

CATIE STATEMENT

on the use of doxyPEP to prevent syphilis

Syphilis rates in Canada are on the rise. This includes a long-standing outbreak among gay, bisexual and other men who have sex with men (gbMSM) and a more recent, rapidly worsening heterosexual outbreak. A steep increase in new syphilis cases among cis women has led to the re-emergence of congenital syphilis (syphilis passed to infants during pregnancy).

The health effects of untreated syphilis can be serious, including neurological disease and disability. Untreated syphilis in a pregnant person often causes miscarriage or stillbirth or results in children being born with syphilis.

The rapid rise in syphilis rates means that new prevention tools are urgently needed. One approach is doxycycline prophylaxis. This involves taking the antibiotic doxycycline to prevent syphilis, either after an episode of condomless sex (doxyPEP) or on a regular, usually daily, basis (doxyPrEP). Of note, doxycycline cannot be used in pregnancy because it can harm the developing fetus.

Research is ongoing to assess the effectiveness of doxyPrEP in preventing bacterial STIs including syphilis.

However, studies have already established that doxyPEP is effective at preventing syphilis among gbMSM and trans women at risk of bacterial STIs. As a result, calls have been made to implement doxyPEP to address the syphilis crisis in these populations.

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This CATIE statement aims to support community-based service providers and health system decision-makers, by providing evidence-informed recommendations on the rollout of doxyPEP in Canada.

KEY MESSAGES

DoxyPEP is an effective strategy to help prevent syphilis among gbMSM and trans women with a recent history of bacterial STIs.

Obstacles need to be addressed to maximize doxyPEP's potential. First, many healthcare providers and community members may lack the knowledge or willingness to use it, undermining equitable access. Second, doxyPEP's potential impact on antibiotic resistance presents an unresolved public health concern. Third, the lack of evidence on effectiveness in cis women is an obstacle to implementing doxyPEP in this disproportionately affected population.

RECOMMENDATIONS

1. Develop national clinical guidelines for doxyPEP

Canada needs national clinical guidelines for prescribing doxyPEP to ensure equitable access for those who need it, maximize effectiveness and minimize risks.

National clinical guidelines can increase access by bolstering healthcare providers' confidence in doxyPEP, and in their ability to prescribe it. Enabling a wider range of providers to prescribe doxyPEP across a variety of settings can help to ensure equitable access to doxyPEP across geographic, socioeconomic and other boundaries. Guidelines can also promote equity by providing standardized clinical criteria for prescribing doxyPEP, so that people can access it on the basis of need rather than their ability to self-advocate.

National clinical guidelines would also help to ensure that the use of antibiotics for STI prevention is safe and effective for people taking them. Guidelines can support providers to prescribe doxyPEP with appropriate assessment of eligibility, consideration of risks, dosage and quantity, and appropriate monitoring.

Similarly, national guidelines can help to limit antibiotic resistance by helping to restrict doxyPEP provision to members of populations for whom it has been proven to work — currently gbMSM and trans women with a recent history of bacterial STI. Guidelines can also help to ensure that continued provision is based on ongoing need, by setting standards for follow-up and reassessment. This encourages providers to

regularly reassess patients' risk for bacterial STIs, which may change over time.

2. Increase awareness and knowledge of doxyPEP among gbMSM and trans women

Awareness strategies should be implemented to reach gbMSM and trans women at risk of syphilis. Increased community awareness and knowledge of doxyPEP can promote access and uptake within these communities. This can empower community members to raise the subject when providers do not, and discuss it with them in an informed way.

Messaging should be accessible and tailored to specific communities of gbMSM and trans women. Key messages should include:

- syphilis symptoms and risk factors
- health consequences of untreated syphilis
- evidence of doxyPEP effectiveness for gbMSM and trans women
- risks associated with doxyPEP for individuals and communities

Diverse approaches can be used to reach as many eligible community members as possible:

- distributing print resources at clinics, community events and organizations, and social venues like baths and bars
- sharing videos and other digital media through websites, email newsletters, social media and hookup platforms
- engaging social media influencers from gbMSM and trans communities
- holding online and in-person events to answer community members' questions

An intersectional approach can help to reach gbMSM and trans women who are also members of other key populations, such as Indigenous, African, Caribbean and Black, and newcomer communities. Efforts can also be made to reach gbMSM and trans women who face geographic, economic or institutional barriers, such as:

- people who live in rural or remote regions
- people who experience homelessness
- people who have experiences of incarceration
- people who do sex work

3. Promote integration and linkage

Linking community members, community-based organizations and healthcare providers can help to create equitable access to

doxyPEP. For community-based organizations, this could mean maintaining lists of healthcare providers willing to prescribe doxyPEP and linking clients to them during conversations about sexual health. Efforts could also be made to build connections between local CBOs and healthcare providers, share information about doxyPEP, and develop strategies together to improve access for community members who need it.

4. Support research on doxyPEP effectiveness in cis women

More research is needed to determine whether doxyPEP is a viable syphilis prevention strategy for non-pregnant cis women. Gaps in this evidence stall efforts to address the syphilis crisis among cis women and among communities in which syphilis is spread mainly through heterosexual sex.

More evidence is needed on the effectiveness of doxyPEP among cis women, as well as the social, structural and behavioural factors impacting its effectiveness (through adherence, for example). Studies are needed with large enough sample sizes, drawn from populations of women with high rates of syphilis. In addition, studies need to account for differences in biology that may impact effectiveness, appropriate dosing and scheduling.

5. Support research and surveillance on antimicrobial resistance (AMR)

Steps should be taken to monitor increased antimicrobial resistance (AMR) caused by widespread use of doxyPEP. Concerns centre around diminished effectiveness of doxycycline against STI and non-STI bacteria, as well as development of *cross-resistance* whereby bacteria become resistant to other antibiotics.

Current evidence is limited on AMR associated with doxyPEP and other ongoing use of doxycycline. However, because of the many unknown risks of AMR, some experts recommend caution and careful monitoring during doxyPEP implementation.

Research is needed to conduct long-term follow-up with sufficient numbers of participants. This research can help to detect the potential effects of doxyPEP on the development of antibiotic resistance. For example, follow-up can help to identify and describe cases of “breakthrough” infections, in which people taking doxyPEP still develop syphilis or chlamydia, with subsequent surveillance in these cases for AMR.

Long-term studies with large numbers of participants can also provide better evidence to support clinical and public-health decision-making for specific populations at risk of syphilis. For example, they can inform clinical guidelines about which

antibiotics to use, or not use, on the basis of whether a particular community bears a disproportionate burden of AMR, or on the basis of an individual’s risk factors. Such information could inform recommendations for the use of doxyPEP.

In addition to long-term follow-up studies with groups of study participants, support is needed to ensure accurate surveillance of AMR across Canada, and sound decision-making to address it. Canada has a robust system for antibiotic resistance surveillance, but there are significant gaps in generating, disseminating and using information to support clinical and public health decision-making.

TOOLS AND RESOURCES

CATIE resources

Doxycycline to help prevent bacterial STIs

Doxy-PEP and doxy-PrEP: Pills to prevent syphilis

Exploring the impact of doxycycline to prevent sexually transmitted infections

Syphilis Guide for Two-Spirit People and Gay, Bisexual and Queer+ Guys

Syphilis resources

Syphilis Fundamentals

Sexually transmitted infections

Guidelines, position statements, policy and program resources

BCCDC Position Statement on Doxycycline as Prophylaxis for Sexually Transmitted Infections – BC Centre for Disease Control

CDC clinical guidelines on the use of doxycycline postexposure prophylaxis for bacterial sexually transmitted infection prevention – Centers for Disease Control and Prevention

Doxycycline Post-Exposure Prophylaxis (doxy-PEP) for the Prevention of Bacterial Sexually Transmitted Infections (STIs) – California Department of Public Health

Updated Recommendations for Prescribing Doxycycline Post-Exposure Prophylaxis – San Francisco Department of Public Health

Syphilis guide: Key information and resources – Public Health Agency of Canada

Doxy-PEP: Medication to prevent syphilis, chlamydia, and gonorrhoea – CBRC; RÉZO

EVIDENCE REVIEW

Doxy-PEP effectiveness

GbMSM and trans women

There is strong evidence that doxyPEP can help prevent syphilis, chlamydia and gonorrhoea in gbMSM and trans women at risk of these infections. A 2024 meta-analysis of randomized controlled trials (RCTs) found that doxyPEP was 77% effective against syphilis, 81% effective against chlamydia, but only 45% effective against gonorrhoea among gbMSM and trans women. The study graded the certainty of this evidence as high.¹

The main sources of evidence for doxyPEP effectiveness among gbMSM and trans women are three RCTs with a combined total of over 1, 200 participants.

The first of these studies was an open-label RCT done in France and published in 2018. This was a sub-study of the IPERGAY HIV PrEP trial, which looked at on-demand HIV PrEP. The doxyPEP substudy included 232 HIV-negative gbMSM who used HIV PrEP and reported having had condomless sex with at least two men within the last six months. Half were randomly assigned to take doxyPEP and the other half did not receive doxyPEP. During the 10-month follow-up period, people taking doxyPEP were 70% less likely to be diagnosed with chlamydia and 73% less likely to be diagnosed with syphilis than those not taking doxyPEP. Taking doxyPEP did not make a significant difference for gonorrhoea in the study.²

A second open-label RCT, called the DoxyPEP study, was done in Seattle and San Francisco, and published in 2023. This study enrolled 501 gbMSM and trans women who have sex with men. Participants were all either living with HIV or taking HIV PrEP, and had been diagnosed with a bacterial STI within the last year. Two-thirds of participants were randomly assigned to take doxyPEP, and the remaining third did not receive doxyPEP. Among HIV PrEP users, doxyPEP reduced the risk of syphilis by 87%, chlamydia by 88% and gonorrhoea by 55%. Among the cohort of people living with HIV, doxyPEP reduced the risk of syphilis by 77%, chlamydia by 74% and gonorrhoea by 57%.³

A third open-label RCT called DOXYVAC done in France was published in 2024. This study included 502 HIV-negative gbMSM who were taking HIV PrEP and who had been diagnosed with an STI in the past year. Two-thirds of participants were randomly assigned to receive doxyPEP, and the remaining third did not receive any doxyPEP. Compared with those not taking it, people taking doxyPEP were 84% less likely to be diagnosed with syphilis or chlamydia (reported as a single outcome) and 51% less likely to be diagnosed with gonorrhoea.^{4,5}

Cis women

There is limited evidence on doxyPEP effectiveness among cis-women. One large open-label RCT in Kenya investigated doxyPEP effectiveness among 449 HIV-negative cis women taking HIV PrEP. Half of the participants were assigned to receive doxyPEP and the other half did not receive doxyPEP. The study did not find any significant difference in the number of STI diagnoses between the two groups. This means that doxyPEP was not found to lower the risk of getting a bacterial STI in this study.⁶

These findings do not necessarily mean that doxyPEP is ineffective among cis women. The authors argue that adherence problems are the most likely explanation for the lack of observed effectiveness. Hair samples from 50 participants in the doxyPEP group suggested that doxycycline was not taken during the majority of study months, and that as many as 44% of participants may not have taken *any* doxycycline during the study.⁶ A qualitative follow-up study with a small subset of participants identified barriers to adherence including nausea, difficulty interpreting instructions, pill burden, stigma and fear of partner reaction.⁷

Other limitations may also help explain the lack of observed effectiveness in this study. The sample size was too small to detect changes in syphilis incidence, given the low syphilis rates in the local population. Participants' history of bacterial STIs was also unknown because of limited access to STI testing in the region. This contrasts with the large *DoxyPEP and DOXVAC studies*, which only included gbMSM and trans women with a bacterial STI diagnosis in the past year.⁶

The lack of observed effect in the Kenyan doxyPEP study is surprising because biological evidence suggests that doxyPEP *should be* effective against syphilis and chlamydia infections of the vagina. A small study looked at concentrations of doxycycline in the vaginal tissue of people at various intervals after they took a 200 mg dose of doxycycline. The researchers found that within 24 hours, concentrations were high enough that they should have been able to prevent syphilis and chlamydia infections. They also found that these concentrations remained sufficiently high for at least three days after the individual received the dose.⁸

Side-effects

In the four clinical trials described above, (IPERGAY, doxyPEP, DOXYVAC and the study in Kenya), no serious doxycycline-related adverse events were reported.^{2-4,6,9}

A 2023 systematic review and meta-analysis found that longer term use of doxycycline (eight or more weeks) is generally

safe and may be associated with minor side-effects, such as gastrointestinal disturbances and skin issues such as a rash.¹⁰

Not recommended during pregnancy

Doxycycline is not recommended during pregnancy unless the prescribing physician judges that the potential benefits to the pregnant person outweigh the risks to the fetus or child. Doxycycline used in pregnancy can have adverse effects, such as impacts on a child's skeletal development, and permanent tooth discolouration.¹¹ Alternative strategies are needed to prevent syphilis in pregnant people.

Antimicrobial resistance

Perhaps the greatest area of concern about doxyPEP is that its widespread use could increase antimicrobial resistance (AMR). AMR is when a medicine (antimicrobial) no longer affects a microbe (bacteria, virus or fungus) that causes an infection, making the infection harder or impossible to treat. It is possible that STI bacteria or non-STI bacteria may develop increased resistance to doxycycline.

There is also a possibility of *cross-resistance*, meaning that STI or non-STI bacteria could develop resistance to other antibiotics when individuals take doxycycline. This could include resistance to other antibiotics in the same class as doxycycline, called *tetracyclines*, as well as more distantly related antibiotics.

Antimicrobial resistance in STI bacteria

To date, there has been no clinically significant evidence of doxycycline-resistant syphilis or chlamydia, even though tetracyclines have been used for over 50 years to treat bacterial STIs.¹² One recent study looked at the long-term effects of doxycycline exposure on a strain of syphilis bacteria in a laboratory and found that no resistance developed.¹³

However, doxycycline is a first-line treatment for chlamydia, and a second-line treatment for syphilis in patients with a penicillin allergy. This makes doxycycline an important treatment option for these harmful infections. The consequences of doxycycline or tetracycline resistance in the bacteria that cause chlamydia and syphilis could be great.¹²

Another concern is doxyPEP's potential impact on AMR in gonorrhoea. In contrast to syphilis and chlamydia, gonorrhoea is highly adaptive. Gonorrhoea has developed resistance to every class of drug used to treat it. This is an issue of significant and increasing public health concern.¹⁴

Gonorrhoea has already shown high levels of resistance to doxycycline. For this reason, doxycycline is not a first-line treatment for gonorrhoea in Canada. However, it may still be

used in cases of treatment resistance to first-line drugs, or penicillin allergy.¹⁵ This means that there is still reason to limit the growth of doxycycline resistance in gonorrhoea.

A recent systematic review and meta-analysis of RCTs spanning 45 years found that the use of tetracyclines to prevent STIs was associated with a two-fold greater prevalence of antimicrobial resistant gonorrhoea, although this effect was not statistically significant.¹⁶

The widespread use of doxyPEP may also cause it to become ineffective as a gonorrhoea prevention tool.¹⁷ The doxyPEP trials described above showed that doxyPEP is much less effective at preventing against gonorrhoea.¹ However, even this relatively low level of protection is significant. Further increases in doxycycline resistance could result in doxyPEP becoming completely ineffective for preventing gonorrhoea.

Antimicrobial resistance in non-STI bacteria

There is also concern that doxyPEP could lead to greater levels of AMR in other bacterial infections that doxycycline and other tetracyclines are used to treat. Examples include bacteria that cause infections of the genital tract, respiratory tract, and gastrointestinal tract. Some evidence suggests that use of tetracycline may increase tetracycline resistance among bacteria in the gums, digestive system and upper respiratory tract.¹⁸

There is limited evidence on the effects of doxycycline and other tetracyclines on AMR in non-STI bacteria. More research is needed to understand the impact that doxycycline could have on antibiotic resistance in non-STI bacteria.

Changes to the microbiome

Broad-spectrum antibiotics like doxycycline can affect the "good" bacteria that are part of the body's microbiome. The microbiome refers to the microbes that live in or on a person's body, including bacteria, viruses and fungi. Many of these microbes are important for the healthy functioning of a person's immune system and their overall health.¹⁹ There are concerns that long-term use of doxycycline could cause changes in a person's microbiome, contributing to negative health outcomes.

Some research suggests that daily long-term doxycycline use has small effects on the microbiome of the digestive system. Other research suggests more significant effects on the microbiomes of the skin and mouth. More research is needed to better understand the impacts of doxycycline use, including doxyPEP, on the body's different microbiomes.²⁰

Implementation considerations

Use of doxyPEP

Evidence suggests that a minority of gbMSM are using doxyPEP or other antibiotic prophylaxis to prevent STIs.

In Canada, the 2022 national *SexNow survey* of over 3,000 gbMSM, trans, Two-Spirit and nonbinary people (2S/GBTQNB+) showed that only 6% of respondents reported having taken doxy-prophylaxis.²¹ Similar levels of use have been found in surveys in other countries, with most falling between 7% and 10% of respondents^{22–26} and a few ranging as high as 16% - 23%.^{27–29}

Some studies have identified participant characteristics associated with the use of doxyPEP and other forms of antibiotic STI prophylaxis, including:

- recent STI diagnosis
- HIV-positive status
- higher number of recent sex partners
- current or previous HIV PrEP use
- recent injection drug use and engagement in chemsex
- education level^{22,23,25,27}

Unmonitored access and use

Some gbMSM using doxyPEP and other antibiotics to prevent STIs, are accessing it with limited oversight from healthcare providers. One small national survey of gbMSM in the United Kingdom (UK) found that nearly half of those who reported using STI prophylaxis were either unsure of what kind of antibiotic they were using, or used an antibiotic for which there is no evidence of effectiveness at preventing STIs.³⁰ Participants in studies in the UK, Netherlands, Australia and Spain have reported sourcing from illegal online vendors, sex partners and their own previous unfinished treatments.^{22,23,31,32}

Awareness of doxyPEP

Studies have found that awareness of doxyPEP and other forms of antibiotic prophylaxis are generally low to moderate among gbMSM and trans women. The Canadian *SexNow survey* found that about 25% of respondents were aware of doxy-prophylaxis.²¹ Recent studies outside of Canada report similar awareness levels, between 25% and 50%.^{24,26,27,33}

A 2024 US study found that the following factors were associated with awareness of doxyPEP:

- college education
- recent bacterial STI diagnosis
- past discussion of HIV PrEP with a healthcare provider
- having taken HIV PrEP
- living in a large city
- living in a state with higher levels of LGBTQ equality²⁴

Interest in doxyPEP

Among gbMSM who have heard of doxyPEP, interest in using it varies considerably. In Canada, the 2022 *SexNow survey* found that a third of those not using doxy-prophylaxis were interested in it, while another third were unsure and the remaining third were unwilling to use it.²¹ Studies conducted outside of Canada have shown higher levels of interest, ranging from 49% to 96%.^{25–27,29,34}

Some gbMSM prefer doxyPEP to other prevention options. A recent Australian national survey of over 2,000 gbMSM and nonbinary people found that 76% rated doxyPEP as an acceptable form of STI prevention, compared with condoms at 45% and STI-PrEP at 54%.³⁵ Similarly, a 2018 survey of 436 gbMSM attending sexual health clinics in Vancouver and Toronto found that 60% of participants would be willing to use doxyPEP to prevent syphilis, while only 44% would be willing to use doxyPrEP.³⁶

Studies have identified participant characteristics associated with interest in or willingness to take doxyPEP:

- recent STI diagnosis
- higher number of sex partners
- recent, new sex partners
- taking HIV PrEP
- perceiving risk of bacterial STIs to be high
- previous use of antibiotics to prevent bacterial STIs^{21,26,33,35,36}

Concerns about the long-term consequences of using doxyPEP influence how willing some gbMSM are to consider it. In one study, 80% of participants were initially willing to consider taking doxyPEP. However, after reading about its potential effects on AMR, this number dropped to 60%.²⁵ In another study, participants who reported being concerned about AMR were less likely to rate doxyPEP as an acceptable form of STI prevention.³⁵

Prescription practices, knowledge and attitudes among healthcare providers

There appears to be no published academic research on prescription practices, awareness or acceptability of doxyPEP among healthcare providers in Canada. However, a recent, informal, national consultation of community-based organization staff, frontline healthcare providers, and public health officials across ten provinces and territories, suggested that many healthcare providers have limited awareness and knowledge of doxyPEP.³⁷

In 2022, the United States Centers for Disease Control and Prevention (CDC) published results from an online survey of 1,500 healthcare providers (51% STI providers; 49% non-STI providers). Overall, 32% of respondents reported that they had prescribed doxycycline for the prevention of sexually transmitted infections. As expected, this proportion was higher among STI providers, at 42%, than among non-STI providers, at 21%.³⁸

In terms of willingness to prescribe doxycycline for STI prevention, the limited available research suggests an even split between those willing and those unwilling to prescribe. In the same CDC study, 42% of providers said that the benefits of prescribing doxycycline as prevention to patients at high risk of STIs outweighed the risk of increasing antibiotic resistance (47% among STI providers; 37% among non-STI providers).³⁸

In a smaller U.S. study of 76 healthcare providers, 43% agreed or strongly agreed that they would be willing to prescribe doxyPEP to their gbMSM patients. Interestingly, this increased to 90% when participants were asked the same question under the then hypothetical scenario that the CDC had recommended the strategy.³⁴

A qualitative study using interviews with 30 healthcare providers from 13 US cities with high STI prevalence found generally positive attitudes towards doxyPEP. However, some participants reported apprehension due to concerns about AMR. Participants felt that more data on long-term safety would increase their confidence in doxyPEP, and that clinical guidelines would help them prescribe it responsibly, with appropriate eligibility assessment, dosing and treatment management.³⁹

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