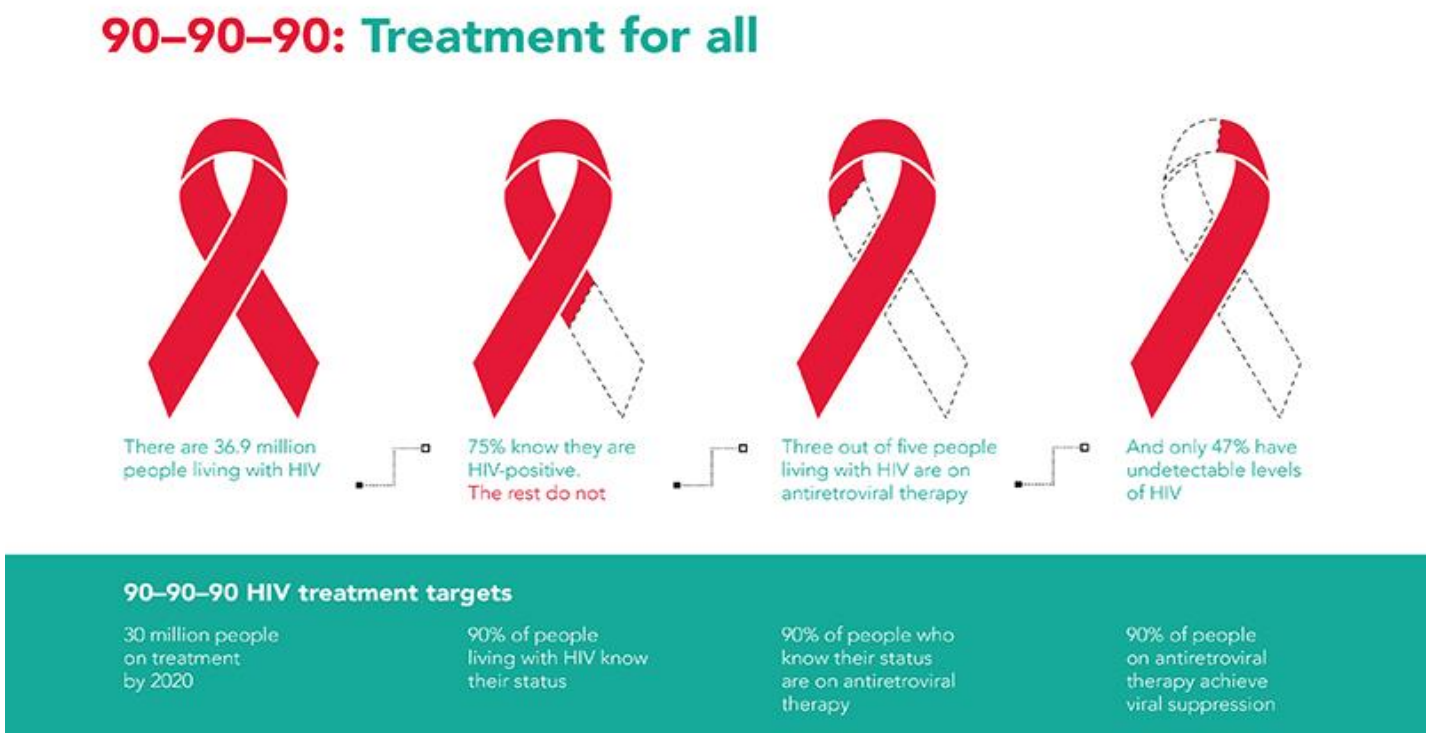
Barrier to Access

- Heterosexism
  - *An assumption that all persons are 'heterosexual' and the only valid choice and that any other form(s) of sexuality apart from heterosexuality is 'deviant'*
- Homophobia
  - *Hatred or fear of a person (or group of people) who is homosexual [and acts to] dehumanize a large group of people, to deny their humanity, their dignity and personhood* [similar to sexism / racism / anti-Semitism]
- Equal Rights = Human Rights
- *GLBTIQ Gay Lesbian Bisexual Transgender Intersex Queer etc [Non heterosexual]

Behind sex and desire lies the idea of sexuality. Sexuality – a complex of powerful symbols and cultural, social and psychological meanings that suffuse not only sexual activity but many areas of life. Sexuality, sets the context within which sex occurs. However much we feel that it is deeply personal and peculiar to ourselves, sexuality is both culturally and historically shaped…and brings with it issues of power.

[Anthony Coxon]

UNAIDS 90-90-90;
IAS Conference Melbourne 2014



First 90%: Screening and Early Detection

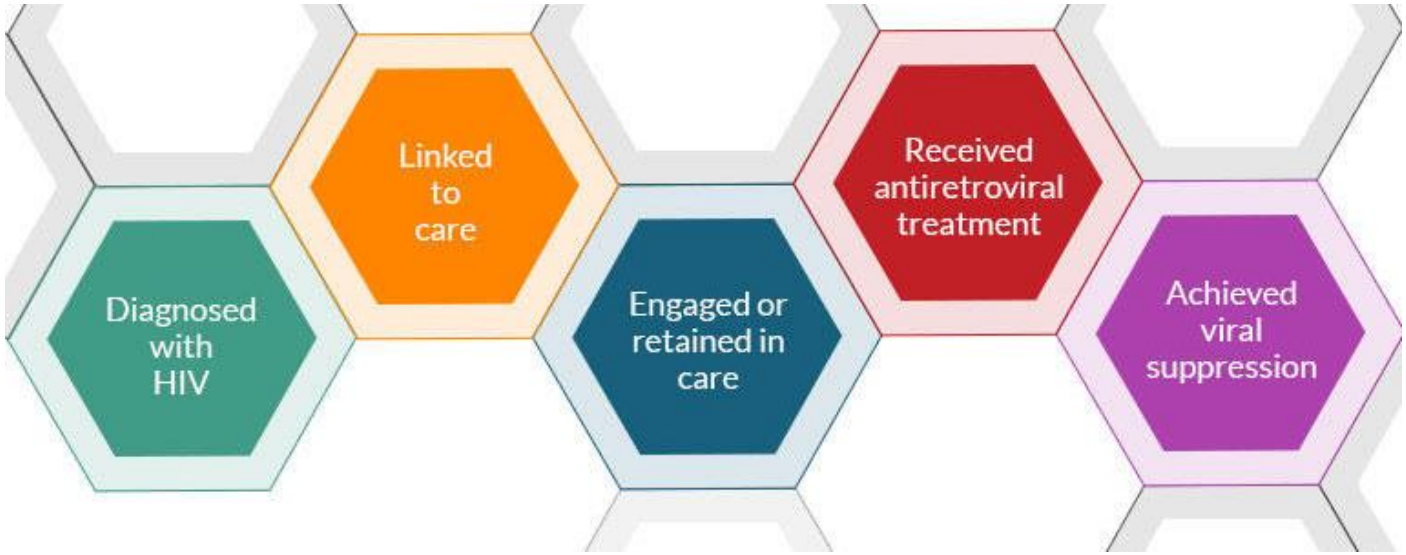
- ~ 89% of People Living With HIV (PLWH) are aware of their HIV status
  - ~70 – 74% are in GMSM (Gay and Men-Who-Have –Sex-With-Men)
- ~29% are diagnosed late in HIV infection (AIDS defining illness, suppressed CD4)
- 45% of late diagnosis are in heterosexual women

Second 90% - Treatment as Prevention

- 84% are on treatment with combined anti retrovirals (cART = S100 drugs in Australia)
  - **HPTN-052 study**
  - **Partner study**
  - **Opposites Attract Study**

In summary, no participants with an undetectable viral load transmitted HIV to their sexual partner during the study.

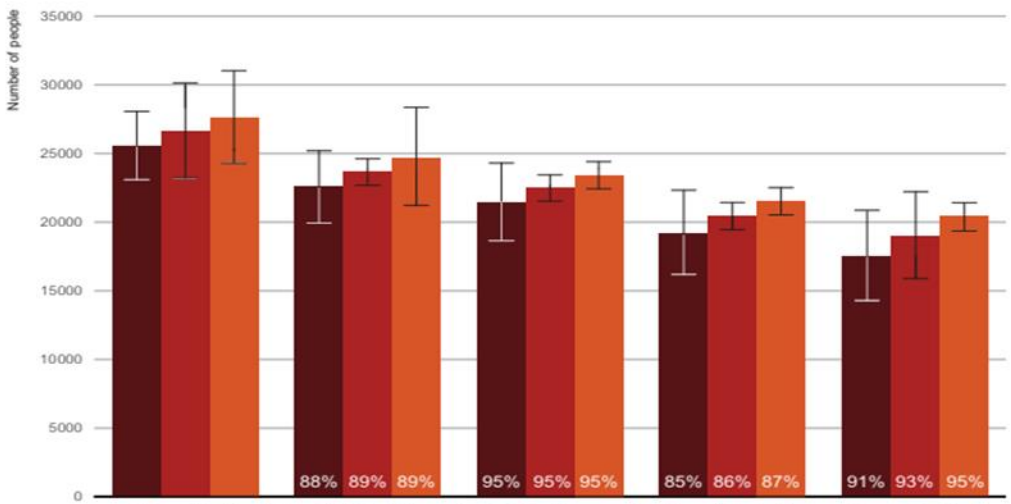
Third 90% - HIV treatment Cascade = Chronic Health Management



92% of people accessing ARV treatment were estimated to have an undetectable viral load.

2017 HIV Surveillance Data (Kirby Institute)

Figure 1.4.1 The HIV diagnosis and care cascade, 2015–2017



	Living with HIV	Living with HIV and diagnosed	Retained in care	Receiving antiretroviral therapy	Supressed viral load
2015	25 543	22 583	21 454	19 164	17 505
2016	26 578	23 644	22 462	20 413	18 945
2017	27 545	24 646	23 414	21 560	20 412

Source: See Methodology for details of mathematical modelling used to generate estimates.

5% not in care

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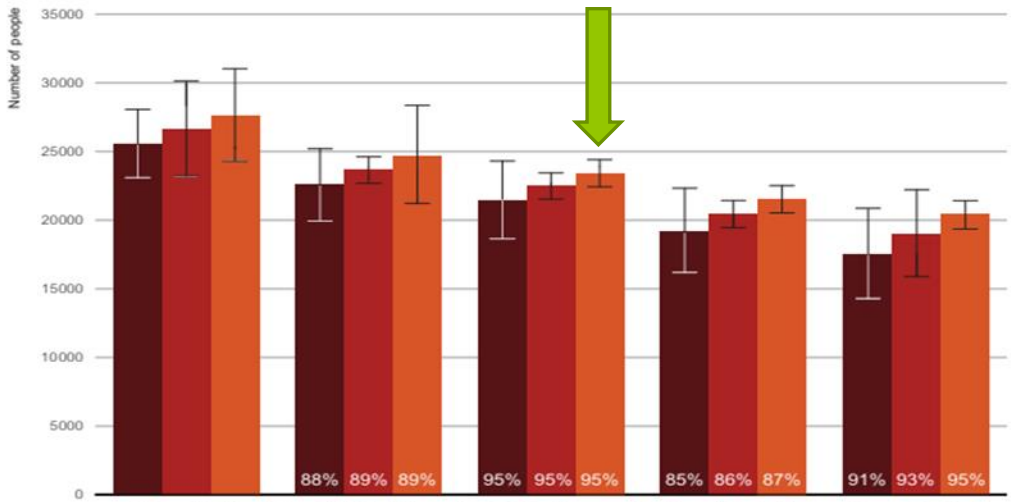

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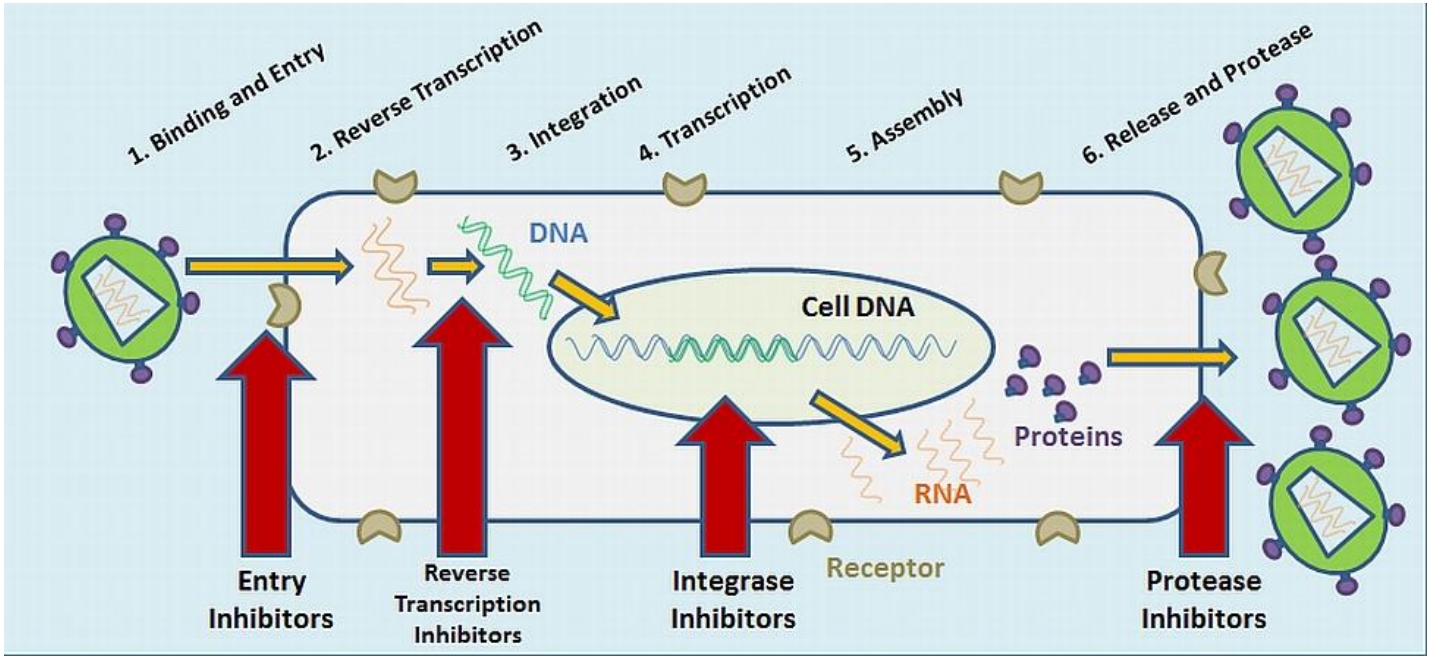
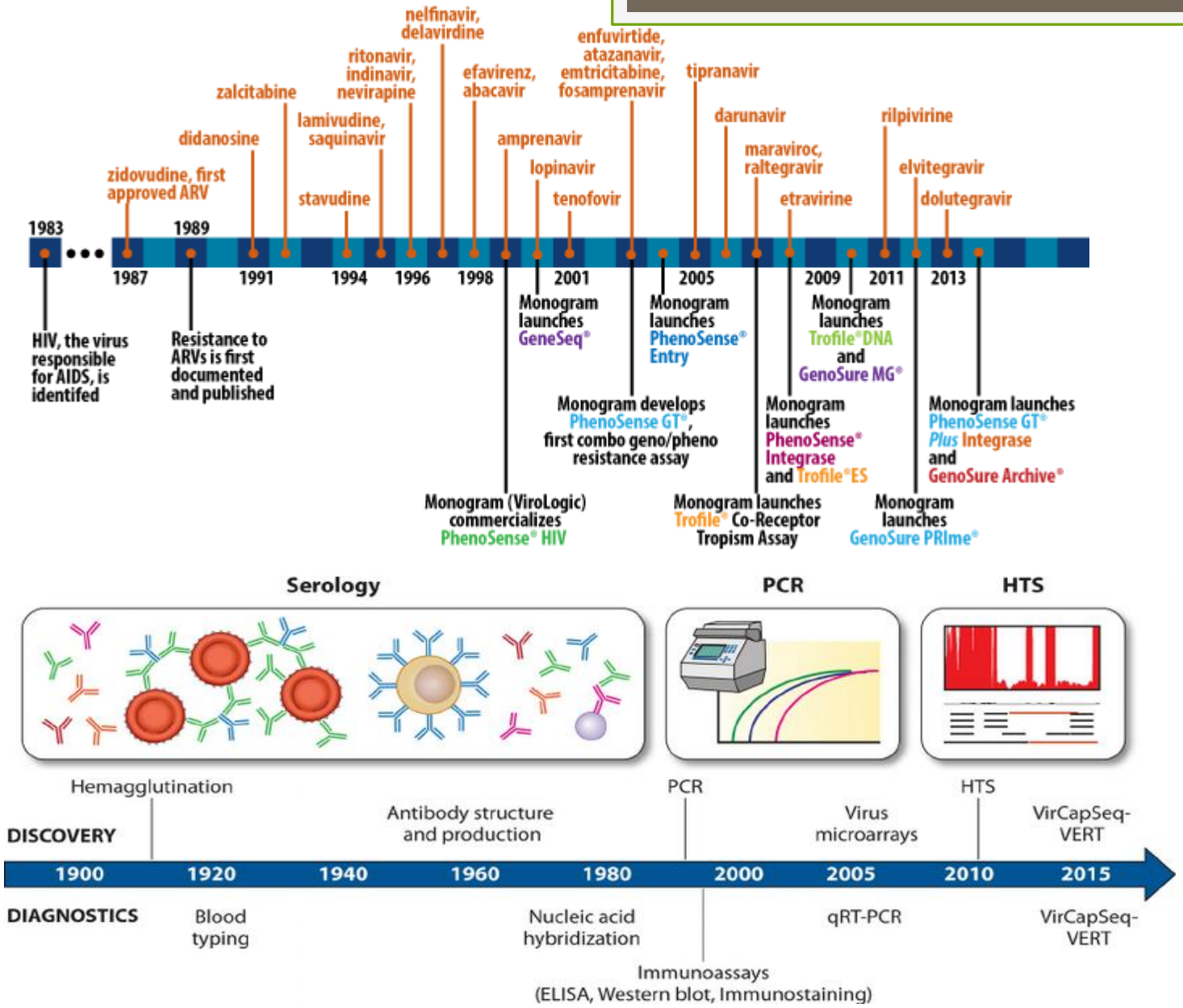
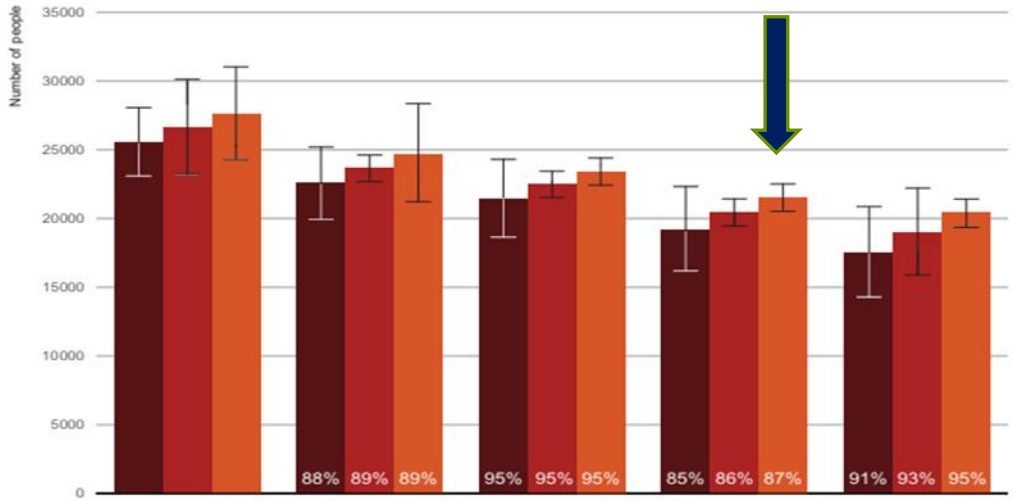
Combined Anti-retroviral drugs




nelfinavir, delavirdine
ritonavir, indinavir, nevirapine
enfuvirtide, atazanavir, emtricitabine, fosamprenavir
efavirenz, abacavir
tipranavir
zalcitabine
lamivudine, saquinavir
darunavir
rilpivirine
didanosine
amprenavir
maraviroc, raltegravir
elvitegravir
zidovudine, first approved ARV
lopinavir
etravirine
dolutegravir
stavudine
tenofovir
1983
1989
1987
1991
1994
1996
1998
2001
2005
2009
2011
2013
HIV, the virus responsible for AIDS, is identifed
Resistance to ARVs is first documented and published
Monogram launches GeneSeq®
Monogram launches PhenoSense® Entry
Monogram launches Trofile®DNA and GenoSure MG®
Monogram develops PhenoSense GT®, first combo geno/pheno resistance assay
Monogram launches PhenoSense® Integrase and Trofile®ES
Monogram launches PhenoSense GT® Plus Integrase and GenoSure Archive®
Monogram (ViroLogic) commercializes PhenoSense® HIV
Monogram launches Trofile® Co-Receptor Tropism Assay
Monogram launches GenoSure PRIme®
Serology
PCR
HTS
Hemagglutination
PCR
HTS
DISCOVERY
Antibody structure and production
Virus microarrays
VirCapSeq-VERT
1900
1920
1940
1960
1980
2000
2005
2010
2015
DIAGNOSTICS
Blood typing
Nucleic acid hybridization
qRT-PCR
VirCapSeq-VERT
Immunoassays (ELISA, Western blot, Immunostaining)

13% not on treatment

Figure 1.4.1 The HIV diagnosis and care cascade, 2015–2017



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Safety Profile of cART and Adverse Drug Reactions

Newer HIV regimens cause fewer side effects than regimens used in the past.

- Renal failure (Acute / Chronic)
- Hepatotoxicity
- Heart disease
- Diabetes or insulin resistance
- hyperlipidaemia
- lipodystrophy
- osteoporosis
- peripheral neuropathy
- Mental health-related effects, including insomnia, depression, and thoughts of suicide

Case Study: CA

- 38 year old man. Initial HIV diagnosis Jan 2016. Seroconversion illness. Last HIV negative test June 2015.
- Initial contact was SOPV outreach with a Sexual Health Nurse
- Multiple presentations since 2010
  - Red Flags
    - Male – not engaging
    - STI every presentation
    - Chem sex – IDU speed initially then Ice; never sober with sex
    - Multiple same sex partners; never opposite sex

HEADDS: CA

- H: Lives with flat mates; fractured family dynamics and in touch with Mother. 3 siblings. Mother – ETOH and 'ex' Heroin; Father – not present since aged 15 years old.
- E: Completed Year 12 then TAFE – hospitality
- A: Works as a Front Manager in a 5* restaurant. Full time. Not many absences. Enjoys works. Outside of work, no other interest / activities
- D: Smoker since aged 11 years; cannabis aged 15 years. IDU around same time. ETOH - >6 standard drinks per day; drunk at work but manages to keep this 'hidden' Has worked under IDU at work.
- S: First age of SI 14 years old; SSA only; identifies as a gay man. Out to family – mother OK with sexuality; out at work. Meets most men on line; not GLB+ community connected.
- S: Has not been formally diagnosed with MH issues. Has never sought counselling. ETOH not seen as an issue. Drug use is 'under control'

Status

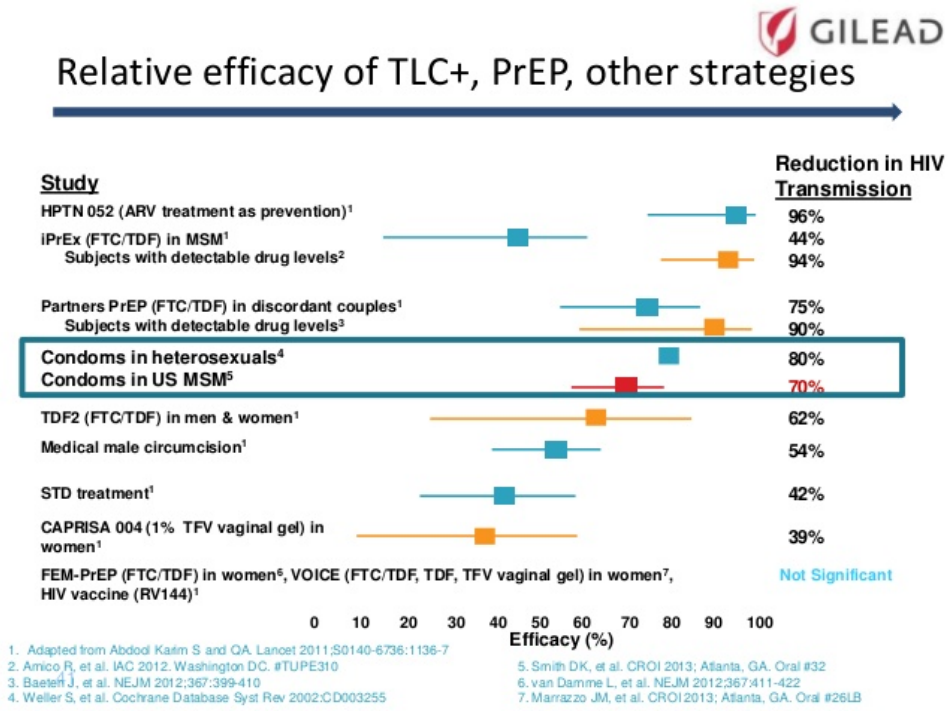
- Since HIV diagnosis, has been 'chaotically' engaging in HIV treatments and has an undetectable HIV VL
- ETOH / Substance use – multiple attempts – IP detox/ rehab / OP/ NA/ AA → has reduced use but still over >6 standard drinks a day (Manages to maintain good body image); ice down to weekly
- Hep C negative; LFTs → fatty liver
- Responses well to RNs via phone but misses appointments ++++ (HIV Clinic, Metabolic and Liver Clinics); lots of excuses but never misses scripts for cART
- Engages well with Primary NP; never sees the same Registrar or MO every visit because of changes in roles

PrEP Biomedical Prevention

- **Evidence**
  - iPrEX study, the
  - PROUD study
  - IPERGAY

TGA Approved
May 2016

PBAC listed as a S85
1/4/2018

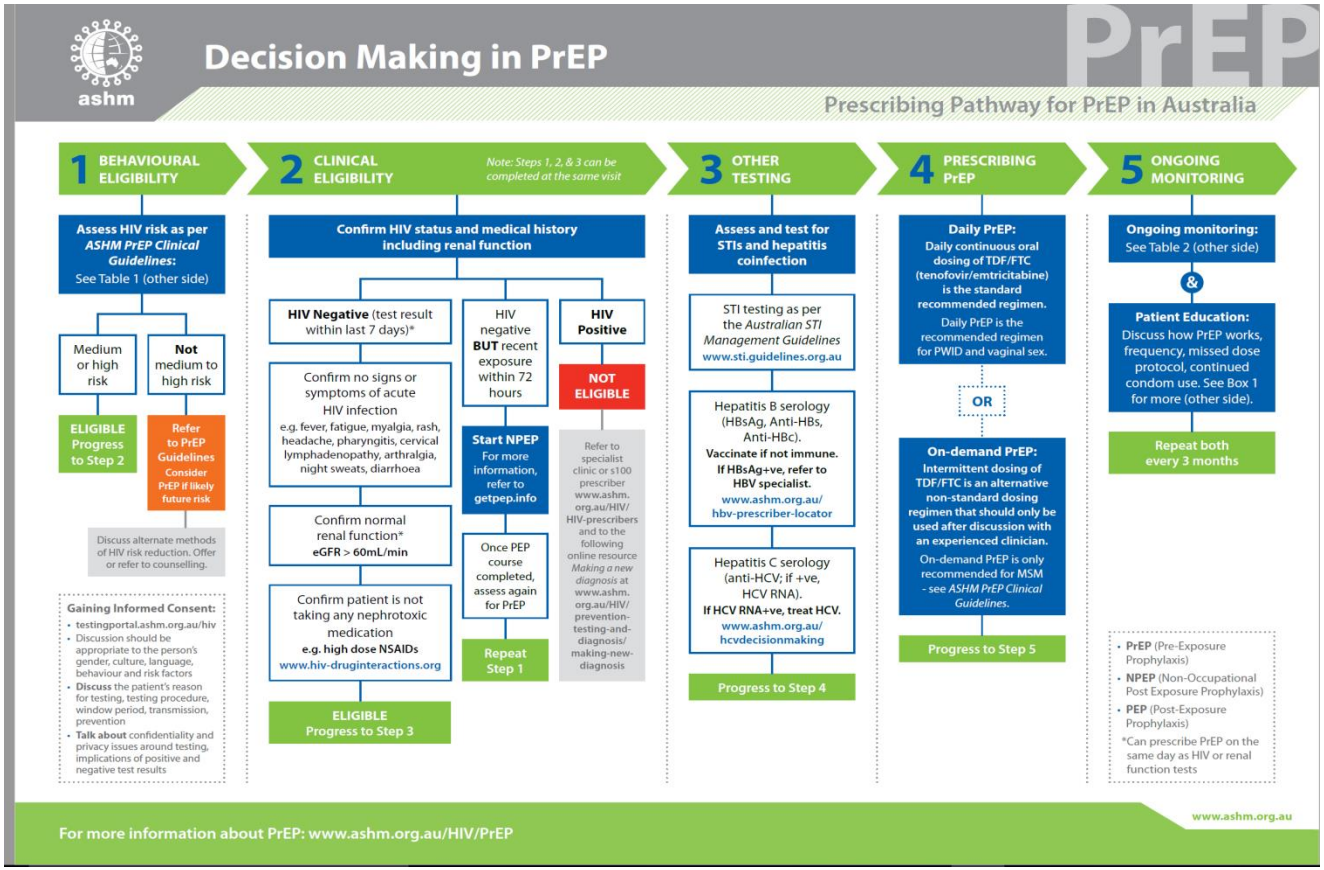


PrEP (Listed as S85)

Tenofovir disiproxil fumarate (TDF) and emtricitabine (FTC) well established nucleoside reverse transcriptase inhibitors already used for treatment of HIV-1

- Clinical trials have evaluated oral TDF, oral TDF/FTC combination and TDF vaginal gel
  - Safe, potent and well tolerated
  - Available co-formulated in single pill (Truvada)
  - Both FTC and TDF have long plasma (10 to 17 hours) and intracellular (39[1] and 150[2] hours) half-lives
  - Have high penetration in vaginal and rectal tissues
  - *Post-Exposure Prophylaxis (PEP) is not approved by TGA or PBAC but is the same formulation as PrEP (TDF/FTC) and only prescribed as part of a Research Study (Cost $296 per month + $665 for 3rd drug) vs in past ($1200 per month in 2016)*

PrEP


ashm
Decision Making in PrEP
PrEP
Prescribing Pathway for PrEP in Australia
1 BEHAVIOURAL ELIGIBILITY
2 CLINICAL ELIGIBILITY
Note: Steps 1, 2, & 3 can be completed at the same visit
3 OTHER TESTING
4 PRESCRIBING PrEP
5 ONGOING MONITORING
Assess HIV risk as per ASHM PrEP Clinical Guidelines: See Table 1 (other side)
Medium or high risk
Not medium to high risk
ELIGIBLE Progress to Step 2
Refer to PrEP Guidelines Consider PrEP if likely future risk
Discuss alternate methods of HIV risk reduction. Offer or refer to counselling.
Gaining Informed Consent:
testingportal.ashm.org.au/hiv
Discussion should be appropriate to the person's gender, culture, language, behaviour and risk factors
Discuss the patient's reason for testing, testing procedure, window period, transmission, prevention
Talk about confidentiality and privacy issues around testing, implications of positive and negative test results
Confirm HIV status and medical history including renal function
HIV Negative (test result within last 7 days)*
Confirm no signs or symptoms of acute HIV infection
e.g. fever, fatigue, myalgia, rash, headache, pharyngitis, cervical lymphadenopathy, arthralgia, night sweats, diarrhoea
Confirm normal renal function* eGFR > 60mL/min
Confirm patient is not taking any nephrotoxic medication
e.g. high dose NSAIDs
www.hiv-druginteractions.org
ELIGIBLE Progress to Step 3
HIV negative BUT recent exposure within 72 hours
Start NPEP For more information, refer to getpep.info
Once PEP course completed, assess again for PrEP
Repeat Step 1
HIV Positive
NOT ELIGIBLE
Refer to specialist clinic or s100 prescriber www.ashm.org.au/HIV/HIV-prescribers and to the following online resource Making a new diagnosis at www.ashm.org.au/HIV/prevention-testing-and-diagnosis/making-new-diagnosis
Assess and test for STIs and hepatitis coinfection
STI testing as per the Australian STI Management Guidelines www.sti.guidelines.org.au
Hepatitis B serology (HBsAg, Anti-HBs, Anti-HBc). Vaccinate if not immune. If HBsAg+ve, refer to HBV specialist. www.ashm.org.au/hbv-prescriber-locator
Hepatitis C serology (anti-HCV; if +ve, HCV RNA). If HCV RNA+ve, treat HCV. www.ashm.org.au/hcvdecisionmaking
Progress to Step 4
Daily PrEP: Daily continuous oral dosing of TDF/FTC (tenofovir/emtricitabine) is the standard recommended regimen. Daily PrEP is the recommended regimen for PWID and vaginal sex.
OR
On-demand PrEP: Intermittent dosing of TDF/FTC is an alternative non-standard dosing regimen that should only be used after discussion with an experienced clinician. On-demand PrEP is only recommended for MSM - see ASHM PrEP Clinical Guidelines.
Progress to Step 5
Ongoing monitoring: See Table 2 (other side)
&
Patient Education: Discuss how PrEP works, frequency, missed dose protocol, continued condom use. See Box 1 for more (other side).
Repeat both every 3 months
PrEP (Pre-Exposure Prophylaxis)
NPEP (Non-Occupational Post Exposure Prophylaxis)
PEP (Post-Exposure Prophylaxis)
*Can prescribe PrEP on the same day as HIV or renal function tests
For more information about PrEP: www.ashm.org.au/HIV/PrEP
www.ashm.org.au

S100 – Highly Specialised Drugs Program

- The Highly Specialised Drugs (HSD) Program provides access to specialised Pharmaceutical Benefits Scheme (PBS) medicines for the treatment of chronic conditions which, because of their clinical use and other special features, have restrictions on where they can be prescribed and supplied. In most cases, medical practitioners are required to undertake specific training or be affiliated with a specialised hospital unit to prescribe these medicines.
- Medical Practitioners who hold a S100 prescriber licence are allowed to prescribe but not GPs who are not S100 prescriber or NP **who are** S100 prescribers

S100 Prescribing

Prescriber eligibility

To write HSD prescriptions, a prescriber must be a medical practitioner issued with a PBS prescriber number and meet at least 1 of the requirements in the following table:

must be:	must be:
•a staff hospital specialist, or a visiting or consulting hospital specialist affiliated with the public or private hospital unit •an accredited prescriber of HIV/AIDS medicine •a general practitioner or non-specialist hospital doctor who provides maintenance therapy under the guidance of a treating specialist	•an accredited prescriber of HIV antiretroviral therapy, clozapine maintenance therapy or chronic hepatitis B therapy - community or hospital-

S100 Prescribing

- Section 100 Programs and include:
  - Highly Specialised Drugs Program
  - Efficient Funding of Chemotherapy
  - Botulinum Toxin Program
  - Growth Hormone Program
  - IVF Program
  - Opiate Dependence Treatment Program

Barriers to 90-90-90

- HIV is a chronic manageable condition
- Anti-retro-viral drugs are efficacious and safer than previous HAART and side effects can be monitored by a NP
- The cost of cART has significantly reduced since off-patent and generic versions are available
- Co-morbidities such as cardiovascular issues and endocrine problems can be managed by NPs in collaboration with a GP or Specialist
- For most PLWH monitoring is done every 6 months and if their CD4 is robust, they can even be monitored annually
- There are patient access issues to appointments: there are 240 S100 prescribers in Australia, most of them concentrated in CBD Sydney and Melbourne