Australian consensus statement on doxycycline post-exposure prophylaxis (doxy-PEP) for the prevention of syphilis, chlamydia and gonorrhoea among gay, bisexual and other men who have sex with men

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Abstract

Introduction: Doxycycline post-exposure prophylaxis (doxy-PEP) involves consuming 200 mg of doxycycline up to 72 hours after a condomless sex act to reduce the risk of bacterial sexually transmitted infections (STIs). Recent clinical trials of doxy-PEP have demonstrated significant reductions in syphilis, chlamydia and, to a lesser degree, gonorrhoea among gay, bisexual and other men who have sex with men (GBMSM). There is a high level of interest in doxy-PEP in the GBMSM community and, in response, the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) held a national consensus conference with the aim of creating preliminary guidance for clinicians, community, researchers and policy makers.

Main recommendations: There was broad agreement that doxy-PEP should be considered *primarily* for the prevention of syphilis in GBMSM who are at risk of this STI, with a secondary benefit of reductions in other bacterial STIs. At the end of the consensus process, there remained some disagreement, as some stakeholders felt strongly that doxy-PEP should be considered *only* for the prevention of syphilis in GBMSM, and that the risk of increasing antimicrobial resistance outweighed any potential benefit from reductions in other bacterial STIs in the target population. The national roundtable made several other recommendations for clinicians, community, researchers and policy makers, as detailed in this article. ASHM will support the development of detailed clinical guidelines and education materials on doxy-PEP (www.ashm.org.au/doxy-pep).

Changes in management as a result of this consensus statement: For GBMSM at high risk of syphilis, and perhaps other bacterial STIs, clinicians may consider prescribing doxy-PEP for a limited period of time, followed by a review of ongoing need. Unlike human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP), doxy-PEP may not be suitable as a population-level intervention and should instead be used more selectively.

In Australia, diagnoses of bacterial sexually transmitted infections (STI), especially syphilis and gonorrhoea, have increased substantially over the past decade, particularly among gay, bisexual and other men who have sex with men (GBMSM).[1] For Australian GBMSM, this STI increase has occurred in the context of guideline recommendations for increased STI testing frequency, widespread uptake of human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP), and widespread uptake of highly effective HIV treatment that eliminates the risk of onward HIV transmission.[2-4] Doxycycline post-exposure prophylaxis (doxy-PEP) is a new biomedical STI prevention tool that involves consumption of 200 mg of doxycycline (immediate release) up to 72 hours after a condomless sex act to reduce the risk of bacterial STIs. Among GBMSM, clinical trials of doxy-PEP have demonstrated significant reductions in syphilis (by 70–80%) and chlamydia (by 70–90%), and, to a lesser degree, gonorrhoea (ineffective in some trials, or 50–55% reduction in other trials, due to varying levels of tetracycline resistance in gonococcal isolates in different populations).[5] However, uncertainty remains regarding unintended outcomes from doxy-PEP. These may include harms to individuals taking doxy-PEP, such as disruptions to their microbiome and increased antimicrobial resistance (AMR) in STIs and other organisms, and harms to the community through increased population-level AMR. As such, individuals who might benefit from doxy-PEP and their clinicians need guidance on the potential benefits versus the potential harms from using doxy-PEP, while considering whether this STI prevention strategy is suitable for them in their current context, in addition to conventional STI prevention strategies such as condoms.

Although doxy-PEP is an effective strategy to prevent bacterial STIs such as chlamydia, gonorrhoea and syphilis among GBMSM, the risk–benefit calculation is most favourable for the prevention of syphilis. Of the bacterial STIs, syphilis carries the greatest morbidity among GBMSM, especially among GBMSM living with HIV.[6,7] In contrast, chlamydia and gonorrhoea infections among GBMSM are often asymptomatic, and they rarely cause complications.[8-10] In addition, doxy-PEP is less likely to be effective to prevent gonorrhoea in the Australian context, due to high rates of tetracycline resistance in Australian gonococcal isolates.[11]

Known risk factors for STIs include sexual behaviour history (eg, sex without condoms, casual sex partners, sexualised drug use), current use of PrEP, and HIV-positive status.[12-14] A recent analysis of clinical data from Boston, United States, explored the effectiveness of different doxy-PEP prescribing strategies to prevent one case of bacterial STI.[15] This analysis found that prescribing doxy-PEP for 12 months to individuals with one or more recent STI diagnosis (within the previous 12 months) was an efficient strategy for reducing the amount of doxy-PEP prescribed, with the number needed to treat (NNT) ranging from 1.3 to 1.5 to prevent one bacterial STI case over 12 months. As discussed above, the prevention of syphilis deserves particular attention, and the same analysis found that prescribing doxy-PEP to individuals currently diagnosed with syphilis resulted in the most efficient strategy for preventing subsequent syphilis diagnoses (NNT of 9.5 if doxy-PEP is used for 12 months). Similarly, having been diagnosed with two STIs (not syphilis) in the preceding six or 12 months conferred NNTs of 10.8 and 11.3, respectively, to prevent one case of syphilis if doxy-PEP were used for 12 months.[15]

STIs have additional implications for GBMSM with cisgender female sex partners or other sex partners with a uterus due to the risk of transmission to these partners. In women and other

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people with a uterus, chlamydia and gonorrhoea can cause pelvic inflammatory disease and associated complications, such as infertility, chronic pain and ectopic pregnancy.[16] Transmission of syphilis to a person who is pregnant, or who subsequently becomes pregnant, can result in complications including miscarriage, stillbirth, neonatal death and congenital syphilis with severe disability.[16] Because of these additional risks, a lower threshold may be warranted for prescribing doxy-PEP to GBMSM with concurrent cisgender female sex partners or other sex partners with a uterus. However, it should be noted that doxy-PEP has not been studied in terms of prevention benefit for sex partners.

The recommendations listed below are intended for GBMSM and do not apply to other communities or populations. Importantly, doxy-PEP was found to be ineffective in a study of cisgender women in Kenya, although further analysis has suggested that this may have been the result of low adherence to doxy-PEP.[17] Guidance for other communities or populations will need to be developed as evidence emerges.

Evidence for the effectiveness of doxy-PEP and considerations around potential risks of doxy-PEP are detailed in the interim position statement previously published by the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM).[5] This statement also highlighted evidence gaps, particularly regarding potential effects on AMR and users' microbiome. The statement posed clinical practice and implementation challenges regarding how or whether to recommend doxy-PEP to patients, how to support clinicians and patients in decision making, and how to identify priorities for future research and evaluation. Given these complexities, the statement concluded that further clinical guidance should be developed through a consultation process with community representatives, clinicians and relevant experts. For this purpose, ASHM embarked on a consensus-building process, as described here, with the aim of producing clear recommendations for community, clinicians, researchers and policy makers in Australia.

Methods

The consensus process consisted of a structured national roundtable (consensus conference) to discuss issues pertinent to doxy-PEP and formulate recommendations, followed by three rounds of online feedback on the draft recommendations, followed by a survey of participants to measure consensus on the final recommendations.

The roundtable was planned by a steering committee, with two co-chairs (Supporting Information 1), and assisted by ASHM staff. Members of the steering committee were invited based on their expertise and their leadership in the sexual health sector and included representatives from the affected community. The steering committee was tasked with setting the agenda for the planned roundtable day, including topics for formal presentation by expert speakers. If an expert speaker was not available to present, they were asked to nominate an alternative speaker. The steering committee's second task was to draw up a list of roundtable invitees, with the aim of ensuring adequate representation of relevant expertise and representation from affected communities (Supporting Information 1). The steering committee recommended which fields and disciplines were required for the consensus conference, in particular, those outside the sexual health field, such as antimicrobial stewardship and representatives from community organisations for people living with HIV, including representatives who are living with HIV. People living with HIV have a personal interest in AMR, as their community is disproportionally affected by bacterial infections such as pneumococcal pneumonia.[18] Members of the steering committee were themselves also participants in the roundtable and subsequent rounds of feedback. Before the roundtable, participants were provided with a copy of the ASHM interim position statement[5] to ensure that all participants had access to relevant data to inform their deliberations.

The national roundtable was convened on 17 March 2023 at the Kirby Institute, University of New South Wales, and was attended by community representatives, clinicians, researchers and experts in infectious diseases, public health, epidemiology, microbiology and antimicrobial stewardship (Supporting Information 1). Participants who were unable to attend in person were able to join online. The day started with expert presentations (Supporting Information 2). This was followed by small-group discussions, where participants self-selected to join one of the following discussion groups, which were each joined by a scribe to record the deliberations:

- AMR considerations;
- clinical and epidemiological considerations;
- community considerations; and
- a separate group consisting of participants joining online.

These groups then provided feedback to the entire group, with opportunity for all participants to contribute further thoughts, which were also recorded by a scribe.

The full summary of issues discussed during the roundtable is presented in the Supporting Information 3. Following the roundtable, based on the recorded notes, ASHM drafted a list of recommendations for clinicians, the community sector, researchers, and policy makers. These draft recommendations were circulated among the roundtable participants for three rounds of online feedback and re-drafting. During this process, participants were invited to comment on all aspects of the recommendations. The final version of the consensus statement, as presented below, was sent out to participants on 17 September and launched at the Australasian Sexual and Reproductive Health Conference in Manly, New South Wales, and online on 20 September 2023.

The consensus process was not prospectively registered on a trial registry. This consensus process was not funded, and neither the co-chairs, the steering committee members, nor the participants were reimbursed for their time. No participants declared conflicts of interest. Several participants were investigators on the Syphilaxis trial (ClinicalTrials.gov identifier, NCT03709459), a clinical trial on the use of doxycycline to prevent STIs, but the trial had completed recruitment at the time of the roundtable and hence in the view of the organisers did not pose a conflict of interest.

This consensus statement has been endorsed by the organisations listed in Supporting Information 1.

Consensus measurement

During the roundtable there was broad agreement on the recommendations listed below, except one specific point: of the listed participants, four expressed the view that doxy-PEP should be considered only for the prevention of syphilis among

Participant responses to final consensus survey*

Questions	Number of responses
Total number of responses	49
Which version of the statement do you most agree with?	
a) Doxy-PEP should be considered *primarily* for the prevention of syphilis in GBMSM who are at risk of this STI, although for some individuals the reduction in chlamydia and the lesser reduction of gonorrhoea might be important.	45
b) Doxy-PEP should be considered *only* for the prevention of syphilis in GBMSM.	4
c) I don't agree with either of these statements.	0
Do you have any further comments regarding the above statements? (individual quoted comments)	
"I am happy to say that doxy-PEP should be primarily for the prevention of syphilis though I would be happier if it was stated it is for the prevention of all 3 bacteria (gono[rrhoea], chlamydia, and syphilis)."	
Do you agree with the other recommendations in the consensus statement?	
Total number of "yes" responses	47
Total number of "no" responses	2
If not, can you please explain what you disagree with? (individual quoted comments)†	
Disagreeing participant 1: "I don't believe bacterial STIs should be included as a criteria [sic] for use."	
Disagreeing participant 2: "1. I don't think doxy-PEP should be used as a strategy to prevent gonorrhoea — the risk of driving further AMR in multiple classes of antimicrobial agents through an impact on the bacterial efflux pump is too high to warrant recommending it for widespread use. 2. I only think doxy-PEP should be used as a strategy to prevent chlamydia in bisexual men with a proven history of past urethral chlamydial infections, in order to protect female partners from pelvic inflammatory disease and other high consequence complications of chlamydia infection in women. I don't think protection against oral/anal chlamydia infections in GBMSM are particularly relevant in this setting. In my practice, urethral chlamydia infection is very rarely seen in GBMSM."	
All other final comments from participants (individual quoted comments):	
"I agree with the rest of the statement, but I am worried about how the statement against daily doxy PrEP impacts Syphilaxis participants. Currently participants are told they can choose whether to take daily PrEP or episodic PEP."	
"I would prefer to have Recommendation 3 include the wording 'required' rather than 'recommended', although understand the difficulties around this."	
"I think doxy-PEP should be offered with GBMSM who present for HIV PEP as a combination, especially in people who may not return for full STI screening. This might help reduce the possibility of syphilis and chlamydia in this group."	
"In my view, the definition of 'recent' in relation to previous STIs should be better defined than it is currently. Specifically, the statement 'within 6 or 12 months' does not make good sense. It's either 6 or 12, or 6 for one group and 12 for another. I think being more specific, this statement will be more helpful for clinicians, particularly general practitioners."	

AMR = antimicrobial resistance; doxy-PEP = doxycycline post-exposure prophylaxis; GBMSM = gay, bisexual and other men who have sex with men; HIV = human immunodeficiency virus; PrEP = pre-exposure prophylaxis; PEP = post-exposure prophylaxis; STI = sexually transmitted infections. * One respondent declined to be named as a participant and asked to withdraw their participation; their stated reason for withdrawal was that doxy-PEP should only be used by GBMSM who are at high risk of syphilis, and they felt that this viewpoint was not in agreement with the consensus statement. † Both participants agreed with "version b" of the statement listed above (ie, "Doxy-PEP should be considered only for the prevention of syphilis in GBMSM"). ◆

GBMSM, rather than primarily be considered for this purpose, due to concerns that doxy-PEP might increase AMR in gonococci and other organisms; one additional participant (not listed) withdrew their participation for this same reason. Hence, after the consensus statement was finalised, all participants were emailed an online survey to assess their agreement with the final recommendations (Box).

Recommendations

Recommendations for community and clinicians

Recommendation 1. Doxy-PEP should be considered *primarily* for the prevention of syphilis in GBMSM who are at risk of this STI, although, for some individuals, the reduction in chlamydia and the lesser reduction of gonorrhoea might be important. Four of the listed stakeholders held the view that doxy-PEP should be considered *only* for the prevention of syphilis in GBMSM, for the reasons listed above.

Recommendation 2. Although the evidence for appropriate suitability criteria for commencing doxy-PEP is limited, the following might be appropriate for considering doxy-PEP until further data emerge:

- GBMSM with a recent syphilis diagnosis (eg, within the previous six or 12 months); or
- GBMSM with two or more recent other (ie, not syphilis) bacterial STI diagnoses (eg, within the previous six or 12 months), as a marker for syphilis risk; or
- GBMSM who identify an upcoming period of heightened STI risk (eg, attendance at a sex event, or holiday plans that likely involve sexual activity with multiple casual sex partners);
- GBMSM with concurrent male and cisgender female sex partners or other sex partners with a uterus, recognising the additional health risks posed by chlamydia, gonorrhoea and syphilis for people with a uterus;
- GBMSM who present for HIV PEP can also consider doxy-PEP, although the indications for HIV PEP do not necessarily indicate a need for doxy-PEP.

Recommendation 3. Given that STI risk is often not static, it is recommended to use doxy-PEP for a pre-defined period (eg, three to six months), followed by review of the need for ongoing use.

Recommendation 4. Doxy-PEP users should be assisted to maximise the benefits of doxy-PEP while minimising overall antibiotic consumption. For example, if a doxy-PEP user tends to have multiple sex partners during weekends but few during the week, then a single Monday morning dose of 200 mg doxy-PEP should adequately cover their STI risk, rather than multiple doses over the weekend.

Recommendation 5. In general, it is not recommended to use daily doxycycline as pre-exposure prophylaxis (doxy-PrEP, 100 mg daily), as this often results in greater antibiotic consumption than doxy-PEP and fewer data support the use of doxy-PrEP. However, for some people, doxy-PrEP might be appropriate during periods of frequent (daily) sexual activity that places them at risk of STIs.

Recommendation 6. Other antibiotics (eg, azithromycin) should not be used instead of doxycycline for STI prevention.

Recommendation 7. Doxy-PEP users should continue to undergo STI screening in line with STI testing guidelines for GBMSM, as the ideal STI screening interval for people using doxy-PEP has not yet been determined. Current guidelines recommend screening every three months for chlamydia, gonorrhoea and syphilis for this population, but this recommendation might change. In addition, doxy-PEP users should be encouraged to attend for STI testing whenever they have symptoms.

Recommendation 8. Culture samples must be collected for all gonorrhoea diagnoses prior to administration of antibiotics to treat gonorrhoea, to enable AMR surveillance for *Neisseria gonorrhoeae*.

Recommendation 9. It is recommended to discuss personal and population-level AMR risks with doxy-PEP users. Resources should be made available to assist clinicians to raise AMR issues during these conversations in a manner that is appropriate and sensitive to the patient's needs.

Recommendation 10. HIV infection risk must be assessed and addressed during doxy-PEP use. GBMSM who are HIV-negative must be supported to access effective HIV infection prevention strategies such as HIV PrEP, and GBMSM living with HIV who are not accessing HIV care must be supported to do so.

Recommendations for research, guidelines and policy

Recommendation 1. Formal clinical guidelines need to be developed as more evidence emerges. Guidelines may include suitability criteria, scenarios for prescribing, dosing recommendations, and background information on AMR.

Recommendation 2. Education and support materials should be codesigned by clinicians, researchers, and community to ensure that information is consistent across resources, understanding that GBMSM are likely to be a source of doxy-PEP information for clinicians, and vice versa.

Recommendation 3. Further research is needed to understand community members' and other stakeholders' views of doxy-PEP, including priority populations such as GBMSM, sex workers, and Aboriginal and Torres Strait Islander people.

Recommendation 4. Doxy-PEP education should be incorporated into existing STI resources, including the *Australian STI management guidelines* (https://sti.guidelines.org.au/), decision-making tools, and STI-related training courses, such as HIV PrEP courses.

Recommendation 5. Clear guidance for clinicians should be developed on whether and how to monitor for the emergence of AMR, both in bacterial STIs and in bystander organisms.

Recommendation 6. Molecular tests to monitor AMR should be developed, which could be deployed as reflex tests on all samples positive for *Chlamydia trachomatis* and *N. gonorrhoeae* (and swabs positive for *Treponema pallidum* polymerase chain reaction [PCR]), to comprehensively monitor for the emergence of AMR in STIs and other organisms.

Recommendation 7. Pathology and public health bodies should be appropriately funded to monitor AMR.

Recommendation 8. Clinical and community-controlled HIV organisations should be appropriately funded to develop and maintain up-to-date clinical and other educational resources on doxy-PEP.

Recommendation 9. Concerns about AMR are broader than doxy-PEP and warrant a broad review of STI management in Australia. This review should include revision of optimal STI screening intervals, as frequent STI screening drives up antibiotic consumption and antibiotic prescribing practices for both index patients and their sex partners.

Discussion

This Australian consensus statement recommends that doxy-PEP may be a suitable STI prevention strategy for some GBMSM in Australia who are at risk of STIs, particularly syphilis. The statement also acknowledges that doxy-PEP use could result in increased AMR and adverse effects on users' microbiome, although these risks are currently difficult to quantify due to limited available data. This consensus statement proposes future directions for research and clinical practice, including the need to strengthen surveillance for antimicrobial resistance. Importantly, ASHM advocates that any implementation of doxy-PEP should occur within a comprehensive STI prevention framework that promotes access to condoms, regular STI testing, HIV PrEP and PEP, contraception for people who can become pregnant, and vaccination for hepatitis A and B and for human papilloma virus, when appropriate. This consensus process did not include consideration of meningococcal vaccination, which has recently been studied as a gonorrhoea prevention tool (ClinicalTrials.gov identifier, NCT04597424), as effectiveness data had not yet been published.

International position statements and guidance documents on doxy-PEP vary considerably. In the United Kingdom, Public Health England and the British Association for Sexual Health and HIV do not endorse the use of doxy-PEP, but in recognition of the importance of person-centred care, their position statement provides clinicians with information to enable them to adequately support people who are using doxy-PEP.[19] In contrast, in the United States, doxy-PEP is now recommended by several local departments of public health, including in California, New Mexico, New York City and Seattle.[20-23] The San Francisco Department of Public Health was the first among these to endorse doxy-PEP, and does so most liberally: they advise to "recommend doxy-PEP to [cisgender (cis)] men and [transgender (trans)] women who: 1) have had a bacterial STI in the past year and 2) report condomless anal or oral sexual contact with ≥1 cis

male or trans female partner in the past year". Furthermore, they advise to "offer doxy-PEP using shared decision making to cis men, trans men and trans women who report having multiple cis male or trans female sex partners in the prior year, even if they have not previously been diagnosed with an STI".[24] The US Centers for Disease Control and Prevention (CDC) are currently engaged in a consultation process to develop national guidelines on the use of doxy-PEP.[25] This Australian consensus statement strikes a middle ground between these international position statements.

A major strength of this ASHM consensus process was the involvement of a diverse range of leading experts, clinicians and researchers on subject matter areas that are relevant to doxy-PEP, including those outside the sexual health field, and the inclusion of representatives from communities that carry a high burden of STIs. The facilitated discussions during the roundtable centred around pre-specified themes, but their otherwise open-ended format permitted exploration of a wide range of issues within those themes. A limitation of this approach is that participants were not able to provide anonymous contributions during the roundtable. However, we sought to overcome this limitation through using small-group discussions, where participants with a particular interest (eg, "community", "AMR" and "clinical/epidemiology") were able to join together and then convey their group contributions to the whole group. Furthermore, participants were able to provide confidential feedback to the co-chairs during the three rounds of online feedback, and, finally, individual responses to the final survey were also kept confidential.

In response to this consensus statement, ASHM will facilitate a process to develop detailed clinical guidelines and education materials on doxy-PEP for clinicians (www.ashm.org.au/doxy-pep). ASHM will also continue to collaborate with community organisations to ensure that communities affected by high rates of STIs have access to appropriate and accurate information on doxy-PEP, including its benefits and risks.

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Supporting Information

Additional Supporting Information is included with the online version of this article.