

# Patient-delivered partner therapy for chlamydia in Australia: can it become part of routine care?

Jane L. Goller<sup>A,K</sup>, Jacqueline Coombe<sup>A</sup>, Christopher Bourne<sup>B,C</sup>, Deborah Bateson<sup>D</sup>, Meredith Temple-Smith<sup>E</sup>, Jane Tomnay<sup>F</sup>, Alaina Vaisey<sup>A</sup>, Marcus Y. Chen<sup>G,H</sup>, Heather O'Donnell<sup>I</sup>, Anita Groos<sup>J</sup>, Lena Sancic<sup>E</sup> and Jane Hocking<sup>A</sup>

<sup>A</sup>Melbourne School of Population & Global Health, University of Melbourne, 207 Bouverie Street, Parkville, Vic. 3010, Australia.

<sup>B</sup>NSW STI Programs Unit, NSW Ministry of Health, NSW 2010, Australia.

<sup>C</sup>Sydney Sexual Health Centre, Sydney, NSW 2001, Australia.

<sup>D</sup>Family Planning NSW, Ashfield, NSW 2131, Australia.

<sup>E</sup>Department of General Practice, The University of Melbourne, Vic. 3010, Australia.

<sup>F</sup>Centre for Excellence in Rural Sexual Health, Department of Rural Health, The University of Melbourne, Vic. 3630, Australia.

<sup>G</sup>Central Clinical School, Monash University, Melbourne, Vic. 3004, Australia.

<sup>H</sup>Melbourne Sexual Health Centre, 580 Swanston Street, Carlton, Vic. 3053, Australia.

<sup>I</sup>Victorian Government, Department of Health and Human Services, Vic. 3000, Australia.

<sup>J</sup>Communicable Diseases Branch, Queensland Department of Health, Brisbane, Qld 4006, Australia.

<sup>K</sup>Corresponding author. Email: jane.goller@unimelb.edu.au

**Abstract.** *Background:* Patient-delivered partner therapy (PDPT) is a method for an index patient to give treatment for genital chlamydia to their sexual partner(s) directly. In Australia, PDPT is considered suitable for heterosexual partners of men and women, but is not uniformly endorsed. We explored the policy environment for PDPT in Australia and considered how PDPT might become a routine option. *Methods:* Structured interviews were conducted with 10 key informants (KIs) representing six of eight Australian jurisdictions and documents relevant to PDPT were appraised. Interview transcripts and documents were analysed together, drawing on KIs' understanding of their jurisdiction to explore our research topics, namely the current context for PDPT, challenges, and actions needed for PDPT to become routine. *Results:* PDPT was allowable in three jurisdictions (Victoria, New South Wales, Northern Territory) where State governments have formally supported PDPT. In three jurisdictions (Western Australia, Australian Capital Territory, Tasmania), KIs viewed PDPT as potentially allowable under relevant prescribing regulations; however, no guidance was available. Concern about antimicrobial stewardship precluded PDPT inclusion in the South Australian strategy. For Queensland, KIs viewed PDPT as not allowable under current prescribing regulations and, although a Medicine and Poisons Act was passed in 2019, it is unclear if PDPT will be possible under new regulations. Clarifying the doctor–partner treating relationship and clinical guidance within a care standard were viewed as crucial for PDPT uptake, irrespective of regulatory contexts. *Conclusion:* Endorsement and guidance are essential so doctors can confidently and routinely offer PDPT in respect to professional standards and regulatory requirements.

**Additional keywords:** contact tracing, expedited partner therapy, partner notification, policy, sexually transmissible infections.

Received 18 February 2020, accepted 13 May 2020, published online 3 August 2020

## Introduction

Partner management (informing, testing and treating) is an essential aspect of sexually transmissible infection (STI) control as it can reduce the duration of infection for treated partner(s) and the risk of re-infection for the index case.<sup>1,2</sup>

Further, the treatment of sexual partner(s) and prevention of re-infection may reduce the risk of STI complications for both the index case and partners.

For chlamydia, re-infection is common. A study based in Australian primary care reported that 22% of women treated for

genital chlamydia tested positive again within 4 months of treatment.<sup>3</sup> In the UK, chlamydia re-infection rates of 30% within 12 months of treatment have been reported.<sup>4</sup> Re-infection can occur as a result of suboptimal partner management. In Australia, the diagnosing clinician is responsible for initiating discussion with the index case about the need for and potential methods of partner notification.<sup>2</sup> Many patients opt to notify partner(s) themselves (patient referral), either directly or via web-based tools (e.g. [www.letthemknow.org.au](http://www.letthemknow.org.au)). However, these methods require partners to seek treatment from a healthcare provider, which may hamper timely treatment.<sup>5</sup>

Models of care seeking to increase the number of partners treated and to reduce time to partner treatment have been developed for managing chlamydia infection. In Australia, patient-delivered partner therapy (PDPT) refers to the process whereby the medical doctor prescribes or provides antibiotic treatment for both the index case and their sexual partner(s). The index case then passes the prescription or treatment to their partner(s).<sup>6</sup> For chlamydia, the recommended treatment for PDPT is azithromycin given as a single oral 1 g dose. In randomised trials, PDPT for genital chlamydia involving a single 1-g dose of azithromycin was found to treat more partners per index case and to reduce re-infections compared with simple patient referral.<sup>1,7</sup> Further, studies suggest PDPT is safe, with no major adverse drug reactions reported.<sup>7-9</sup> In the United States (US), PDPT is known as Expedited Partner Therapy (EPT), a term that encompasses prescription or medication delivery. EPT has been endorsed by the US Centers for Disease Control (CDC) and is currently permissible within 44 states.<sup>6</sup>

In Australia, PDPT for chlamydia has been discussed as a partner management option since the Australasian Chapter of Sexual Health Medicine (ACHSHM) released a position paper supporting use of PDPT for chlamydia infection in heterosexual partners of men and women in 2009.<sup>10</sup> In the decade since, health departments in three of eight Australian jurisdictions [Northern Territory (NT), Victoria (Vic.) and New South Wales (NSW)] have provided PDPT guidance to medical practitioners, allowing the prescription of PDPT for chlamydia infection.<sup>11-21</sup> STI testing and care in Australia is provided through a mix of government-funded specialist sexual health clinics and family planning clinics; and mainstream primary care clinics (general practice), where most chlamydia infections in Australia are diagnosed,<sup>22</sup>

thereby making general practice an important setting for PDPT provision. However, aside from a recent pilot in specialist clinics in NSW, there are few data available about PDPT provision in Australian primary care.<sup>23</sup> Interviews with Australian general practitioners (GPs) have highlighted medico-legal concerns and lack of clarity about providing PDPT with regard to prescribing and clinical requirements.<sup>5,24</sup> In view of these uncertainties, this research sought to explore the policy environment relevant to PDPT across Australia and to identify what is needed to establish PDPT within routine care by medical doctors (doctors) in Australia.

## Methods

This research comprised key-informant (KI) interviews and an appraisal of documentation relevant to PDPT. KIs were purposively recruited via the authors' research, clinical and policy networks. Representatives from State and Territory Health Departments with senior roles involving chlamydia control, medicine regulation or specialist sexual healthcare provision were identified and invited to participate in a 20- to 40-min telephone interview. They were also asked to nominate other appropriate informants who could comment at a State or Territory systems level. Structured interviews were undertaken that asked KIs to provide opinion about PDPT permissibility in their jurisdiction, the barriers to PDPT and what is needed for PDPT to become routine care in the KI's jurisdiction. KIs were also asked to identify and comment on the key documents (they were aware of) relevant to PDPT. Interviews were conducted during November 2018 to March 2019 and were audio-recorded and transcribed.

Documents relevant to PDPT at State, Territory and National level were identified by searching government websites for prescribing regulations; and by further searching government and peak body (such as the Australasian Society for HIV Medicine) websites for guidelines and policies using the terms 'partner notification' or 'contact tracing', 'patient-delivered partner therapy' or 'expedited partner therapy', 'sexually transmitted infections' or 'chlamydia'. We also verified with our KIs that we had identified the main documents related to professional practice and the main documents publicly available. There were no formal exclusion criteria. Rather, we included documents published until September 2019 that specifically referred to PDPT (e.g. guidelines and policies) and documents that did not mention PDPT (e.g. prescribing regulations).

### Box 1. Key topics explored in the key informant (KI) interviews and document appraisal

For each **State or Territory**, the following topics were explored:

1. The current context for patient-delivered partner therapy (PDPT)
  - Identification of the main policies, guidelines or regulations that would govern PDPT for chlamydia and KI comment on the permissibility of PDPT with respect to these documents
2. The challenges to PDPT
  - The main benefits or concerns regarding PDPT
  - The main barriers or facilitators to formalising PDPT permissibility
3. What is needed for PDPT to become part of routine care
  - The key actions that were taken or are needed to formalise PDPT permissibility in a jurisdiction
  - The key actions needed for PDPT to become part of routine care

The key research topics explored in the KI interviews and document appraisal are provided in Box 1. Interview transcripts and documents were managed in NVivo Version 12 (QSR International Pty Ltd, Burlington, MA, USA) and analysed together using directed content analysis<sup>25</sup> to explore the key research topics. This approach involved establishing an initial coding framework based on the PDPT research and policy context, then systematically coding these textual data to identify themes and to describe their content. Finally, we provide a classification for PDPT permissibility (allowable, potentially allowable, not allowable) in each jurisdiction. Although this classification draws on an assessment of EPT legality in the US,<sup>26</sup> aside from jurisdictions in which PDPT guidance had been provided, we have based our designation on KI opinion about the policy environment for PDPT in their respective jurisdiction.

The study was approved by the University of Melbourne Ethics Committee (ID: 1852979).

## Results

A total of 10 KIs representing six of eight Australian jurisdictions [Vic., NSW, South Australia (SA), Western Australia (WA), Queensland (Qld), Tasmania (Tas.)] were interviewed. KIs (female  $n = 6$ , male  $n = 4$ ) included senior representatives from State government communicable disease control and sexual health programs (KI-CDC) ( $n = 4$ ), pharmacists with responsibilities for medicines regulation (KI-P) ( $n = 3$ ) and sexual health doctors or nurses (KI-SH) ( $n = 4$ ) working in State government-funded sexual health clinics. One KI had two roles.

### Current context for PDPT

The key steps in developing formal guidance for PDPT (where relevant) and the documents appraised in respect to PDPT in each jurisdiction and nationally are summarised in Table 1. Overarching this framework at the national level is the Medical Board of Australia Good Medical Practice Code of Conduct (the 'Code').<sup>27</sup> This Code sets out a standard for all doctors registered to practice medicine in Australia and outlines the principles that characterise good medical practice, including obtaining informed consent for examination and treatment. Also, nationally, general support for PDPT is provided in STI strategy, contact tracing and treatment guidelines,<sup>28–30</sup> and three jurisdictions, NT, Vic. and NSW, have provided formal support for PDPT.<sup>11–21</sup> However, across the KIs, interpretation of how PDPT would sit with the Code<sup>27</sup> varied. A KI from one jurisdiction was concerned that PDPT where a doctor treated a partner they had not seen or spoken with was not consistent with the Code. This KI raised the possibility that a telehealth consultation might address this issue. In contrast, in Vic. and NSW, PDPT was viewed as acceptable medical practice because the doctor has a duty of care to their patients that extends to the partners of their patients (Table 1).<sup>15,21,23</sup> PDPT guidance in both these jurisdictions also emphasised that doctors should encourage partners to seek medical advice.

Table 1 also provides a classification for each jurisdiction regarding PDPT permissibility. For NT, Vic. and NSW, where

State Governments have provided formal guidance, PDPT is allowable. Actions towards PDPT in these jurisdictions began with clarification via legal advice as to whether PDPT was allowable under relevant medicines and prescribing acts and regulations.<sup>11–21</sup> In the NT, the Medicines, Poisons and Therapeutic Goods Act was amended to allow PDPT for chlamydia<sup>12</sup> and summarised in a PDPT information sheet<sup>11</sup> specifying the legal basis and prescribing conditions. For Vic., a legal review determined that PDPT was not expressly illegal under prescribing regulations.<sup>14</sup> A PDPT clinical guideline<sup>15</sup> was developed for Victoria that specified that use of PDPT in accordance with the guideline would satisfy prescribing regulations. In NSW, it was recognised that an index case may not know the full address of their partner(s) and the Poisons and Therapeutic Goods Regulations<sup>18</sup> and Health Practitioner Regulations (NSW)<sup>19</sup> were amended to allow for a partner's name and email address or mobile phone number to be recorded as an address on the prescription. No formal guidance was available in other jurisdictions. However, most KIs viewed PDPT as potentially allowable under relevant regulations. In WA, the Medicines and Poisons Regulations<sup>31</sup> were described as 'silent' (neither prohibitive or permissive) on PDPT with one KI saying '*... whether or not you're the person the doctors see or someone related to the person through some sort of sexual contact, the legislation is really silent. It doesn't distinguish. If a prescriber says, 'I agree you or someone else that you know needs this medicine,' they can instruct that be supplied.'*' (KI-P-3) Similarly, in Tas.,<sup>32</sup> the Australian Capital Territory (ACT)<sup>33</sup> and SA,<sup>34</sup> our KIs perceived that relevant regulations did not expressly prohibit or permit PDPT. In SA, work towards implementing PDPT was ceased in 2016 following the emergence of azithromycin-resistant gonorrhoea, and single dose azithromycin PDPT for chlamydia treatment is now not recommended.<sup>35,36</sup> For Qld, PDPT was viewed as not allowable under existing regulations, with reasons including that the prescribing doctor must have a treating relationship with a patient and would require a physical address to write a prescription.<sup>37</sup> In 2019, the Qld Parliament passed a new Medicine and Poisons Bill,<sup>38</sup> and it is unclear if PDPT will be possible under the new Act and amended regulations.

When asked about PDPT use in their jurisdiction, most KIs were of the opinion that PDPT use was infrequent, but that it occurred with or without formal guidance. One KI described *ad hoc* PDPT use as a reason to formalise PDPT provision, saying '*we knew that GPs were sort of doing it anyway. We would get people coming in and saying, 'The doctor already gave me some tablets to give to my boyfriend' rather than a script or anything. So there was that sort of thing going on and we were a bit concerned that it was happening a bit ad hoc and tried to put some framework around that.'*' (KI-CDC-4) Many KIs believed it occurred in specialist services (e.g. sexual health, family planning) and general practice, although specialist services were viewed as more conducive to PDPT use due to longer consultation times, onsite pharmacy and different funding mechanisms.

Some KIs described circumstances for PDPT in their own clinical setting, with clinical judgement and knowledge of

Table 1. Summary of the current environment for PDPT by Australian jurisdiction

State or Territory	Steps taken	Relevant documents	PDPT permissibility <sup>A</sup>
NT	<ul style="list-style-type: none"> <li>Amended medicines, poisons and therapeutic Goods Act to allow PDPT for chlamydia</li> <li>Developed PDPT information sheet to the Act</li> </ul>	<p><b>Medicines &amp; Poisons Control Information Sheet No. 320.8</b><sup>11</sup> specifies the legal basis for PDPT as <b>Section 89</b> of the <b>Medicines, Poisons and Therapeutic Goods Act 2012</b><sup>12</sup> and the conditions for prescribing PDPT as <b>Regulation 12</b>.<sup>13</sup></p> <ul style="list-style-type: none"> <li>The patient (index case) must have been diagnosed with microbiologically confirmed chlamydia (by nucleic acid amplification test or related technologies) and</li> <li>The sexual partner is at significant risk of contracting chlamydia; and</li> <li>The prescription may only be for a single dose of azithromycin.</li> </ul>	Allowable
Vic.	<ul style="list-style-type: none"> <li>Legal advice that PDPT was not expressly illegal in Victorian prescribing regulations</li> <li>Developed PDPT clinical guideline and FAQs for clinicians</li> </ul>	<p><b>Drugs, Poisons and Controlled Substances Regulations 2006</b><sup>14</sup></p> <ul style="list-style-type: none"> <li>Regulation 8(2) and 9(2) a registered health practitioner must not administer, prescribe, sell or supply a Schedule 4 poison unless for medical treatment of a person under their care; and they have taken all reasonable steps to ensure a therapeutic need exists.</li> </ul> <p><b>PDPT clinical guidelines</b><sup>15</sup> and <b>FAQ for clinicians</b><sup>16</sup></p> <ul style="list-style-type: none"> <li>A practitioner who prescribes or supplies azithromycin for PDPT for a microbiologically confirmed chlamydia infection generally will be considered to have satisfied regulation 8(2) or 9(2) if they provide therapy in accordance with the PDPT Clinical Guidelines.</li> </ul>	Allowable
NSW	<ul style="list-style-type: none"> <li>Amended poisons and therapeutic goods regulation and the NSW health practitioner regulations so an email or phone number sufficed as a PDPT prescription address</li> <li>Developed PDPT procedures</li> <li>PDPT pilot in SHC and FPC</li> </ul>	<p><b>Drugs Poisons and Controlled Substances Regulations 2017</b><sup>17</sup> updated regulations continue to allow PDPT.</p> <p><b>Poisons and Therapeutic Goods Regulation 2008</b><sup>18</sup> (amended 2017) and the <b>Health Practitioner Regulation (NSW) Amendment (Records of Partners) Regulation 2017</b><sup>19</sup> provide the legal basis for PDPT. Part 3, Division 3, Clause 35:</p> <ul style="list-style-type: none"> <li>A prescription for a restricted substance must include the issuing date, treatment and name and address of the patient.</li> <li>Where the treatment is for a patient's partner and the prescription is for azithromycin for chlamydia, the partner's name and email address or mobile phone number can be recorded in lieu of the full address.</li> <li>A partner of a patient includes any of the patient's spouse, de facto, or person with whom the patient is or was in a sexual relationship.</li> </ul> <p><b>PDPT guidance for NSW sexual health and family planning services</b><sup>20,21</sup> provide PDPT procedures and advice regarding a doctor's duty of care to patients and partners:</p> <ul style="list-style-type: none"> <li>'It is an established law that a health professional owes a duty of care to their patients. This duty extends to partners of patients for whom they are providing or prescribing medication. This does not mean the partner must become a patient of the clinician, because the clinician does not need to have a traditional doctor–patient relationship with the partner in order to owe the partner a duty of care.'</li> </ul>	Allowable Guidance for SHC and FPC
WA		<p><b>Medicines and Poisons Act 2014 and Medicines and Poisons Regulations 2016</b><sup>31</sup></p>	Potentially allowable Regulations in WA, Tas., ACT do not expressly support or prohibit PDPT.
Tas.		<p><b>Poisons Regulations 2018</b><sup>32</sup></p> <p>Part 4, 45 Prescriptions for restricted substances</p>	
ACT		<p><b>Medicines, Poisons and Therapeutic Goods Act 2008</b><sup>33</sup></p>	
SA		<p><b>Controlled Substances (Poisons) Regulations 2011</b><sup>34</sup></p> <ul style="list-style-type: none"> <li>Section 33(1) a prescriber must give a prescription for a drug in writing to the person for whom the drug is to be supplied, or a person acting on behalf of that person.</li> </ul> <p><b>SA STI Implementation Plan 2016–18</b><sup>35</sup> and <b>STI guidelines</b><sup>36</sup></p> <ul style="list-style-type: none"> <li>PDPT for chlamydia using azithromycin is not recommended due to circulating strains of azithromycin-resistant gonorrhoea and <i>Mycoplasma genitalium</i>.</li> </ul>	Potentially allowable Regulations in SA do not expressly support or prohibit PDPT. PDPT not recommended in policy.
Qld		<p><b>Health (Drugs and Poisons) Regulation 1996</b><sup>37</sup> and <b>Medicines and Poisons Act 2019</b><sup>38</sup></p>	Not allowable
National		<ul style="list-style-type: none"> <li>Good Medical Practice: a code of conduct for doctors in Australia<sup>27</sup></li> <li>National Sexually Transmissible Infections Strategy 2018–22<sup>28</sup></li> <li>Australasian Contact Tracing Manual<sup>29</sup></li> <li>Australasian STI Management Guidelines for Use in Primary Care<sup>30</sup></li> </ul>	

<sup>A</sup>PDPT permissibility. Allowable—based on availability of PDPT guidance; Potentially allowable or Not allowable—based on KI opinion about the policy environment for PDPT in their respective jurisdiction.



patient or partner(s) deemed important. Reasons to offer PDPT included if a patient was assessed as at high risk of re-infection (e.g. partner may not seek treatment) or access issues (e.g. patient or partner(s) live long distances from the clinic). One KI said: *'Yeah absolutely under no illusion that doctors will give it [PDPT] sometimes. Of course they will. You don't need a guideline to do it. GPs - some GPs will do it'* ((KI-SH-5) and *'I imagine that in our clinic some of our clinicians occasionally do it where it seems clinically the most likely to prevent reinfection. Although we certainly don't have a policy supporting it. I've done [PDPT] fairly rarely but I have because sometimes it seems the only way.'* (KI-SH-5) A PDPT offer might also include a phone call to partner(s) to check for allergies and to provide an explanation of PDPT.

### Challenges to PDPT

Key informants identified a range of challenges to implementing PDPT, as outlined under the headings below.

#### Chlamydia and STI epidemiology

In the context of increasing diagnoses of heterosexually transmitted gonorrhoea and syphilis in Australia,<sup>39</sup> several KIs were concerned that PDPT for chlamydia would impede STI testing for the partner, thereby potentially missing other STIs. Further, there was concern about using azithromycin for PDPT in view of emergence of azithromycin-resistant gonorrhoea in some areas of Australia.<sup>35,36</sup> The importance of testing sexual partners to allow pathogen specific treatment was highlighted. *'We need to establish more about azithromycin resistance in coinfections and about how common coinfections are in contacts.'* [KI-SH-5] However, the public health benefit of facilitating treatment of more partners was acknowledged.

#### Medico-legal and regulatory concerns

Key informants were cognisant of concerns of doctors with respect to providing PDPT for individuals they had not examined. One KI expressed concern that a treating relationship between a doctor and partner for PDPT was not clear in respect to the Medical Board Code of Conduct<sup>27</sup> or to prescribing regulations stating: *'no-one has addressed that issue around what is the treating relationship with the partner, what does that look like? What is adequate? What is enough? And about getting consent around considering other factors in treating a person with a medicine, so are they on any other medicines? Have they previously had an adverse event to this medicine?'* and *'So treatment is not defined and the patient – for me, when I read that [the regulations], I would say that you have to have a treating relationship with the person.'* (KI-P-1) This doctor–partner relationship was viewed as important by other KIs, and as a separate issue to prescribing regulations: *'most doctors won't do it [PDPT] . . . They haven't examined you [the partner]. They might not know what medicines you're taking or allergies you have. They won't get paid for it as a consult. They're liable for it and what does their insurance say of that situation? Now our legislation [prescribing regulations] is absolutely unconnected with any of those issues.'* (KI-P-3)

These concerns were underscored by recognition of a lack of clinical guidance for PDPT in terms of how and for whom to provide it.

#### Priorities and funding

PDPT was often viewed as one of many competing priorities in a jurisdiction's STI response, and issues such as increasing gonorrhoea and syphilis diagnoses (with risk of congenital syphilis) took precedence over allocating the human resources needed to develop PDPT guidelines and procedures for that State or Territory. One KI said: *'So it's [PDPT] up there amongst the priorities. It's just not the top priority'* and *'I have to deal with syphilis. Syphilis kills babies and I have to spend what resources I have on that.'* (KI-SH-5) For other KIs, workforce development was viewed as a priority, as was leadership to develop PDPT guidance *'from the top down it's [PDPT] not really been a priority to have any clinical or regulatory policies around it to then promulgate it.'* (KI-SH-6) Further, a lack of research funding was viewed as a constraint to establishing an evidence base for patients to which PDPT could be safely promoted.

Practical considerations such as how to prescribe and document PDPT were identified, particularly if partner(s) were not patients of the clinic. Although KIs were mindful that prescribing regulations require a partner's physical address (with the exception of NSW) for a PDPT prescription, they were also aware that an index patient may not know these details, as emphasised by one KI *'As far as writing a prescription is concerned, the address is necessary'* and *'Not everyone has the name and contact details of their partner to be able to give a script for them.'* (KI-P-9) In terms of recording PDPT, one option was to create a new record, but this was generally discounted because index cases may have insufficient details of their partner (e.g. address) and it posed an administrative burden. An alternative discussed was to record partner(s) details in the index case's file, although this would preclude generation of PDPT prescriptions from the electronic medical record (EMR) and there was lack of clarity about whether it was allowable to record partner details in the EMR: *'and secondly, they're unclear if they should be storing those names and contact details in their patient's file.'* (KI-CDC-8) These issues were viewed as more pertinent to general practice than specialist clinics with onsite medication: *'in the documentation . . . in sexual health service if we don't know the partner . . . in the index cases file it would just say something like medication and consumer medical information given to the index case for partner. We wouldn't create a new file. Because we have the medicine in our imprest [medication stock held in the clinic].'* (KI-SH-6)

#### What is needed for PDPT to become part of routine care?

Several actions for PDPT to become part of routine care were described by KIs as outlined below.

The need to clarify the PDPT legal and policy environment was recognised. In view of many jurisdictions' prescribing regulations being silent on PDPT, regulatory change was often viewed as unnecessary: *'So it's [the regulations] silent as to whether or not the prescriber would need to physically review*

*a patient who they prescribe for, so that is not a barrier. So it wouldn't be a legal problem, it would be really the clinical one.'* (KI-SH-6)

Development of guidance in respect to State or Territory regulations and clinical guidance from relevant professional organisations, such as the Royal Australian College of General Practitioners (RACGP), was viewed as crucial to addressing medico-legal concerns and in supporting doctors to make decisions about PDPT within a standard of care that PDPT could be assessed against. Highlighting this, KI-CDC-4 said: *'So if there was something in writing to say that the College of GPs had recommended it or the chapter of sexual health, ... then it was probably okay to go ahead.'* (KI-CDC-4) On a similar note, KI-CDC and KI-SH-7 said: *'GPs typically want to do the right thing by patients and themselves and they want to protect their own back. So, our job is to show them that they are protected. Protected in a professional sense because that's where the legal stuff comes from and if it's a professionally accepted practice they won't be sued.'* (KI-CDC and KI-SH-7)

In the context of professional liability and a standard of care, PDPT guidance in Vic.<sup>15</sup> and NSW<sup>21,23</sup> both highlighted that PDPT can be considered as part of a doctor's duty of care to the index case and to partners of patients with an STI (whether or not PDPT is offered). The benefits are that partners are informed of their potential exposure and that treating a partner could prevent re-infection in the index patient and complications from undiagnosed and untreated infection in the partner. This was emphasised as follows: *'providing care to the partner of a patient came under the doctor's duty of care. Duty of care extended from the individual they were seeing because the outcome for that index case depended on the treatment of the partner because of the likely potential for re-infection and complications within their sexual network.'* (KI-CDC and KI-SH7)

On a practical note, several KIs highlighted that protocols and resources for how and for whom PDPT can be prescribed and documented; resources for patient and partners; and education and training were all important elements of establishing PDPT within a standard of care. This was emphasised as follows: *'But certainly, one of the things that the feedback to us was saying was that more workforce development was needed to highlight the availability of the provisions [PDPT guidelines], how it's [PDPT] implemented in general practice. ...'* (KI-CDC-8)

## Discussion

This research found that PDPT for chlamydia infection was largely viewed as possible under relevant prescribing regulations for most Australian jurisdictions. To date, three jurisdictions have provided formal guidance, giving doctors the authorisation to distribute PDPT. For others, development of guidance in respect to State or Territory regulations was seen by KIs as crucial to creating an environment that doctors could feel confident to practice within and to address state-specific issues and medico-legal concerns. Endorsement or clinical guidance from professional organisations such as RACGP was deemed crucial to establishing a standard of care against which PDPT provision could be assessed.

Clarification of the doctor-partner treating relationship was also viewed as important.

This study is the first to investigate the policy environment for PDPT in Australia. An important strength is that by using structured interviews, our KI responses provided insights into the context for PDPT in their own jurisdiction, thereby facilitating interpretation of the documents appraised. There are several limitations. First, we only interviewed a small number of KIs and it is possible their responses do not represent the main considerations for PDPT in their jurisdiction or that we did not reach saturation of themes. However, KIs were invited for interview based on their responsibilities and expertise and were given opportunity to nominate others for interview as they deemed appropriate. Second, although some KIs had clinical roles, these were in government-funded sexual health services and therefore did not directly represent the general practice setting. Although further consultation with GPs and patients is crucial if PDPT is to be implemented in general practice, our KIs were important with regards to PDPT policy within their jurisdictions. Finally, although medico-legal challenges are often perceived as a barrier to PDPT, this study is not a legislative review. Rather, it has sought to understand the policy context and the challenges and drivers for PDPT; the results do not constitute legal advice.

For PDPT to become routine, a multifaceted approach is crucial. In the US, this has involved action from legal representatives, professional organisations, policymakers and academics at state and national levels. EPT is supported by the CDC as a *'useful option to facilitate partner management, particularly for treatment of male partners of women with chlamydial infection or gonorrhoea'*<sup>6</sup> and is included in STI treatment guidelines.<sup>40</sup> The American Bar Association has recommended removal of legal barriers to EPT,<sup>41</sup> and position statements have been provided from adolescent medicine,<sup>42</sup> obstetrics and gynaecology bodies<sup>43</sup> and the American Medical Association.<sup>44</sup> Many US states have enacted laws that expressly support EPT<sup>26</sup> or issued guidelines and procedures for providing EPT in respect to local regulations and considerations.<sup>45</sup> Although uptake can be variable, a community-level trial reported for its final study year that free-of-charge PDPT was offered to 38% and 52% of heterosexual patients with chlamydia and gonorrhoea respectively and of these patients 34% accepted the offer.<sup>9</sup>

In Australia, general support for PDPT is provided nationally in the STI strategy,<sup>28</sup> contact tracing<sup>29</sup> and treatment guidelines,<sup>30</sup> and a standard of care is provided in AChSHM guidelines that outline patient selection, contraindications, recommended treatment and advice for prescribing and documentation.<sup>10</sup> However, in view of perceived medico-legal barriers to PDPT reported previously by Australian GPs,<sup>24</sup> endorsement and guidance from other key professional organisations such as the RACGP is essential to move PDPT into routine care. Furthermore, there is a need for clarification of a doctor's treating relationship to the sexual partners of their patient. Ideally, this would be provided by the Medical Board of Australia and would be complemented by legal amendments

(if warranted) and jurisdictional guidance regarding the regulatory context and procedures for providing PDPT.

Drawing on the experience of NT, Vic. and NSW, key actions towards providing PDPT guidance began with clarification of the permissibility (or not) of PDPT and amendments to prescribing or professional regulations (NT and NSW). Subsequent steps involved issuance of state-specific guidelines and procedures (albeit with varying detail) outlining the legal basis for PDPT, eligibility criteria, contraindications and advice for prescribing and documentation. As noted above, both the Vic. and NSW guidelines emphasise that a registered health practitioner has a duty of care to their patients and to the partners of their patients with an STI (irrespective of a PDPT offer). Eligibility criteria were consistent with AChSHM guidelines, recommending PDPT particularly for patients with laboratory-diagnosed chlamydia and heterosexual partners who are unlikely to seek timely health care.

Irrespective of whether PDPT guidance was provided, there was a sentiment from KIs that clarification of the doctor–partner treating relationship; more detail in PDPT resources and procedures; and workforce training and education were all crucial to promoting PDPT as an option for partner management. Alongside this, there is a need for systems to measure the uptake of PDPT within jurisdictions. One option could be to capture non-identifiable prescribing data from the EMR, although this would only capture electronic prescribing if the doctor created a medical record for the partners at the clinic. Such a measure could be incorporated into established data collection and reporting systems for general practice.<sup>46</sup>

To conclude, we return to our study title – can PDPT for chlamydia become part of routine care in Australia? Although there are many challenges to routine use of PDPT, they are not insurmountable. The benefits of PDPT to patients, their partners and the wider population are well established and it is recognised in Australian STI strategies and guidelines as an important option for expediting treatment of sexual partners of a patient with chlamydia. PDPT was viewed by our KIs as possible under prescribing regulations for most Australian jurisdictions, but formalisation of support and clarification of the doctor's duty of care, including the doctor–partner treating relationship, must be prioritised to provide an approach to PDPT that is acceptable to all jurisdictions. This must be complemented by endorsement and guidance from key professional organisations so that doctors can confidently and routinely offer PDPT in respect to professional and regulatory standards.

### Conflicts of interest

The authors declare no conflicts of interest. This research forms part of the Management of Chlamydia Cases in Australia (MoCCA) project, funded by a NHMRC Partnership Grant (APP1150014).

### Acknowledgements

We wish to thank our key informants for participating in an interview and for their valuable contribution to improving understanding of the context

for PDPT in Australia. We also wish to acknowledge Ms Tayla McKechnie and the MoCCA partner organisations: Victorian Government, Department of Health and Human Services, NSW Ministry of Health, Queensland Health, North Western Melbourne Primary Health Network, Central and Eastern Sydney Primary Health Network, Family Planning Victoria, Family Planning NSW, True Relationships & Reproductive Health, Victorian Cytology Service Pathology and Sydney Sexual Health Centre.

### References

- Althaus C, Turner K, Mercer C, Auguste P, Roberts T, Bell G, *et al.* Effectiveness and cost-effectiveness of traditional and new partner notification technologies for curable sexually transmitted infections: observational study, systematic reviews and mathematical modelling. *Health Technol Assess* 2014; 18: 1–100. doi:[10.3310/hta18020](https://doi.org/10.3310/hta18020)
- Reddel S, Edmiston N. Contact tracing for STIs: new resources and supportive evidence. *Aust Fam Physician* 2012; 41: 128–32.
- Walker J, Fairley C, Bradshaw C, Tabrizi SN, Chen M, Twin J, *et al.* *Chlamydia trachomatis* incidence and re-infection among young women – behavioural and microbiological characteristics. *PLoS One* 2012; 7: e37778. doi:[10.1371/journal.pone.0037778](https://doi.org/10.1371/journal.pone.0037778)
- LaMontagne DS, Baster K, Emmett L, Nichols T, Randall S, McLean L, *et al.* Incidence and reinfection rates of genital chlamydial infection among women aged 16–24 years attending general practice, family planning and genitourinary medicine clinics in England: a prospective cohort study by the Chlamydia Recall Study Advisory Group. *Sex Transm Infect* 2007; 83: 292–303. doi:[10.1136/sti.2006.022053](https://doi.org/10.1136/sti.2006.022053)
- Wood H, Hall C, Ioppolo E, Ioppolo R, Scaccia E, Clifford R, *et al.* Barriers and facilitators of partner treatment of chlamydia: a qualitative investigation with prescribers and community pharmacists. *Pharmacy* 2018; 6: 17. doi:[10.3390/pharmacy6010017](https://doi.org/10.3390/pharmacy6010017)
- Centers for Disease Control and Prevention. Expedited Partner Therapy. Atlanta: United States Centers for Disease Control and Prevention; 2019. Available online at: <https://www.cdc.gov/std/ept/default.htm> [verified 9 January 2020].
- Trelle S, Shang A, Nartey L, Cassell J, Low N. Improved effectiveness of partner notification for patients with sexually transmitted infections: systematic review. *BMJ* 2007; 334: 354–7. doi:[10.1136/bmj.39079.460741.7C](https://doi.org/10.1136/bmj.39079.460741.7C)
- Schillinger JA, Kissinger P, Calvet H, Whittington WL, Ransom RL, Sternberg MR, *et al.* Patient-delivered partner treatment with azithromycin to prevent repeated *Chlamydia trachomatis* infection among women: a randomized, controlled trial. *Sex Transm Dis* 2003; 30: 49–56. doi:[10.1097/00007435-200301000-00011](https://doi.org/10.1097/00007435-200301000-00011)
- Golden MR, Kerani RP, Stenger M, Hughes JP, Aubin M, Malinski C, *et al.* Uptake and population-level impact of expedited partner therapy (EPT) on *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: the Washington State Community-Level Randomized Trial of EPT. *PLoS Med* 2015; 12: e1001777. doi:[10.1371/journal.pmed.1001777](https://doi.org/10.1371/journal.pmed.1001777)
- Australasian Chapter of Sexual Health Medicine. Brief to Royal Australasian College of Physicians College Policy & Advocacy Committee – guidelines for patient delivered partner therapy (PDPT) for uncomplicated genital infection caused by *Chlamydia trachomatis*: position paper. Sydney: RACP; 2009.
- Northern Territory Government, Department of Health. Medicines & Poisons Control Information Sheet No. 320.8. Darwin: Northern Territory Government; 2015. Available online at: <https://digitalibrary.health.nt.gov.au/prodjsui/handle/10137/895> [verified 9 January 2020].
- Northern Territory Government. Medicines, Poisons and Therapeutic Goods Act 2012. Darwin: Northern Territory Government; 2012.



- Available online at: <https://legislation.nt.gov.au/en/legislation/medicines-poisons-and-therapeutic-goods-act-2012> [verified 9 January 2020].
- 13 Northern Territory Government. Medicines, Poisons & Therapeutic Goods Regulations. Darwin: Northern Territory Government; 2014. Available online at: <https://legislation.nt.gov.au/en/Legislation/MEDICINES-POISONS-AND-THERAPEUTIC-GOODS-REGULATIONS-2014> [verified 28 January 2020].
  - 14 Victorian Government. Drugs, Poisons and Controlled Substances Regulations 2006 S.R. No. 57/2006. Authorised Version No. 010. Authorised by the Chief Parliamentary Counsel. Melbourne: State Government of Victoria; 2006. Available online at: [http://www.legislation.vic.gov.au/domino/Web\\_Notes/LDMS/LTObject\\_Store/LTObjSt6.nsf/DDE300B846EED9C7CA257616000A3571/CBB80677A53FB2B4CA2578B1000601ED/\\$FILE/06-57sra010%20authorised.pdf](http://www.legislation.vic.gov.au/domino/Web_Notes/LDMS/LTObject_Store/LTObjSt6.nsf/DDE300B846EED9C7CA257616000A3571/CBB80677A53FB2B4CA2578B1000601ED/$FILE/06-57sra010%20authorised.pdf) [verified 9 January 2020].
  - 15 Department of Health and Human Services. Patient delivered partner therapy clinical guidelines. Melbourne: State Government of Victoria; 2015. Available online at: <https://www2.health.vic.gov.au/about/publications/policiesandguidelines/pdpt-clinical-guidelines> [verified 9 January 2020].
  - 16 Department of Health and Human Services. Patient Delivered Partner Therapy Clinical FAQs for Clinicians. Melbourne: State Government of Victoria; 2015. Available online at: <https://www2.health.vic.gov.au/about/publications/factsheets/pdpt-faq-clinicians> [verified 28 January 2020].
  - 17 Victorian Government. Drugs, Poisons and Controlled Substances Regulations 2017 S.R. No. 29/2017. Authorised by the Chief Parliamentary Counsel; 2017. Melbourne: State Government of Victoria; 2017. Available online at: [http://www.legislation.vic.gov.au/Domino/Web\\_Notes/LDMS/PubStatbook.nsf/b05145073fa2a882ca256da4001bc4e7/C3217A0343C6A914CA25812200151801/\\$FILE/17-029sra%20authorised.pdf](http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/b05145073fa2a882ca256da4001bc4e7/C3217A0343C6A914CA25812200151801/$FILE/17-029sra%20authorised.pdf) [verified 18 February 2020].
  - 18 NSW Government. Poisons and Therapeutic Goods Regulation 2008. Sydney: NSW Government; 2008. Available online at: <https://www.legislation.nsw.gov.au/#/view/regulation/2008/392/part3/div3/sec35> [verified 9 January 2020].
  - 19 NSW Government. Health Practitioner Regulation (New South Wales) Amendment (Records of Partners) 2017. Sydney: NSW Government; 2017. Available online at: <https://www.legislation.nsw.gov.au/regulations/2017-687.pdf> [verified 9 January 2020].
  - 20 NSW Health Sexual Health Services. Standard Operating Procedures Manual: patient-delivered partner therapy for chlamydia. Sydney: NSW Government; 2018. Available online at: <https://stipu.nsw.gov.au/gp/hiv-and-sti-clinical-management/patient-delivered-partner-therapy-for-chlamydia/> [verified 9 January 2020].
  - 21 NSW STI Programs Unit. Patient delivered partner therapy for treatment of chlamydia in eligible patients: clinic pathway in publicly funded sexual health services. Sydney: NSW Government; 2017. Available online at: <https://stipu.nsw.gov.au/gp/hiv-and-sti-clinical-management/patient-delivered-partner-therapy/> [verified 28 January 2020].
  - 22 Hocking J, Fairley C, Counahan M, Crofts N. The pattern of notification and testing for genital *Chlamydia trachomatis* infection in Victoria, 1998–2000: an ecological analysis. *Aust NZ J Public Health* 2003; 27: 405–8. doi:10.1111/j.1467-842X.2003.tb00417.x
  - 23 Lorch R, Bourne C, Burton L, Lewis L, Brown K, Bateson D, et al. ADOPTing a new method of partner management for genital chlamydia in New South Wales: findings from a pilot implementation program of patient-delivered partner therapy. *Sex Health* 2019; 16: 332–9. doi:10.1071/SH18169
  - 24 Pavlin NL, Parker RM, Piggan AK, Hopkins CA, Temple-Smith MJ, Fairley CK, et al. Better than nothing? Patient-delivered partner therapy and partner notification for chlamydia: the views of Australian general practitioners. *BMC Infect Dis* 2010; 10: 274. doi:10.1186/1471-2334-10-274
  - 25 Hsieh H, Shannon S. Three approaches to qualitative content analysis. *Qual Health Res* 2005; 15: 1277–88. doi:10.1177/1049732305276687
  - 26 Hodge J, Pulver A, Hogben M, Bhattacharya D, Brown E. Expedited partner therapy for sexually transmitted diseases: assessing the legal environment. *Am J Public Health* 2008; 98: 238–43. doi:10.2105/AJPH.2007.113381
  - 27 Medical Board of Australia. Good medical practice: a code of conduct for doctors in Australia. 2014. Available online at: <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx> [verified 15 January 2020].
  - 28 Department of Health. Fourth National Sexually Transmissible Infections Strategy 2018–2022. Canberra: Australian Government; 2018. Available online at: [https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1/\\$File/STI-Fourth-Nat-Strategy-2018-22.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1/$File/STI-Fourth-Nat-Strategy-2018-22.pdf) [verified 9 January 2020].
  - 29 Australasian Society for HIV Viral Hepatitis and Sexual Health Medicine. Australasian Contact Tracing Manual. Sydney: ASHM; 2016. Available online at: <http://ctm.ashm.org.au/> [verified 9 January 2020].
  - 30 Australasian Sexual Health Alliance. Australasian STI Management Guidelines for Use in Primary Care. Sydney: ASHA; 2018. Available online at: <http://www.sti.guidelines.org.au/> [verified 30 January 2020].
  - 31 Western Australian Government. Medicines and Poisons Regulations 2016. Version 00-c0-02. Perth: Western Australian Government; 2016.
  - 32 Tasmanian Government. Poisons Regulations. Hobart: Tasmanian Government; 2018. Available online at: <https://www.legislation.tas.gov.au/view/html/inforce/2019-04-17/sr-2018-079> [verified 9 January 2020].
  - 33 ACT Parliamentary Counsel. Medicines, Poisons and Therapeutic Goods Act. Canberra: Australian Capital Territory Government; 2008. Available online at: <https://www.legislation.act.gov.au/View/a/2008-26/current/PDF/2008-26.PDF> [verified 28 January 2020].
  - 34 South Australian Government. Controlled Substances (Poisons) Regulations 2011. Version: 18.4.2019. Adelaide: Government of South Australia; 2019. Available online at: [https://www.legislation.sa.gov.au/LZ/C/R/Controlled%20Substances%20\(Poisons\)%20Regulations%202011.aspx](https://www.legislation.sa.gov.au/LZ/C/R/Controlled%20Substances%20(Poisons)%20Regulations%202011.aspx) [verified 9 January 2020].
  - 35 South Australian Department for Health and Ageing. South Australian STI Implementation Plan 2016–2018. Adelaide: Government of South Australia; 2015.
  - 36 SA Health. Sexually transmitted infection guidelines. Adelaide: Government of South Australia; 2017. Available online at: <https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/sexually+transmitted+infection+guidelines> [verified 9 January 2020].
  - 37 Queensland Government. Health (Drugs and Poisons) Regulation 1996. Queensland: State of Queensland; 2017.
  - 38 Parliamentary Counsel Queensland. Medicines and Poisons Bill 2019. Brisbane, Queensland: State of Queensland; 2019.
  - 39 The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia. Annual Surveillance Report 2018. Sydney: University of NSW; 2018.
  - 40 Centers for Disease Control and Prevention Sexually transmitted diseases treatment guidelines, 2006. *MMWR* 2006; 55(No RR-11): 5–6.
  - 41 American Bar Association. Recommendation 116A. Chicago: American Bar Association; 2008. Available online at: <https://www.cdc.gov/std/ept/onehundredsixteena.authcheckdam.pdf> [verified 9 January 2020].



- 42 Burstein G, Eliscu E, Ford K, Hogben M, Chaffee T, Straub D, *et al.* Expedited partner therapy for adolescents diagnosed with chlamydia or gonorrhea: a position paper of the Society for Adolescent Medicine. *J Adolesc Health* 2009; 45: 303–9. doi:[10.1016/j.jadohealth.2009.05.010](https://doi.org/10.1016/j.jadohealth.2009.05.010)
- 43 American College of Obstetricians and Gynecologists. ACOG Committee Opinion Number 737 - Expedited partner therapy. *Obstet Gynecol*; 2018; 131: e190–3. Available online at: <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Expedited-Partner-Therapy> [verified 9 January 2020].
- 44 American Medical Association. Expedited partner therapy: code of medical ethics opinion 8.9. Chicago: American Medical Association; 2016. Available online at: <https://www.ama-assn.org/delivering-care/ethics/expedited-partner-therapy> [verified 9 January 2020].
- 45 STD Control Branch. Standard of care for patients with chlamydia and gonorrhea: expedited partner therapy (EPT). Richmond: California Department of Public Health; 2016. Available online at: [https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/EPT-for-CT-GC-Patients\\_Essential%20Access.pdf](https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/EPT-for-CT-GC-Patients_Essential%20Access.pdf) [verified 9 January 2020].
- 46 Canaway R, Boyle D, Manski-Nankervis J, Bell J, Hocking J, Clarke K, *et al.* Gathering data for decisions: best practice use of primary care electronic records for research. *Med J Aust* 2019; 210: S12–6. doi:[10.5694/mja2.50026](https://doi.org/10.5694/mja2.50026)