

# Patient Delivered Partner Therapy Clinical Guidelines

## Purpose

Provide guidance on the use of patient delivered partner therapy for chlamydia infection in Victoria.

## Procedure/Guideline

### Background

Treating the sexual partners of people diagnosed with a sexually transmissible infection (STI) reduces reinfection rates and is considered important in the reduction of rates of infection in the population.

Patient delivered partner therapy (PDPT) describes the practice in which treatment is prescribed for the sexual partner/s of an index patient diagnosed with a sexually transmitted infection, as well as the index patient. The patient then delivers a prescription, or the treatment, to their partner/s.

PDPT aims to target those partners who are unwilling, unlikely or unable to consult a health professional in a timely manner.

### PDPT effectiveness

PDPT, with a single dose of azithromycin, has been shown to be a safe and effective method of treating sexual partners of people with chlamydia. International studies have demonstrated that PDPT is more effective than the traditional practice of asking a patient to advise their sexual partner(s) to seek treatment.<sup>1234</sup>

PDPT increases partner notification, increases the number of partners treated and reduces the risk of persistent or recurrent infection in the index patient.

### PDPT adverse effects

Azithromycin is a safe and well tolerated antibiotic. The most commonly reported adverse effects include mild diarrhoea, nausea, vomiting, abdominal pain and dyspepsia.<sup>5 6</sup>

There have been no serious adverse effects reported from azithromycin associated with PDPT trials or ensuing surveillance in the United States.<sup>7</sup>

The proportion of patients who report partners reacting aggressively after being offered treatment is very low and no higher than with other forms of contact tracing.<sup>8</sup>

Partners who use PDPT may not attend for STI testing and clinical assessment. This means that their other partners cannot be advised of the need to seek treatment. It also means that co-infections and complicated infections may be missed. Due to this PDPT is not recommended in populations with a high rate of HIV, such as men who have sex with men, and should be used with caution in populations with a high rate of gonorrhoea co-infection. The lack of clinical assessment may lead to a failure to appropriately manage complicated infections such as pelvic inflammatory disease.

While the negative impact of these factors may be partly overcome through careful counselling of patients and the provision of written information for partners it is recommended that PDPT is only used when traditional means of notifying partners are unlikely to be successful.

## Legal aspects of PDPT

In Victoria the supply of Schedule 4 poisons (Prescription Only Medicines), including azithromycin, to a patient by a health practitioner is governed by the *Drugs, Poisons and Controlled Substances Act 1981* (the Act) and the *Drugs, Poisons and Controlled Substances Regulations 2006* (the Regulations).

Regulation 8(2) and regulation 9(2) provide that a registered health practitioner\* must not administer, prescribe, sell or supply a Schedule 4 poison unless that poison is for the medical treatment of a person under his or her care; and that he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison. The Department of Health & Human Services provides guidelines, *the Guide to the Drugs, Poisons and Controlled Substances Regulations 2006*, to assist practitioners in complying with the Regulations, including the regulations that require the practitioner to take all reasonable steps.

The steps outlined in these Clinical Guidelines inform the practitioner about how he/she may use PDPT in Victoria. A practitioner who uses PDPT in accordance with the Clinical Guidelines would generally be considered to have satisfied the requirements of regulation 8(2) and regulation 9(2) when providing PDPT.

The *Guide to the Drugs, Poisons and Controlled Substances Regulations 2006* has been amended to explain to practitioners that using PDPT will not automatically represent a contravention of the Regulations.<sup>9</sup> Azithromycin, or a prescription for azithromycin, can be provided to a person with microbiologically confirmed chlamydia infection in order for them to deliver to their partner.

PDPT can be supplied to named individuals by means of a written prescription, or by the practitioner. It must be prescribed, administered or supplied in accordance with the Regulations.

## Liability issues

The *Guide to the Drugs, Poisons and Controlled Substances Regulations 2006* clarifies that acting in accordance with these Clinical Guidelines will generally mean that the practitioner can be considered to have satisfied the requirements of regulation 8(2) and regulation 9(2) when providing PDPT.

For caution, the practitioner should take reasonable steps to assess the partner's symptom status, particularly symptoms indicative of a complicated infection; pregnancy status; and risk for severe medication allergies.

Practitioners should provide the patient with information (preferably written) for the partner that includes consumer information about azithromycin, information about *Chlamydia*, the means to seek health care and the contact details of the clinic providing the prescription. [Click here](#) to access a patient information sheet.

It should also be noted that practitioners have a duty of care to the partners of patients with a STI regardless of whether PDPT is used. This duty includes providing assistance with contact tracing in situations where PDPT is not provided.<sup>10 11</sup> These Clinical Guidelines provide guidance in the use of PDPT but should not be considered as legal advice. In the case of doubt the practitioner should seek independent legal advice.

## Guidelines for use

### Selecting patients

In general the use of PDPT should be restricted to situations where other means of partner notification have failed or are considered highly likely to fail.

PDPT is most appropriate for:

- partners who refuse to attend a health service;
- partners unable or unwilling to attend a health service due to travel or commitment during regular work hours; and
- patients with repeat infections whose partner/s have not been treated.

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\* A registered health practitioner refers to a registered medical practitioner or a registered nurse practitioner. [Click here](#) for further information on the legislative requirements of nurse practitioners.

Additionally, there are some situations where particular caution should be taken due to risk of other STI or adverse effects.

PDPT should generally NOT be used for:

- patients diagnosed with more than one STI;  
patients whose partners are pregnant;<sup>\*\*</sup> and
- partners at high risk of HIV infection such as men who have sex with men.

## Applying PDPT in practice

### *Recommended treatment regimen*

PDPT involves providing the patient with a prescription for 1 gram of azithromycin written in the partners name (or supplying 1 gram of azithromycin) along with instructions to deliver to the partner.

Information (preferably written) should also be given including consumer medication information about azithromycin and information about *Chlamydia* as well as the means to seek health care and the contact details of the clinic providing the prescription. [Click here](#) to access a patient information sheet.

### *Patient records*

The use of PDPT, including number of prescriptions provided (or doses supplied), should be documented in the patient's medical record. The nature of the information provided to patients to relay to their partners should also be documented in each patient's record.

A written prescription (or dose supplied) must be documented in the name of each partner. This should be stored along with a record of any other relevant medical information known about the partner at the time of the consultation. In the event the partner is a patient of the clinic this may be documented in their existing medical record. Where the partner is not an existing patient of the clinic the prescription and medical information should be stored in a secure location that enables the information to be accessed should the need arise. For example a new medical record could be created for the partner or PDPT script could be kept in a dedicated file.

PDPT could be supplied for any partner with whom unprotected sexual intercourse occurred in the past six months. There is no limit to the number of partners for whom PDPT can be used.

## Key information for patients

- Patients and their partners should abstain from sex until seven days after they and all their partners have been treated.
- Patients and their partners should return for retesting at three months following treatment to detect any reinfection.
- Partners are advised to seek a STI check at a general practitioner or their local clinic.
- Partners who are unsure whether they may be allergic to azithromycin should seek medical advice before using the medication.
- Partners who have any symptoms or are pregnant should seek medical advice.

## Key Documents

- [Guide to the Drugs, Poisons and Controlled Substances Regulations](#)
- [Key legislative requirements for nurse practitioners](#)
- [Australasian STI Management Guidelines for Use in Primary Care](#)
- [Australasian Contact Tracing Manual](#)

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<sup>\*\*</sup> Azithromycin is safe in pregnancy but pregnant women and their partners should see their doctor first to have other STIs excluded.

## References

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- <sup>1</sup> Golden, M.R., et al., Effect of expedited treatment of sex partners on recurrent or persistent gonorrhoea or chlamydial infection. *New England Journal of Medicine*, 2005. **352**(7): p. 676-85.
- <sup>2</sup> Kissinger, P., et al., Patient-delivered partner treatment for male urethritis: a randomized, controlled trial. *Clinical Infectious Diseases*, 2005. **41**(5): p. 623-9.
- <sup>3</sup> Schillinger, J.A., et al., Patient-delivered partner treatment with azithromycin to prevent repeated Chlamydia trachomatis infection among women: a randomized, controlled trial. *Sexually Transmitted Diseases*, 2003. **30**(1): p. 49-56.
- <sup>4</sup> Trelle, S; Shang A; Nartey L, et al. Improved effectiveness of partner notification for patients with sexually transmitted infections; systematic review. *British Medical Journal*, 2007: **334**: 354
- <sup>5</sup> Hopkins S. Clinical toleration and safety of azithromycin. *Am J Medicine*. 1991 Sep 12: **91**(3A):40S-45S.
- <sup>6</sup> FDA Azithromycin Drug Labels Reference ID: 3263750. Silver Spring: U.S. Food and Drug Administration 2013. Available from: [http://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2013/050710s039\\_050711s036\\_050784s023ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/050710s039_050711s036_050784s023ltr.pdf).
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- <sup>8</sup> Nuwaha F, Kambugu F, Nsubuga PS, Höjer B, Faselid E. Efficacy of patient-delivered partner medication in the treatment of sexual partners in Uganda. *Sexually Transmitted Diseases*. 2001; **28**(2):105–10.
- <sup>9</sup> Guide to the Drugs, Poisons and Controlled Substances Regulations 2006. Available at: [https://www2.health.vic.gov.au/getfile/?sc\\_itemid=%7b10959861-96E7-452F-A944-1BDFB7A86D36%7d&title=Guide%20to%20the%20Drugs%20Poisons%20and%20Controlled%20Substances%20Regulations%202006](https://www2.health.vic.gov.au/getfile/?sc_itemid=%7b10959861-96E7-452F-A944-1BDFB7A86D36%7d&title=Guide%20to%20the%20Drugs%20Poisons%20and%20Controlled%20Substances%20Regulations%202006)
- <sup>10</sup> Australasian STI Management Guidelines for Use in Primary Care, Australasian Sexual Health Alliance (ASHA) available at: <http://www.sti.guidelines.org.au/>.
- <sup>11</sup> Australasian Contact Tracing Manual, ASHM, available at: <http://ctm.ashm.org.au/>.