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Developing a sustainable HIV,
viral hepatitis & sexual health workforce

Empowering Clinical Practice: Leveraging the Doxy-PEP Decision-Making Tool for Better Outcomes

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Program and Learning Outcomes

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Learning Outcomes

RACGP CPD Approved Activity — Educational Activities 1 hours

- Understand the key components of the Doxy-PEP Decision-Making Tool and how to integrate it into clinical practice
- Identify best practices for prescribing and managing Doxy-PEP for patients in various clinical scenarios
- Apply real-life case examples to improve decision-making and patient care when implementing Doxy-PEP
- Enhance clinical confidence in using Doxy-PEP through practical strategies and effective workflow integration

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Topic areas of today's session include...

1. Welcome and Introductions
2. What is Doxy-PEP?
3. Doxy-PEP prescribing
4. Integrating the DMT into practice
5. Q&A

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What is Doxy-PEP?

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What is Doxy-PEP?

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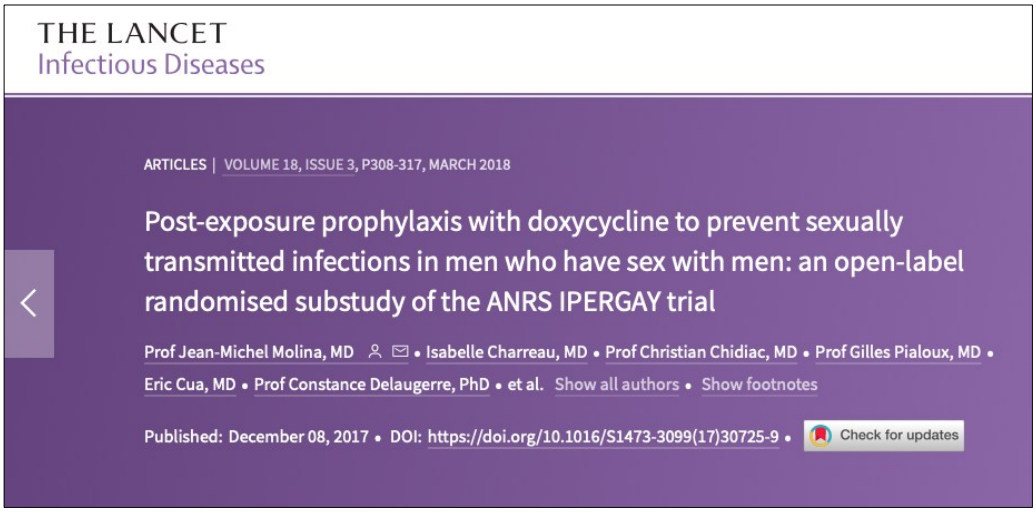
Ipergay – Doxy-PEP substudy



THE LANCET
Infectious Diseases

ARTICLES | VOLUME 18, ISSUE 3, P308-317, MARCH 2018

Post-exposure prophylaxis with doxycycline to prevent sexually transmitted infections in men who have sex with men: an open-label randomised substudy of the ANRS IPERGAY trial

Prof Jean-Michel Molina, MD • Isabelle Charreau, MD • Prof Christian Chidiac, MD • Prof Gilles Pialoux, MD • Eric Cua, MD • Prof Constance Delaugerre, PhD • et al. Show all authors • Show footnotes

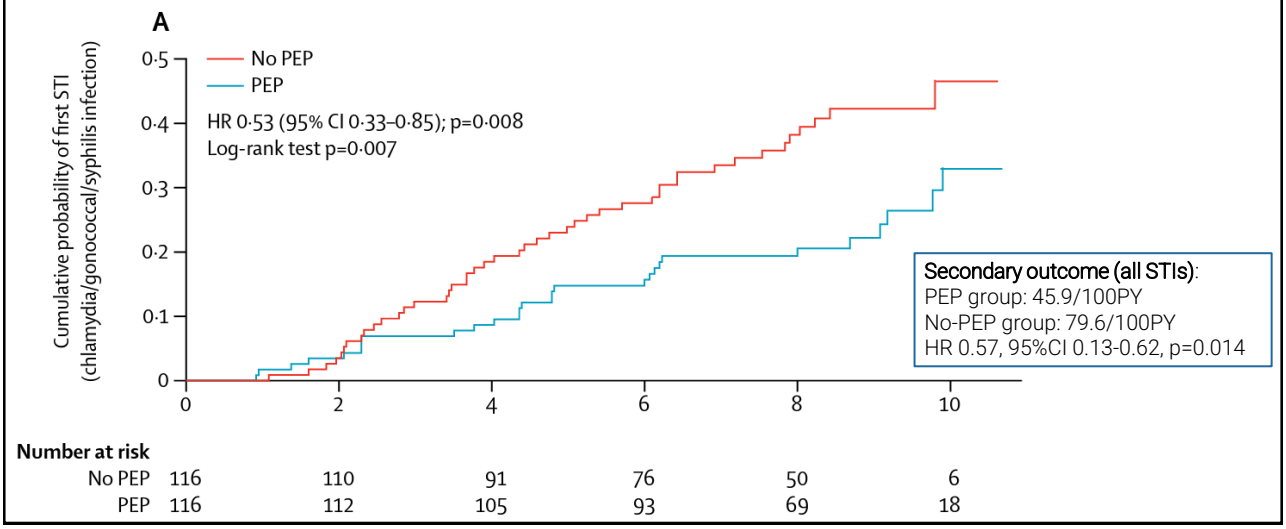
Published: December 08, 2017 • DOI: https://doi.org/10.1016/S1473-3099(17)30725-9 • Check for updates

Ipergay – Doxy-PEP substudy

- 232 GBMSM enrolled in the ANRS Ipergay PrEP Study in France.
- Randomised 1:1 to "doxy" or "no doxy" (open label).
- Doxycycline intervention:
  - 200mg (2 pills) within 24h (no later than 72h) after sex.
  - No more than 6 pills per week.
- Tested for STIs every 2 months:
  - Syphilis serology
  - Chlamydia and gonorrhoea pcr on anal/throat swabs and urine.
  - Gonococcal cultures prior to treatment.
- Up to 11 months of follow-up (depending on date of enrolment).
- Primary outcome: Occurrence of a first STI after enrolment, as an intention-to-treat analysis.
- Secondary outcome: Occurrence of all episodes of STIs during the trial.

Adherence:
Median 6.8 pills/month
(IQR 2.8-14.5)
For 83% of occasions of sex,
doxy was taken within 24h after sex.

Ipergay – Doxy-PEP substudy – any first STI



Number at risk

No PEP	116	110	91	76	50	6
PEP	116	112	105	93	69	18

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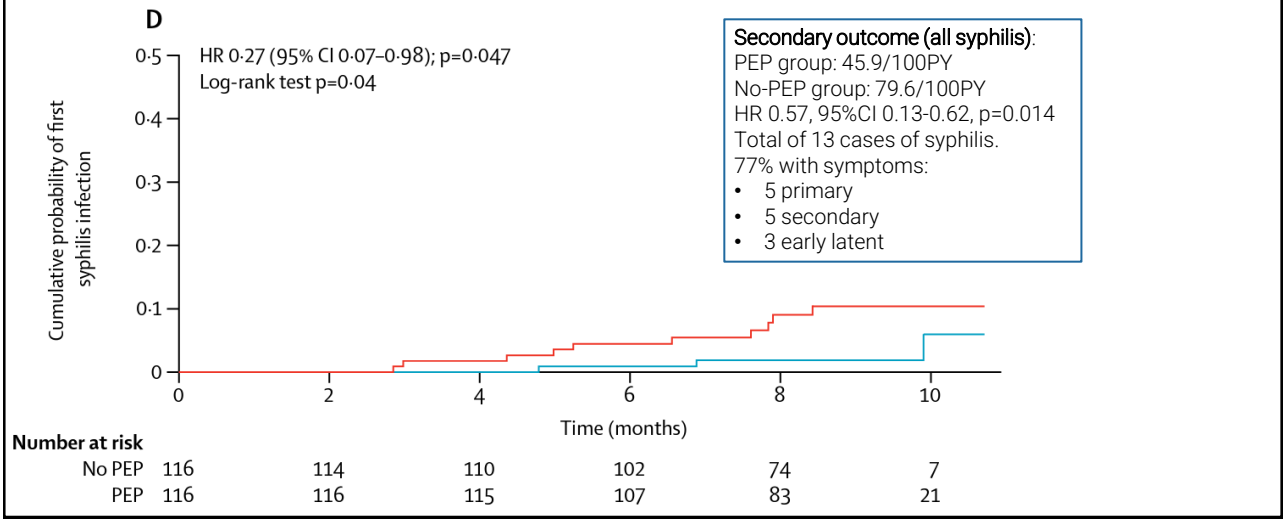
Ipergay – Doxy-PEP substudy – first syphilis



Number at risk

No PEP	116	114	110	102	74	7
PEP	116	116	115	107	83	21

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Co-Chairs Choice

Doxycycline post-exposure prophylaxis for prevention of STIs among MSM and TGW who are living with HIV or on PrEP

Annie Luetkemeyer, Julie Dombrowski, Stephanie Cohen, Deborah Donnell, Cole Grabow, Clare Brown, Cheryl Malinski, Rodney Perkins, Melody Nasser, Carolina Lopez, Susan Buchbinder, Hyman Scott, Edwin Charlebois, Diane Havlir, Olusegun Soge, Connie Celum on behalf of the **DoxyPEP Study Team**

AIDS 2022

DOXYPEP

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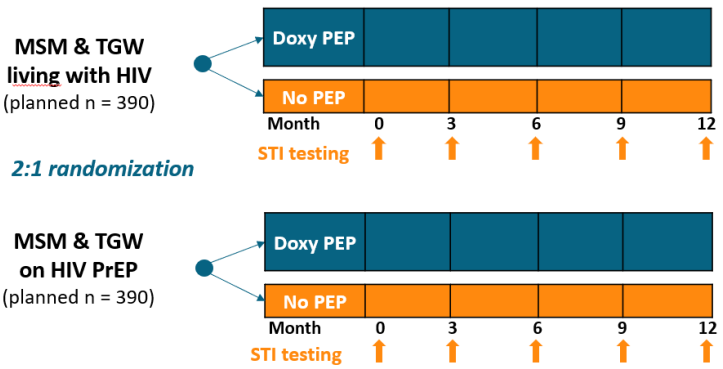
Intervention: Open label doxycycline 200mg taken as PEP within 72 hours after condomless sexual contact

Maximum of 200 mg every 24 hours



Inclusion criteria:
- Male sex at birth
- Living with HIV or on PrEP
- ≥ 1 STI in past 12 months
- Condomless sex with ≥ 1 male partner in past 12 months

STI Testing: Quarterly 3 site GC/CT testing + RPR, GC culture before treatment

Sites: San Francisco & Seattle HIV & STI clinics

Stopped early due to significant effectiveness in both cohorts

AIDS 2022

DOXYPEP

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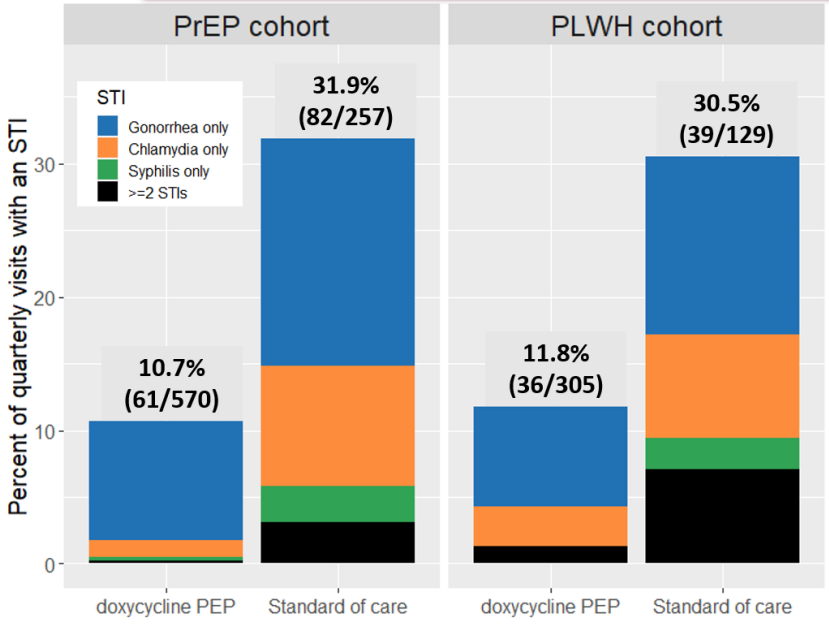
Primary Endpoint: STI incidence per quarter



Reduction in STI incidence/quarter	
	risk reduction (95% CI)
PrEP	0.34 (0.24 - 0.46)
Living with HIV	0.38 (0.24 - 0.60)
Total	0.35 (0.27 - 0.46)

all p< 0.0001

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Summary - Effectiveness

- **Syphilis:**
  - **ANRS Ipergay Doxy-PEP:** 73% reduction in "first" syphilis (p=0.04)
  - **ANRS DOXVAC:** 80% reduction in "first" syphilis (p<0.001)
  - **US DOXYPEP:** 80% reduction in quarterly syphilis (p<0.01 in PrEP users, not sig in PLWHIV
- **Chlamydia:**
  - **ANRS Ipergay Doxy-PEP:** 70% reduction in "first" chlamydia (p=0.006)
  - **ANRS DOXVAC:** 90% reduction in "first" chlamydia (p<0.0001)
  - **US DOXYPEP:** 80% reduction in quarterly chlamydia (p<0.001)
- **Gonorrhoea:**
  - **ANRS Ipergay Doxy-PEP:** No significant reduction in "first" gonorrhoea (p=0.52)
  - **ANRS DOXVAC:** 55% reduction in quarterly gonorrhoea (p=0.001)
  - **US DOXYPEP:** 50% reduction in "first" gonorrhoea (p=0.001) attributable to Doxy-PEP.
- **Mgen:**
  - **ANRS Ipergay Doxy-PEP:** 45% reduction in "first" Mgen (p=0.015)

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Summary – AMR and microbiome

- **US DOXYPEP: (median follow-up 9 months)**
  - S. aureus: Doxy-PEP → 14% reduction in colonisation, 8% increase in TCN-R.
  - Other Neisseria spp.: Present in 2/3 participants, no change in TCN-R.

- **ANRS DOXYVAC: (median follow-up 9 months)**
  - N. gonorrhoeae: No significant difference in TCN-R
  - MRSA: No significant difference on pharyngeal swabs.
  - ESBL E.coli: No significant difference on anal swabs.

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Integrating the Doxy-PEP Decision Making Tool

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DoxyPEP Decision Making Tool

DoxyPEP is 200mg of doxycycline taken after sex by gay or bisexual men, or transgender women to reduce risk of syphilis

1. Suitability

Gay and bisexual men and transgender women[1] who

- Are at increased risk of syphilis (see box 1 overleaf), or
- Are at increased risk of serious consequences of chlamydia or syphilis[2], e.g.
  - Psychosocial consequences
  - Transmission to women (or person with a uterus).

And

- Have no contraindications to taking doxycycline[3]
- Makes an informed decision after considering risks and benefits to take doxyPEP.

Notes:

1. *No data currently on effectiveness or dosing in cis-gender women, transgender men or other people who are assigned female at birth. There is evidence of effectiveness in heterosexual men, although syphilis or STI risk is usually much lower.*
2. *Asymptomatic chlamydia is clinically insignificant in most gay and bisexual men. However, in some people, symptomatic chlamydia and syphilis might be a significant concern. For example, pyschosocial consequences (e.g. anxiety about receiving an STI diagnosis), relationship circumstances, or potential for transmission to women (or other people with a uterus) who might experience severe clinical manifestations (including congenital syphilis or pelvic inflammatory disease).*
3. *Contraindications are uncommon and include (risk of) pregnancy and previous or anticipated severe adverse reactions to tetracyclines and/or doxycycline which cannot be managed or mitigated (including allergy, drug eruptions, photosensitivity or gasto-esophageal reflux).*

2. Assessment and Testing

Part of a holistic and comprehensive sexual health approach including STI, HIV and blood borne virus testing and vaccination which should include:

- Assess and offer HIV pre-exposure prophylaxis (PrEP) if there is an identified risk of HIV
- Provide referrals to HIV care and encourage sustained engagement where appropriate
- Conduct testing for STIs and blood-borne viruses in line with the Australian STI Management Guidelines
- Offer vaccinations as indicated (mpox, hepatitis A and B, HPV)
- Patient education (see box 2).

3. Prescribing DoxyPEP

Explain dosing

200mg (2x100mg) tablets within 24 hours and no later than 72 hours after sex. Repeat dosing no more than every 24 hours (i.e. max 200mg/day). (see patient education box).

Prescribe

Doxycycline 100mg tablet, TT PO, (200mg) within 24 hours (up to 72 hours), max 200mg/24h.

Quantity

- Estimate quantity based on expected frequency of use, patient wishes and duration of next review (e.g. median 10 tablets/month in studies, patient prefers enough to last until expected 6 month review = 60 tablets)
- Only 7 tablets + 1 repeat are PBS subsidised (unrestricted)
- Larger quantities can be prescribed as a private prescription for total quantity or for 28 tablets plus sufficient repeats.

4. Ongoing Monitoring

- Ongoing/regular STI testing (gonorrhoea, chlamydia, syphilis and HIV if not already HIV positive)
- No specific additional monitoring for those taking doxyPEP (e.g. renal or liver) is required
- Review ongoing need for doxyPEP and patient preferences. Consider duration of review for ongoing prescriptions (e.g. 6 months)
- Anyone diagnosed with gonorrhoea should have a swab collected for gonococcal culture prior to the administration of antibiotics.

Interpreting STI results and diagnosis and management of concurrent STIs:
No change with doxyPEP

- Syphilis serology interpretation – as per guidelines
- Sexual contacts of syphilis – treat as per guidelines
- Test and manage sexual contacts of other bacterial STIs according to guidelines, and wait for results in most cases, except when there has been recent contact with gonorrhoea
- Risk or sexual contact with HIV: post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) as per guidelines.

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Box 1: Patient Education

- Doxy-PEP is not 100% effective: approximately 80% for syphilis and chlamydia, and much less or not effective against gonorrhoea. Continue to test for STIs, particularly syphilis and HIV.
  - Clinical need for, and ideal frequency of, testing for asymptomatic gonorrhoea and chlamydia is not known
  - HIV and syphilis blood testing have important clinical and public health benefits
- Side effects and how to manage them (e.g. reflux, nausea, rash/photosensitivity).

Antimicrobial resistance

- Normal body bacteria (skin, intestines) may develop resistance – the health impact is not known.
- Similar to other ongoing use indication for tetracyclines, taking doxy-PEP may contribute to overall antibiotic resistance in the community.

Box 2: STI results and diagnosis

Interpreting STI results and diagnosis and management of concurrent STIs:
No change with doxy-PEP

- Syphilis serology interpretation – as per guidelines
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- Risk or sexual contact with HIV: post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) as per guidelines.

Box 3: Footnotes

1. *No data currently on effectiveness or dosing in cis women, trans men or other people who are assigned female at birth. There is evidence of effectiveness in heterosexual men, although syphilis or STI risk is usually much lower.*
2. *Asymptomatic chlamydia is clinically insignificant in most gay and bisexual men. However, in some people, symptomatic chlamydia might be a significant concern. For example, psychosocial consequences (e.g. anxiety about receiving an STI diagnosis), relationship circumstances, or potential for transmission to women (or other people with a uterus) who might experience severe clinical manifestations (including congenital syphilis or pelvic inflammatory disease).*
3. *Contraindications are uncommon and include (risk of) pregnancy and previous or anticipated severe adverse reactions to tetracyclines and/or doxycycline which cannot be managed or mitigated (including allergy, drug eruptions, photosensitivity or gasto-esophageal reflux).*
4. *Not all PrEP users are at increased risk of STI.*
5. *Many gay and bisexual men prefer to manage their risk through frequent STI testing rather than doxy-PEP.*

ASHM would like to thank Dr Nicholas Medland and the clinicians who advised on and reviewed this resource.

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Side effects:

Common but non-serious side effects

- nausea, vomiting and diarrhoea
- skin may become more sensitive to sunlight, causing a rash or sunburn

Rare but serious reactions

- allergies
- oesophageal ulcers
- liver damage

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pregnancy

- after 18 weeks of pregnancy, can cause bone and teeth defects
- advise about options for contraception.

However:

- *Doxy-PEP was found to be ineffective in a study of cisgender women in Kenya, although further analysis has suggested that this was the result of low adherence to Doxy-PEP*

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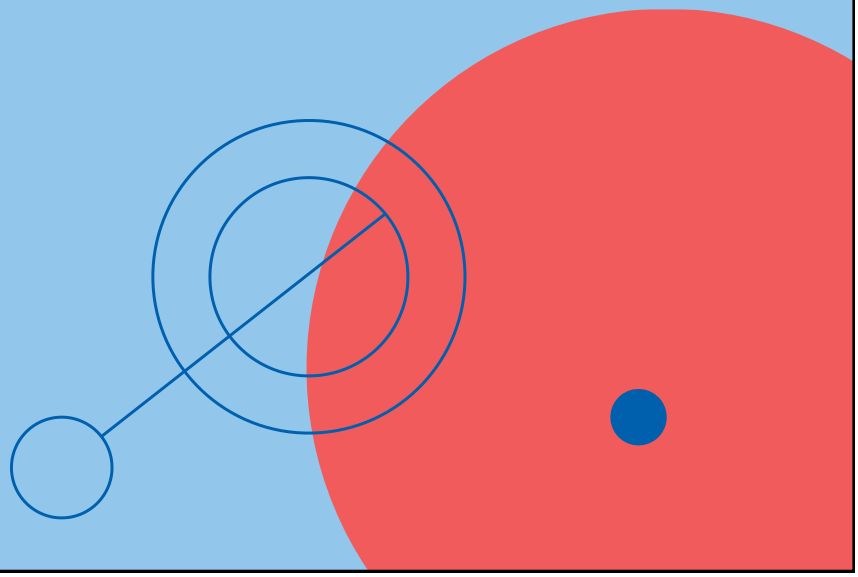
Case Studies



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Jack

Jack is a 36 year old homosexually active man, he attends for a routine PrEP screen and script

" My partner is taking doxy-PEP. Can you tell me about it?, can I take it?"

What do you need to know to assess Jacks suitability?

What do you need to discuss with Jack?

What do you advise regarding follow-up, monitoring and ongoing management of doxy-PEP?

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Front page

1. Suitability

Gay and bisexual men and trans women[1] who

- Are at increased risk of syphilis (*See below*), or
- Are at increased risk of serious consequences of chlamydia[2] or syphilis, e.g.
  - Psychosocial consequences
  - Transmission to women (or person with a uterus).

And

- Have no contraindications to taking doxycycline[3]
- Makes an informed decision after considering risks and benefits to take doxy-PEP.

Population Risk Factors

Markers of syphilis/STI risk in gay and bisexual men and trans women to consider for doxy-PEP

- Recent diagnosis (e.g. within the last year) of infectious/early syphilis (e.g. primary, secondary or evidence of acquisition within two years)
- Recent diagnoses (e.g. two or more within in 12 months) of other bacterial STIs (e.g. gonorrhoea, chlamydia)
- Periods of increased risk (e.g. sex parties, chemsex, holidays)
- At risk-patients who have both cis male and partner/s with a uterus, to protect their partners from syphilis and chlamydia.

Opportunities to discuss risk and consider Doxy-PEP if:

- Starting or continuing HIV PrEP[4]
- Seeking STI testing because of risk[5]

2. Assessment and Testing

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4. *Not all PrEP users are at increased risk of STI.*
5. *Many gay and bisexual men prefer to manage their risk through frequent STI testing rather than doxy-PEP.*

Tom

Tom is a 56 year old man who has sex with both male and female partners. He uses condoms 100%. He has a history of GORD. He attends for follow-up testing following a diagnosis of secondary syphilis.

1. Would Tom be eligible for DoxyPEP?, why or why not?
2. What information do you need?
3. what advice to you give to Tom?