International Journal of Drug Policy 69 (2019) 46–52

Contents lists available at ScienceDirect

International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo

Research Paper

# Why aren't Australian pharmacists supplying naloxone? Findings from a qualitative study

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ARTICLE INFO

*Keywords:*
Naloxone
Pharmacists
Over the counter
Opioid
Overdose
Community pharmacy

ABSTRACT

*Background:* Opioid overdose is a significant public health issue among people who use pharmaceutical opioids and/or heroin. One response to reducing overdose deaths is to expand public access to naloxone. The Australian Therapeutic Goods Administration down-scheduled naloxone from prescription only (S4) to pharmacist only over-the-counter (OTC, schedule 3) in February 2016. There is little research examining pharmacists' perspectives or experiences of this change.

*Methods:* Thirty-seven semi-structured interviews with Australian community pharmacists were conducted in 2016–2017 to investigate pharmacists' attitudes to and experiences of OTC naloxone. Transcripts were thematically analysed, guided by a broad interest in facilitators and barriers to OTC supply.

*Results:* Around half of the pharmacists were aware of the down-scheduling and only two had provided OTC naloxone. Core barriers to pharmacist provision of OTC naloxone included limited understanding of opioid overdose, confusion about the role and responsibilities of pharmacists in providing OTC naloxone, concerns about business, stigma related to people who inject drugs (PWID) and system-level challenges.

*Conclusion:* Pharmacy provision of OTC naloxone offers an important opportunity to reduce overdose mortality. Our study suggests this opportunity is yet to be realised and highlights several individual- and structural-level impediments hindering the expansion of public access to naloxone via community pharmacies. There is a need to develop strategies to improve pharmacists' knowledge of OTC naloxone and opioid overdose as well as to address other logistical and cultural barriers that limit naloxone provision in pharmacy settings. These need to be addressed at the individual level (training) as well as the system level (information, regulation and supply).

## Introduction

Opioid-related mortality continues to rise in many parts of the world (Guy et al., 2017). In Australia, opioid overdose deaths have increased each year since 2006, with a 64% increase in overdose deaths in the ten years leading up to 2015 (Roxburgh & Burns, 2017). On a global level, Australia has a higher than average drug mortality rate with opioids being the leading cause of drug-related death (United Nations Office for Drug Control & Crime, 2017). In most cases, these deaths are accidental and preventable and population level responses are required to reverse these concerning trends.

One strategy with demonstrated effectiveness for preventing overdose deaths is the implementation of take-home naloxone programs. Take-home naloxone programs involve the provision of naloxone, an opioid antagonist, for administration in community settings by a trained layperson at the time that an overdose is witnessed. Recent systematic reviews have confirmed that these programs are safe and effective (McDonald & Strang, 2016; Olsen, McDonald, Lenton, & Dietze, 2017). Further, the availability of naloxone has not been shown to increase opioid use (Jones, Campbell, Metz, & Comer, 2017; Wagner et al., 2010), a concern initially expressed by some (Fenichel, 2004). Indeed, studies that have measured this outcome have shown that

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https://doi.org/10.1016/j.drugpo.2019.03.020

opioid consumption has been shown to *decrease* following naloxone provision and overdose training use (Jones et al., 2017; Wagner et al., 2010).

In addition to take-home naloxone programs operating from services for people who use drugs, pharmacists are increasingly being recognised as potential educators and distributers of naloxone (Bailey & Wermeling, 2014; Green, Dauria, Bratberg, Davis, & Walley, 2015; Jones, Lurie, & Compton, 2016; Shafer, Bergeron, Smith-Ray, Robson, & O'Koren, 2017). However, few countries are yet to enact policy to allow naloxone provision in this setting. According to available literature, only Italy and some US states have naloxone available without a prescription (Lenton, Dietze, & Jauncey, 2016), and more recently, Australia. In Australia, naloxone was down-scheduled from prescription only (Schedule 4) to pharmacist only over-the-counter (OTC, Schedule 3) in February 2016 (Lenton et al., 2016). This required a change to the *Standard for the Uniform Scheduling of Medicines and Poisons* legislation administered by the Australian Therapeutic Goods Administration (TGA) in order to 'down-schedule' naloxone from its existing Schedule 4 status as a 'prescription only' medicine to a 'pharmacist only' (Schedule 3) medicine. Schedule 3, or OTC medicines are stored behind the counter at pharmacies and a pharmacist must be involved in the sale to ensure safe use of medicines. Previously in Australia, patients needed a prescription from their general practitioner either via traditional medical appointments, or though attendance at a specialised overdose prevention training workshop (Lenton et al., 2015, 2016). The down--scheduling enables pharmacists to initiate naloxone supply and allows members of the public to request naloxone from pharmacies.

A scoping review and Australian national online survey of pharmacists completed in 2015 revealed that community pharmacists hold positive attitudes towards provision of illicit drug related harm reduction services, including naloxone supply (Nielsen & Van Hout, 2016; Nielsen, Menon, Larney, Farrell, & Degenhardt, 2016). Yet pharmacists displayed limited knowledge of naloxone and reported low confidence in their ability to identify appropriate patients or train them in administering the drug (Nielsen et al., 2016). Little is known about why pharmacists report low knowledge and confidence, or their experiences supplying naloxone since the drug was made available without prescription.

In this paper, we present findings from a qualitative study investigating Australian pharmacists' attitudes to and experiences with OTC naloxone. The aim of the study was to better understand pharmacists' views on the acceptability and feasibility of OTC naloxone provision by pharmacists in Australia. We also aimed to better understand the system level barriers and facilitators to pharmacist provision of OTC naloxone.

## Methods

Thirty-seven Australian pharmacists from four different jurisdictions were recruited and interviewed in 2016 and 2017. The jurisdictions were New South Wales (n = 10), Queensland (n = 9), Victoria (n = 10), and the Australian Capital Territory (n = 8). These jurisdictions were chosen to reflect a range (four out of eight) of Australian jurisdictions and to aid recruitment as the authors have strong networks in these areas. We used a number of different recruitment methods. Initially, we contacted pharmacists by email who had previously participated in a study conducted by author SN in September–November 2015 (Nielsen et al., 2016) and who indicated interest in further research. Subsequently, additionalparticipants were recruited through emails to pharmacist networks advertising the project and calling pharmacies directly in under-represented areas. In order to ensure a variety of experiences and attitudes, we attempted to recruit pharmacists who do and do not provide pharmacy harm reduction services (needle syringe program or opioid pharmacotherapy services) and pharmacists from regional and remote areas as well as metropolitan areas. Interviews were conducted over the telephone using a semi-structured interview guide. Topics included: the role of pharmacists supporting people at risk of opioid overdose; knowledge of and attitudes to OTC naloxone provision; and required information or training. We used a brief survey to collect basic demographic information. Pharmacists were reimbursed AUD$50 for their time which they could choose to take as a payment or donate to a nominated charity.

Interviews were digitally recorded and professionally transcribed. Transcripts were de-identified and data were analysed in Atlas.ti 8.1.28 software using a thematic analysis approach (Braun & Clarke, 2006; Corbin & Strauss, 2008). Although led by social scientists, this paper reflects analysis driven by description, pragmatism and an interest in harm reduction initiatives rather than abstraction or theory. Analysis was descriptive with a focus on describing typological themes rather than interpretative analysis or theory. Preliminary analysis began during data collection and drew on a priori themes reflected in the interview schedule as well as inductive codes resulting in a draft codebook developed by RD and AO. Following the steps outlined by Braun and Clarke (2006), coding and analysis of the full dataset was completed by authors BL and AO. Building on the draft codebook we further refined inductive codes to reflect participant descriptions of and attitudes to OTC naloxone supply and shared this analysis with the full team. As a multi-disciplinary team (social scientists and pharmacists), members had different practical and theoretical sensitivities to particular themes and this impacted on the organisation of data into themes during the draft writing process and final analysis. In particular, pharmacist team members grounded the interpretation and presentation of data in the lived experience of practising as a pharmacist in Australia.

All procedures were approved by University of New South Wales Human Research Ethics Advisory (HREA) Panel G: Health, Medical, Community and Social (HC16598) and University of Queensland School of Pharmacy Ethics Committee (Ref: 2016/7, #2016001381).

## Results

Around half of the sample (n = 20) were women and a majority of participants (46%) were aged 30–39 years with 9 (24%) aged under 30 and 11 (30%) aged over 40. Most (n = 31) were from metropolitan locations with some from regional (n = 5) and rural (n = 1) locations. Around half provided harm reduction services in their pharmacy including needle and syringe program (n = 20) and/or opioid substitution therapy (n = 23).

Around half of the pharmacists were aware of the down-scheduling and only three had any experience in dispensing and providing education for OTC naloxone. Barriers to pharmacist provision of OTC naloxone included limited understanding about opioid overdose, uncertainty concerning the role of pharmacists in OTC naloxone supply, system level barriers which included logistical challenges, concerns about economics and business impacts, and stigma related to people who inject drugs (PWID).

### *Limited experience and low confidence*

It was common for pharmacists to describe having limited experience with naloxone OTC supply. Only two pharmacists reported having dispensed naloxone OTC, with another reporting educating a concerned family member about availability.

> *… surprisingly we've never been asked for any and I would have thought we would have. I'm not sure how much advertising there's been to the general public … No one has ever mentioned it, even people on the … methadone program have not asked about it. (ID28; female, 60+ years, metropolitan ACT)*

Connected to lack of experience, some pharmacists indicated that they felt unsure about how to advise a patient who requested naloxone, or how to educate patients about the availability of naloxone at the

pharmacy. These concerns were generally discussed in relation to the need to demonstrate how to use naloxone, as well as the sensitivities entailed in identifying someone as a person who uses drugs.

*It's a bit more of a hesitation in terms of initiating a conversation … You know, it's [naloxone] just in a different sort of class still, I think it's still, to most people mentally, it doesn't sort of sit on the S3 [schedule 3] counter with the rest of them to be honest … It's definitely not there in vision [sight] for somebody to recommend like the majority of all other S3s … I don't know if unusual is the right word, but it's not just as common as your Ventolin or it's just not something that you would go, 'hey yeah, can we have a chat over here about it?' (ID 21; female, 40–49 years, metropolitan QLD)*

While the focus of naloxone provision in Australia, and internationally, has been preventing overdose among PWID, a small number of pharmacists mentioned the need to provide naloxone to users of pharmaceutical opioids. In terms of pharmacist confidence, however, approaching patients who use prescription or OTC opioids to discuss overdose was a challenging prospect.

*The confidence to initiate that conversation in the first place, because it can be quite intimidating to walk up to someone and be like, 'Oh hey, you're using really high doses' [of opioids] … You don't want to scare them off what they are taking or what they're doing … (ID05; Female, 20–29 years, regional VIC)*

*It's not really a topic that you could easily say to someone who comes in to get their regular Nurofen Plus or Panadeine Extra. You can't say, 'Oh by the way, keep in mind this product's available in case you do overdose', because then it's kind of incriminating. 'Are you calling me a drug user?' … There's no kind of recommended method in place to create awareness. (ID26; Female, 30–39 years, regional QLD)*

### *Limited knowledge*

Many pharmacists' responses indicated confusion about the drug's purpose and what OTC provision means for the pharmacist. For instance, some pharmacists confused OTC naloxone with other prescription medications, especially opioid substitution therapies that also contain naloxone.

*Is it something like an epi pen … It's through a tablet yeah. I'm pretty sure it's a tablet (ID17; Female, 20–29 years, metropolitan QLD)*

*I think it would come in a … there's a tablet form. I remember with the Suboxone or the Subutex. (ID09; Female, 40–49 years, metropolitan NSW)*

Commonly, pharmacists appeared to misunderstand their role in the supply of naloxone and the circumstances under which OTC naloxone would be dispensed and administered.

*… are they expecting the pharmacists to do it [administer naloxone] on behalf of the patient, or are they expecting the patient to know how to use it? (ID27; Female, 30–39 years, metropolitan ACT)*

Several pharmacists expressed a mistaken notion that it was their role to administer the naloxone to a patient, assuming they would identify potential patients who attended the pharmacy while experiencing an overdose.

*… because we don't actually carry naloxone, I would apply first aid procedures and we would call an ambulance … should we actually have naloxone, I'm not sure actually what the legalities are around whether we could actually administer it … (ID12; Female, 40–49 years, remote NSW)*

*… I mean if someone's passed out in the back street or in the backyard of someone's house, I mean it is not like we're going to go and do a house call and go and assess them. So I am not really sure how … the workflow was going to, you know … (ID22; Female, 40–49 years, metropolitan QLD)*

This suggests poor understanding about the physiological signs and symptoms associated with opioid overdose (in particular unconsciousness) and the common environments in which people overdose. Several pharmacists described scenarios where they presumed that an overdosed patient would walk into their pharmacy and communicate with them about the drugs consumed. One of the key signs of opioid overdose is unconsciousness (a state that renders a person non-ambulant). Furthermore, several pharmacists believed that the naloxone down-scheduling meant that it was their role to administer naloxone within the pharmacy environment.

*…if they are going through opiate overdose, I mean what sort of condition would they be in? Like would they really be able to walk into a pharmacy and present and you know, be able to coherently discuss with you exactly what their needs are? (ID18, Male, 30–39 years, metropolitan QLD)*

*…but like you might come to the pharmacy overdosed already, so I might have to treat him or give him something to inject himself and then I might go through what is happening with him (ID10; Male, 30–39 years, metropolitan NSW)*

*What we can do is be the first response when the patient comes in, then we can save their life instantly, like the fast way… we can question the patient to see what kind of medications they have used. Like opioid and then yeah, I think the person you have to monitor the patient and ask them what have they used, because they will probably know better than us. (ID32; Female, 30–39 years, metropolitan ACT)*

### *System-level barriers*

System-level barrier relate to education and training as well as access and supply issues. Pharmacists reported a number of different avenues through which they were notified about the down-scheduling of naloxone, including through the Pharmaceutical Society of Australia, the Pharmacy Guild, the manufacturer and more generally, through "faxes". Shedding light on the general lack of awareness about naloxone and their role in dispensing this drug to the community, however, they also discussed how such notifications can be easily missed.

*I have seen the odd fax … and I mean sometimes they help, but a lot of the time they end up in the recycle bin. (ID01; Male, 20–29 years, metropolitan VIC)*

Few of the pharmacists had attended any naloxone-specific training and most seemed unaware of available resources or training. One described being aware of the Pharmaceutical Society of Australia resource, but were unable to access it as it requires Society membership.

*I only receive the training how to do the opioid substitution program from my own boss, but I haven't heard anything about naloxone actually from him. (ID07; Male, 20–29 years, metropolitan NSW)*

*I don't really know much at all. I tried to have a look at the PSA [Pharmaceutical Society of Australia] guideline for OTC naloxone, but I'm not a member of PSA, so I couldn't get the guidelines, otherwise I would have had a read of that to see what pharmacists can do. (ID13 Female, 30–39 years, regional NSW)*

Some pharmacists reported problems with naloxone being unavailable from wholesalers soon after the rescheduling decision came into effect (due to changed packaging requirements to meet regulatory requirements for an OTC product).

*when it came down to the crunch, there was just no stock … Like it had gone to the media that it had gone to S3 [schedule 3], but nobody could actually supply it. (ID06; Female, 30–39 years, metropolitan VIC)*

*… So the scheduling is one thing, but [then] supply of an appropriate product is the other, there's actually nothing we can sell a person who wants it. When the down-scheduling occurred, we did sort of prepare. We*

*bought some stock, got ready and trained ourselves and got all the protocols underway. Unfortunately, since the stock has now expired, it's gone in the bin and so we've not actually had to do that and there's been no replacement stock available (ID29; Male, 40–49 years, metropolitan ACT)*

As part of the uncertainty around access and supply, three pharmacists detailed the lack of structure around the down-scheduling. In particular, the need for standardised protocols and processes for labelling, recording and dispensing this new schedule 3 drug.

*… there were some gaps in the requirement. For a Schedule 3 medicine, you have to have enough information to allow the person to use it and that wasn't part of the original packaging, so … we added an administration guide (ID29; Male, 40–49 years, metropolitan ACT)*

*I mean, I can still remember when the morning after pill went S3 [schedule 3] and … [there was] quite a lot of information regarding … it turning S3 and I thought that was pretty well executed actually … With Naloxone, there's nothing … it was just, 'it's gone S3 guys, woohoo you can set a price for it and that's it', which is really scary when you actually think about the potential of what could go wrong. (ID 6; Female, 30–39 years, metropolitan VIC)*

A further supply issue, occurring shortly after the down-schedule to schedule 3, was the withdrawal of the pre-filled syringe naloxone product from the Australian market, which had been used in most training and education initiatives up to that point. This left only a naloxone ampoule product, which requires more steps in the process of preparing it for injecting administration.

*… it's kind of been muddled a bit for me … mini-jets [the pre-filled syringe product] were around and then they vanished and really I have no idea where it's up to now. (ID36; Male, 30–39 years, metropolitan ACT)*

### *Concerns about negative business impact*

A small number of pharmacists expressed negative views about OTC naloxone because of perceived potential impact on their business such as the need to create or expand private counselling spaces, time taken to counsel patients and the need for extra staffing. The following quotations also provide further illustration of the low confidence pharmacists expressed in relation to advising people about naloxone use.

*Yeah, time is a factor in pharmacy, because a lot of the time we are busy multi-tasking … like if the person asks for the naloxone, you might not have like all the time to tell them everything and because sometimes you are doing so many things and your head is full of other thoughts, you might miss out on certain things to tell them… (ID15; Female, 20–29 years, metropolitan NSW)*

*If I'm going to lose money and time and affect my pharmacy environment every time, I'm not going to sell it. Yeah, I'm not going to order it and I'm going to tell them, 'just see the doctor' … We counsel patients on all the medications … counselling on a blood pressure medication or on antibiotics would take like a minute to cover mainly all the questions … but something for overdosing, you have to talk about overdosing symptoms and what if I missed the overdosing symptom and how to inject it? And you are going to spend some time with maybe an overdosed patient… (ID10; Male, 30–39 years, metropolitan NSW)*

Some pharmacists also expressed concerns that OTC dispensing of naloxone might adversely influence the customer base in their pharmacies, attracting patients they deemed disorderly and unable or unwilling to pay for naloxone.

*… you are attracting some drug users into the pharmacy. I guess like from a monetary point of view, like would they pay for it if it's needed in an emergency? How much does it cost? Like who pays for it? (ID13; Female, 30–39 years, regional NSW)*

*I feel there are risk factors in attracting these types of people (ID09; Female, 40–49 years, regional NSW)*

### *Concerns about misuse*

A few pharmacists raised the issue of potential for misuse and their concerns about dispensing naloxone to people without conducting a thorough assessment. Some expressed the idea of naloxone providing a 'safety net' for people who could increase their opioid consumption without concern of death from overdose. This is often referred to in the literature as 'moral hazard' or reference to the undesirable increased utilisation of services due to the reduction in barriers to the consumer (Rattinger, Jain, Ju, & Mullins, 2008).

*…the addict, for lack of a better word… might see it as a silver bullet. Like they can take whatever they want now and then they can just inject themselves and reverse it…(ID01; Male, 20–29 years, metropolitan, VIC)*

*… some people would be concerned that people can overdose now without worrying too much about the consequences, because it's easier to get the antidote for that…I would just like to stress the importance of talking to the media and educating the people about it and giving the patients the correct information and 'we are trying to help you, we are not opening a Golden Door for you to overdose and get high and then get something to fix the problem'. (ID02; Male, 30–39 years, metropolitan VIC)*

### *Negative perceptions of the patient group*

As reflected in the above two themes, pharmacists reported many negative assumptions about PWID. Several pharmacists were reluctant to engage in OTC naloxone provision because of negative stereotypes about this group (prone to crime, violence, aggression, rudeness, impulse and so on).

*I wouldn't say I was a hundred per cent comfortable, because you really don't know who you're dealing with sometimes … I'm happy for them to come in and put their needles in the bin and get a new bag. I do try not to have any contact with them really, physical contact (ID13; Female, 30–39 years, regional NSW)*

*There is always risks involved when you are trying to get involved with these people who need naloxone, because usually it's because they've done something wrong … (ID27; Female, 30–39, metropolitan ACT)*

## Discussion

As one of the first international reports to focus on pharmacists' opinions and attitudes to providing OTC naloxone, this study has the unique advantage of being conducted in a setting where recent policy change now allows pharmacists to initiate supply of OTC naloxone with no additional training requirements or other regulatory barriers. Thus our study has provided insight into pharmacists' experience of the structural changes accompanying down-scheduling of the drug as well as personal views about naloxone and OTC provision.

Around half of the pharmacists were aware of the down-scheduling and only two (of 37) had actually provided OTC naloxone. Low rates of pharmacist naloxone provision have also been reported in the USA where some states have provisions for OTC distribution. In the USA context, it has been suggested that liability concerns, time limitations, and discomfort with discussing overdose risk with patients limit pharmacists' willingness to supply the drug (Devries, Rafie, & Polston, 2017). While Australian pharmacists did not mention concerns about liability, time limitations in a busy business and discomfort discussing overdose risk with patients were common barriers. Pharmacists expressed concerns that supplying naloxone may add too much of a time

burden to their businesses because it involves counselling and instruction. Also, among those pharmacists who misunderstood their role as a supplier and anticipated they were to administer the naloxone, this led to concerns about how tenable it would be to attend to an overdose in their business.

We are aware of online training on naloxone and opioid overdose offered by the Pharmaceutical Society of Australia, however the workshops are only available to members. We are also aware of targeted training programs for health professionals in the state of Victoria. A national response to education in this area is lacking. For example, someoverdose education and naloxone distribution programs were recently delivered to pharmacists across the United States expanding pharmacists' awareness of the opioid overdose and strengthening pharmacists' roles in public health and overdose death prevention (Devries et al., 2017; Monteiro et al., 2017).

Australian pharmacists' concerns about discussing opioid overdose risk with patients appear to be intimately connected to stigma towards people who inject drugs and opioid overdose. Some mentioned that they did not have the confidence to introduce the subject with patients who they felt could be at risk of overdose, while most described feeling reluctant to engage with PWID because of concerns about negative behaviours by the patient, including misuse of the naloxone. A few pharmacists noted that they were not sure how to broach the topic of opioid overdose with patients on prescription opioids as they felt that it may make the patients feel judged. On one level, this indicates an awareness of opioid overdose risk among a range of community members, not only PWID. However, these responses also highlight stigma associated with opioid drug use in that pharmacists did not want their prescription opioid patients to think that they were being associated with PWID.

Extensive literature documents stigmatising, negative attitudes towards PWID (Lang et al., 2013; Rose, Cama, Brener, & Treloar, 2013; van Boekel, Brouwers, van Weeghel, & Garretsen, 2013), including among health care professionals (van Boekel et al., 2013). Health professionals have been shown to have a lower regard for patients who use illicit drugs compared to patients with diseases perceived to have a more organic or biomedical aetiology (Meltzer et al., 2013). The attitudes and perceptions of a health professional when interacting with PWID has been shown to be an important determinant of the subsequent management and health outcomes of such patients (Deehan, Taylor, & Strang, 1997; Johnson, Booth, & Johnson, 2005). For example, pharmacists' attitudes and practices can influence the provision of needles/syringes, opioid substitution treatment, counselling, and dissemination of blood-borne virus prevention and other health promotion materials to PWID (Chaar et al., 2013; Matheson, Bond, & Tinelli, 2007). Optimal health outcomes depend on healthcare workers being accessible, non-judgemental and willing to intervene.

Community pharmacies are a major point of opioid substitution treatment delivery in Australia as well as distribution for clean injecting equipment. Around half of the pharmacists interviewed for this study provided harm reduction services in their pharmacy including needle and syringe program (n = 20) and/or opioid substitution therapy (n = 23). Community pharmacies are located generally at convenient sites and provide an opportunity for drug-related harm reduction service delivery outside of specialist drug treatment services. However, as reflected in the responses of many of those interviewed for this study, community pharmacists do not always embrace the provision of services to PWID (Matheson, Bond, & Mollison, 1999; Winstock, Lea, & Sheridan, 2010).

Limited knowledge and skills about drug-related issues has been shown to be linked to negative attitudes to PWID (Chang & Yang, 2013; Kelleher & Cotter, 2009; Lang et al., 2013; O'Brien & Cullen, 2011). Efforts are needed to better communicate to pharmacists the evidence around drug use and harm reduction, in particular the ways in which health services can be delivered in a respectful and non-discriminatory manner in order to contribute to harm reduction without encouraging drug use. This highlights an important challenge for the pharmacy profession to upskill in these areas to enable the more effective provision of life-saving treatments such as naloxone. Recent research reviewing content of naloxone training for pharmacists has highlighted the importance of educating pharmacists on *how* to communicate about naloxone with patients (Carpenter et al., 2017). Including training on how to communicate on these sensitive issues may be one way improve naloxone delivery in pharmacy practice.

Limited knowledge about naloxone and its application with PWID was also apparent in pharmacists' responses. There were expressions of concern around individuals potentially using naloxone as a means of taking greater risks around dosing with opioids. The concern regarding 'moral hazard' showed a misunderstanding both of the effects of naloxone and its administration. Individuals experiencing overdose do not typically self-administer naloxone; they are reliant on emergency service providers, friends, family or witnesses with access to naloxone to administer the drug. Furthermore, there is little evidence to suggest that naloxone availability gives rise to 'moral hazard' (McDonald & Strang, 2016; Olsen, McDonald, Lenton, & Dietze, 2018). We are aware of one study where a small number of people report increased opioid consumption with access to naloxone (Heavey et al., 2018).

It is worth noting that many of the issues identified in this study mirror the barriers to needle and syringe provision in pharmacies. Barriers such as time limitations, policies and laws and stigma and discrimination limit pharmacists' willingness to supply the injecting equipment from their businesses (Hammett et al., 2014; McVeigh, Hearne, Bates, & Van Hout, 2017; Treloar, Hopwood, & Bryant, 2010). As needle and syringe provision in pharmacies has an established history in Australia, experiences and opportunities from this harm reduction initiative could provide useful strategies for boosting the success of naloxone provision.

It is also the case that OTC naloxone is needed beyond the community of PWID. Increasing prescription opioid use and related harms means that there has been a shift towards opioid-related mortality attributed to pharmaceutical opioids rather than heroin. Opioid overdose is at record levels in Australia; pharmaceutical opioid deaths now exceed heroin deaths (Roxburgh et al., 2017). In 2014 almost 3 million Australians were prescribed at least one opioid under the Pharmaceutical Benefits Scheme (PBS) or Repatriation PBS (RPBS) (Therapeutic Goods Administration, 2018), and opioid utilisation in Australia increased almost four-fold between 1990 and 2014 (Karanges, Blanch, Buckley, & Pearson, 2016). There is accumulating evidence for engaging health care providers who prescribe and dispense pain medication in delivering overdose prevention and naloxone (Coffin et al., 2016; Walley et al., 2013). Pharmacies should be central to provision of overdose information and naloxone because they are the most common community-based health facilities, dispense opioids regularly, and have longer hours of operation than many other health care facilities.

In order to achieve widespread OTC of naloxone however, it is clear from this study that pharmacists not only need education about naloxone, but also opioid overdose. Several pharmacists we interviewed described identifying and treating overdose patients only if they walked into the pharmacy. One of the key signs of opioid overdose is unconsciousness (a state that renders a person non-ambulant). A range of resources on naloxone and opioid overdose have been developed in Australia (The Pennington Institute, 2018), however, these do not appear to be utilised as a source of information by pharmacists.

Much of the research on community naloxone provision has focused on individual level knowledge acquisition, including among people at risk of overdose (Ashrafioun, Gamble, Herrmann, & Baciewicz, 2016; Dietze et al., 2018; Strang et al., 2008), family and friends of those at risk of overdose (Williams, Marsden, & Strang, 2014), and health care providers (Beletsky et al., 2007; Nielsen et al., 2016). While it is clear that basic knowledge of opioid overdose and naloxone administration aids in the successful reversal of opioid overdose in the community, system level issues such as stock shortages and company product

labelling requirements can create insurmountable barriers for the individual. As part of the uncertainty about access and supply, the down-scheduling of the drug was not accompanied by standardised protocols and processes for labelling, recording and dispensing. This was in part because the product sponsor was not involved in the rescheduling process and did not support the changes required in packaging for OTC use or ongoing supply (Pricolo & Nielsen, 2018). The product sponsor withdrew their supply from the Australian market and thus, the pre-filled naloxone product which had been used in most training and education initiatives up to that point was no longer available (Lenton et al., 2016). This disruption of supply of pre-filled syringe products meant that the only available product for the Australian market was naloxone ampoules. Ampoule stock available in Australia is not packaged per schedule 3 guidelines meaning that individual pharmacies are required to change the labelling and instruction manual, and some jurisdiction regulations did not allow pharmacists to do this. Universal labelling, recording and dispensing procedures for naloxone are not readily available for pharmacists and their confusion about this product is reflected in the interviews.

Furthermore, it is apparent from these data that the public are not requesting naloxone from pharmacies. The reasons for this could include a lack of knowledge (i.e the public are unaware that naloxone is available at pharmacies or unaware of naloxone more generally) as well as issues related to fear of stigma (detailed above). In addition to education and training for pharmacists, public education about the drug and its availability would enhance the effectiveness of this public health intervention.

Australian laws and policies currently allow for naloxone distribution OTC, yet the policies and practices that would facilitate the routine dispensing of naloxone OTC do not exist. Laws and policies are only as good as their implementation and political attention is needed at this macro-level. One system-level strategy is academic detailing in which the pharmaceutical industry provides non-commercial outreach education for health care professionals based on research evidence. Academic detailing has been shown to increase naloxone prescribing in the USA (Bounthavong et al., 2017). A universal precautions approach, similar to that proposed for prescribing analgesics, is another strategy that would systematise the identification of overdose risk (Gourlay, Heit, & Almahrezi, 2005). Here the aim is to identify those at risk of overdose and routinely provide education and naloxone.

At the national policy level Scotland has developed a national naloxone delivery program where training and distribution is coordinated across multiple community outlets (drug user organisations, drug treatment services, pharmacists, etc) in order to maximise the reach of these initiatives (National Health Services, 2018). The Naloxone National Reference Group, a coalition of Australian institutes and agencies, is exploring a national program to enhance implementation (Centre for Research Excellence into Injecting Drug Use, 2014). Such large-scale initiatives not only optimise patient access but can reduce the stigma associated with focussing on specific population groups (i.e PWID).

OTC naloxone provided at pharmacies has the potential to reduce overdose mortality, yet our study suggests this opportunity is yet to be realised. Overall, a considerable amount of advocacy will be needed if pharmacies are to reach their potential as venues for delivering opioid overdose services (Hammett et al., 2014). We identified challenges to achieving a truly enabling environment for OTC naloxone provision both at the individual level and the system level. Strategies to improve pharmacists' knowledge of OTC naloxone (e.g., via training) and to address other logistical and cultural barriers (such as information, regulation and supply and stigma) are needed to address barriers to naloxone provision in pharmacies. Our findings indicate considerable scope to improve knowledge and reduce stigma. We hope this will spur the professional pharmacy organisations in Australia and internationally to advocate for strategies to tackle the numerous identified barriers. With improved training opportunities and reduction of system-level barriers, there is the potential for community pharmacy to contribute to much needed reductions in opioid-related mortality.

## Conflicts of interest

SN is a named investigator on untied education grants from Indivior. The authors have no conflicts of interest to declare.

## Acknowledgements

This research was funded in part through an untied education grant from Indivior, and funding from the University of Queensland and Australian National University. We thank the pharmacists in this study for their participation. SN is the recipient of an NHMRC Research Fellowship (#1132433).

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