

## Original Research

# Exploring Australian pharmacists' perceptions and attitudes toward codeine up-scheduling from over-the-counter to prescription only

Melanie MCKENZIE , Jacinta L. JOHNSON , Karen ANDERSON , Richard SUMMERS ,  
Pene WOOD 

Received (first version): 6-Apr-2020

Accepted: 31-May-2020

Published online: 1-Jun-2020

### Abstract

**Objective:** Explore the perceptions, attitudes and experiences of pharmacists relating to the up-scheduling of low dose codeine containing analgesics and the impact on pharmacy practice.

**Methods:** A mixed design method was used consisting of an anonymous online questionnaire survey to quantitatively capture broad pre-scheduling change perceptions paired with a series of in-depth post-scheduling semi-structured interviews to provide a qualitative picture of the impact of codeine up-scheduling on pharmacy practice in Australia.

**Results:** A total of 191 pharmacists completed the quantitative survey and 10 participated in the in-depth interview. The majority of respondents supported the decision to up-schedule over-the-counter combination products containing codeine to some degree. Three main themes emerged from the data: pharmacists' perceptions of the codeine up-scheduling decision, preparing for the up-schedule and impact of the up-schedule on pharmacy practice. Pharmacists were concerned about the impact of up-scheduling on the pharmacy business, patient access to pain relief and the diminishment of their professional role.

**Conclusions:** There were diverse perceptions, preparedness and impact on practice regarding the up-scheduling of low dose codeine products. Further research should be conducted to gauge if and how these perceptions have changed over time and to identify whether pain is being managed more effectively post codeine up-scheduling.

### Keywords

Analgesics; Codeine; Nonprescription Drugs; Pharmacies; Pharmacists; Professional Role; Attitude of Health Personnel; Health Knowledge, Attitudes, Practice; Surveys and Questionnaires; Qualitative Research; Australia

## INTRODUCTION

Excessive use of codeine containing analgesics can result in codeine dependence and life-threatening adverse effects, often due to ingestion of supratherapeutic doses of ibuprofen or paracetamol present in combination products.<sup>1-6</sup> As such, regulatory controls are required to assist in minimising codeine-related harm. Regulations dictating codeine accessibility differ around the world. Codeine containing analgesics are readily available over-the-counter without a prescription in several countries including the United Kingdom, South Africa and Ireland.<sup>7</sup> In other countries such as Austria, France, Germany and the United States, codeine is only available on prescription.<sup>8</sup> In those countries with fewer restrictions, there is greater potential for codeine misuse, as these products are easily accessible by the general population.<sup>7</sup>

In Australia codeine-containing analgesics were up-scheduled from 'Pharmacy Only Medicines', available over-the-counter in pharmacies without pharmacist involvement to 'Pharmacist Only Medicines', requiring pharmacist input in the sale in 2010, due to increasing concern regarding inappropriate use. At this time pack sizes for low dose (up to 15 mg) codeine containing analgesics were also restricted from up to 100 tablets to a maximum of 50 tablets in an attempt to minimise harm.<sup>1</sup>

These regulatory measures were evaluated in a number of ways. A qualitative study confirmed up-scheduling achieved one aim, in that pharmacists became more aware of those who were misusing codeine, through monitoring frequency of supply.<sup>9</sup> However, pharmacists still described some difficulties relating to their capacity to have challenging conversations in a busy pharmacy setting, establishing appropriate therapeutic need, not being able to monitor supply from other pharmacies and a lack of knowledge of appropriate referral pathways for pain and dependency issues.<sup>9</sup>

Despite the 2010 scheduling change, concerns surrounding harm associated with over-the-counter codeine persisted. In 2016 the Australian National Drug Strategy Household Survey established that 75% of people who had misused pharmaceuticals had used over-the-counter codeine, an increase from 33% reporting such use in 2013.<sup>10,11</sup> Similarly, calls to an Australian poisons centre regarding codeine misuse increased from 2004-2015, with no change in call trends post 2010, and the proportion of people seeking opioid substitution therapy for codeine dependence

**Melanie MCKENZIE.** Department of Pharmacy and Biomedical Science, College of Science, Health & Engineering, La Trobe University. Bendigo, VIC (Australia). melaniemckenzie97@gmail.com  
**Jacinta Lee JOHNSON.** School of Pharmacy and Medical Sciences, University of South Australia. Adelaide, SA (Australia). Jacinta.Johnson@unisa.edu.au  
**Karen ANDERSON.** Rural Department of Community Health, La Trobe Rural Health School. Bendigo, VIC (Australia). k.anderson@latrobe.edu.au  
**Richard SUMMERS.** Department of Pharmacy and Biomedical Science, College of Science, Health & Engineering, La Trobe University. Bendigo, Vic (Australia). r.summers@latrobe.edu.au  
**Pene WOOD.** Department of Pharmacy and Biomedical Science, College of Science, Health & Engineering, La Trobe University. Bendigo, Vic (Australia). p.wood@latrobe.edu.au

continued to climb, increasing from 2.7% in 2014 to 4.6% in 2016.<sup>12,13</sup> Subsequently, the Australian Therapeutic Goods Administration (TGA) determined the risk of potential harm outweighed the likely benefit gained from over-the-counter access to low-dose codeine-containing products, and in December 2016, announced the decision to further up-schedule codeine containing analgesics to become Prescription Only Medicines from February 2018.<sup>13,14</sup>

Review of pharmacy-based medications and regulation changes such as this are important for the continued safe and effective practice of pharmacists and to maintain the confidence people have in their pharmacist. Chan and Tran showed this in their study looking at what pharmacy customers value and expect from their pharmacy. They found that pharmacy customers expect the pharmacy/pharmacist to provide trusted and factual information and be a knowledgeable resource in providing safe products.<sup>15</sup>

When medication-scheduling changes, it is important to assess the impact of the change to ensure the regulation achieves intended outcomes. There have been some limited studies emerging investigating the impact post up-scheduling of codeine containing analgesics in Australia in 2018 but as the majority of these studies were quantitative in nature it did not allow for exploration of reasons behind the opinions of some pharmacists. Using a mixed-method design, this study aimed to explore in more depth some of the perceptions, attitudes and experiences of pharmacists in Victoria and South Australia relating to the 2018 up-scheduling of low dose codeine analgesics to prescription only. In particular this study explores the impact of up-scheduling on pharmacy practice.

## METHODS

A mixed design, consisting of an anonymous online survey to quantitatively capture broad pre-scheduling change perceptions was paired with a series of in-depth post-scheduling change semi-structured interviews completed during 2018, just post the up-schedule. to provide a qualitative picture of the impact of codeine up-scheduling on pharmacy practice in Australia.

### Quantitative survey prior to codeine-scheduling change

An 18-item survey was piloted with a convenience sample of 16 pharmacy staff and reviewed by an independent researcher with experience in survey development to minimise question bias. Subsequently, the survey was amended to include an additional 2 items, yielding a final 20-item survey. The final survey included two sections, the first included items regarding participant demographics, role and practice setting; knowledge, attitude and preparation regarding the codeine scheduling change; and participant education preferences. The second section assessed knowledge regarding over-the-counter analgesic dosing and perceived efficacy and safety of specific codeine containing analgesic products. The results of the second section of the survey are beyond the scope of this project.

A convenience sample of pharmacists practicing within Australia was recruited over a 6-month period in late 2017 using the snowball method via social media, pharmacy

organisation newsletters and investigators' networks. All pharmacists registered within Australia were eligible to participate. Pharmacists were provided with written information regarding the purpose of the study and the duration of the survey. Consent was implied through completion of the survey, which was available online (via the University of South Australia survey platform 'TellUs 2') or in print with return via reply paid mail. A subset of survey response data, including the questions relevant to codeine up-scheduling specifically are presented here. Pharmacists who completed the survey are referred to as respondents when presenting results. Data were summarised using quantitative descriptive statistics (Microsoft Excel® for Mac, Version 14.6.9).

### Qualitative interviews post codeine-scheduling change

A semi-structured interview schedule consisting of open-ended questions was derived from current literature and the pre up-scheduling survey data. Purposive sample was used to recruit community pharmacists practicing in either Victoria (VIC) or South Australia (SA). Community pharmacists were the focus for this component of the study as they are most likely to be impacted by the scheduling change. A random number generator was used to select ten community pharmacies from the state-wide pharmacy listings supplied by the Victorian Pharmacy Authority and the Pharmacy Regulation Authority South Australia website. Pharmacies were contacted via telephone and invited to participate in semi-structured telephone interviews if the pharmacist was a registered pharmacist practicing in SA or VIC and was practicing in community pharmacy for the last 12 months. If eligible, they were forwarded the participant information consent form and given a week to consider participating. A follow up telephone call was made to determine the outcome. Due to resource constraints this process was repeated until five pharmacists agreed to participate each from SA and VIC, or until data saturation was reached. Once the signed consent form was returned, the semi-structured interview was conducted over the telephone and audio recorded. Ten over the phone semi-structured interviews were conducted, lasting between 10 and 20 minutes. Interviews were transcribed verbatim and then open coded by two researchers using NVivo.<sup>16</sup> Initial codes generated by the two researchers were compared and refined. Code were then sorted and analysed for themes and sub-themes.

### Ethics

Ethics approval for this project was granted by the University of South Australia Human Research Ethics Committee (HREC 0000036702) and the Science, Health & Engineering College Human Ethics Sub-Committee of La Trobe University (HEC18153).

## RESULTS

### Quantitative survey prior to codeine-scheduling change

A total of 191 pharmacists completed the quantitative survey between March and September 2017, of these 5 were excluded as they were practicing outside of Australia, yielding 186 responses for analysis. Percentage responses were calculated based on the total response for each

Table 1. Demographic summary of quantitative questionnaire respondents and qualitative interview pharmacists		
Characteristic	Questionnaire respondents n (%)	Interview pharmacists n (%)
Gender		
Male	NA	4 (40)
Female	NA	6 (60)
Years of practice		
0 - 5 years	61 (33)	2 (20)
6 – 10 Years	46 (25)	5 (50)
11-15 Years	20 (11)	1 (10)
>15 Years	59 (32)	2 (20)
State of practice		
South Australia	59 (32)	5 (50)
Victoria	37 (20)	5 (50)
Other states	90 (48)	0 (0)
Location of practice		
Metropolitan and inner regional	121 (65)	6 (60)
Outer regional, rural and remote	65 (35)	4 (40)

individual question to accommodate for missing data. Most respondents were practicing in community (n=136, 73%), with a smaller proportion practicing in hospital (n=40, 22%) or other settings (n=25, 13%) (respondents could select multiple practice settings). Pharmacists reported working in their current role for an average of 14 years (SD 13 years). The majority of respondents (n=121, 65%) were practicing in metropolitan or inner regional areas. See Table 1 for a summary of respondent demographics.

The majority of respondents (n=146, 78.5%) supported the decision to up-schedule over-the-counter combination products containing codeine to some degree, with 28.5% (n=53) indicating they strongly supported the decision. Eighteen percent of respondents (n=34) did not support the up-scheduling decision.

A significant proportion of pharmacists rated their own perceived efficacy of over-the-counter combination products containing codeine in managing acute nociceptive pain as high, scoring such products 8, 9 or 10, on a scale from 1 indicating 'not effective' to 10 indicating the product was 'extremely effective'. For a dose of paracetamol 1000 mg / codeine 30 mg, 47% of pharmacists (n=87) rated perceived efficacy in acute nociceptive pain as 8/10 or greater, and for ibuprofen 400 mg / codeine 25.6 mg, 42% of pharmacists rated perceived efficacy as 8/10 or greater (n=79).

Most survey respondents (n=108, 59%) reported they were confident or extremely confident in providing pain management solutions for their patients after over-the-counter combination products containing codeine change to prescription only. Despite confidence in providing pain management solutions, many respondents did not have a clear understanding of the processes involved with referring patients to the nearest multidisciplinary pain management clinic. Forty one percent of respondents (n=77) reported they were 'not sure of the referral process', whilst only 19% (n=35) reported a good or excellent understanding of the process.

At the time of survey completion, 64% (n=119) of respondents had not taken any specific steps to prepare themselves for the scheduling change. The remainder of respondents indicated they had undertaken educational activities to prepare for codeine up-scheduling. Educational activities completed by those that had taken specific steps

to prepare included; attending Pharmaceutical Society of Australia workshops and conference sessions, reading journal articles and newsletter from professional bodies, undertaking pain management courses, reviewing the Therapeutic Goods Administration website, and completing other relevant online modules.

Survey respondents were asked if and how they were working to prepare their patients prior to the up-scheduling of codeine. The majority of pharmacists (n=125, 67%) reported they were informing their patients of the pending changes verbally, with a smaller proportion (n=25, 13%) reporting using written information (leaflets, posters) to provide patients with information around codeine up-scheduling.

#### Qualitative interviews post codeine-scheduling change

For the qualitative component of this study a total of 10 community pharmacists were interviewed, with five practicing in Victoria and five in South Australia. Participant demographics are presented in Table 1. Three main themes emerged from the data: pharmacists' perceptions of the codeine up-scheduling decision, preparing for the up-schedule and impact of the up-schedule on pharmacy practice. These themes are discussed in detail below.

##### 1. Pharmacists' perceptions of the codeine up-schedule

Pharmacists expressed varying opinions regarding the decision to up-schedule codeine, with some pharmacists for the change, others against; and some unsure. Some of the reasons that pharmacists were against the up-schedule included limiting patient access to pain relief, the unaddressed risk of patients doctor shopping, removal of pharmacists' professional judgment and concerns about potential impact on business. Some pharmacists were positive about the up-schedule as they believed it would be beneficial to patients and would ensure therapeutic need is confirmed.

##### 1.1 Negative perceptions of the up-schedule

Some pharmacists indicated they felt the up-schedule was not warranted and could have been avoided if there was real time prescription monitoring and mandatory recording of codeine sales through a real-time monitoring program. They indicated that this was "a really good tool to refer people" and provided the opportunity "to liaise better with

other medical professions" (Participant 8), and further from Participant 4 "I think my stance was that it should be mandatory to record the codeine product on MedsAssist [a real-time monitoring tool] because I've worked as a locum at many pharmacies that don't record it at all, they just wave off those who were misusers of codeine for sure but I think making it mandatory was another option that they should have gone with".

Some pharmacists indicated they do not believe the codeine up-schedule will be effective in reducing misuse or increasing identification of those who may be misusing or dependent on codeine containing products. Participant 8 stated he believes that "it's just sort of passing the buck really" and that real-time monitoring is the key in allowing pharmacists to monitor codeine misuse effectively.

Furthermore, Participant 2 believes that the up-schedule is a negative change for both pharmacists, as it limits opportunity for pharmacists to use professional judgement, and patients as it will limit the patient's ability to treat their pain effectively, as a result of having limited access to GPs in a rural environment:

"I don't think it's a good thing, to tell you the truth. It's limiting access to people who genuinely need it...it's also small regional communities and difficulties in accessing doctors to get scripts for these items...I think it's a step backward, and the relationship between pharmacists and the community in the country is a lot closer than the larger communities in the city. You know where you have a lot of anonymous people coming into the pharmacy, so to me overall I think it's a negative thing for patients and for the pharmacist [be]cause it removes another aspect of how we can help people using our professional judgment. Just that our judgment has been taken away now" (Participant 2).

Pharmacists indicated that the impact of up-scheduling on the pharmacy business was of concern. There were fears about a decrease in sales, loss of business and the corresponding impact on the business financially. Some pharmacists indicated that there has been a "decrease in sales" (Participant 5) and that the up-schedule has "cost us a lot of money" (Participant 9).

Even if pharmacists were not in support, they could still see the rationale for the change "I understood why they were doing it. I think the, like the evidence for low dose codeine was never all that great" (Participant 8).

### 1.2 Positive perceptions of the up-schedule

Some pharmacists stated that the up-schedule was useful as "there was a lot of misuse of medication" (Participant 7) and therefore it "took a lot of pressure" (Participant 9) off the pharmacist, in regard to determining whether the product was appropriate and whether to supply it. Pharmacists indicated codeine up-scheduling is beneficial for patients as it forces them to discuss pain management with the GP to develop an effective pain management plan. However, there are concerns that the up-schedule may lead to patients visiting multiple GP's to obtain prescriptions for opioid analgesics (also known as "doctor

shopping"), which at the time of the up-schedule was not being monitored.

Some pharmacists expressed that despite the potential impact on their business, the up-schedule had merit and could reduce the misuse of codeine as patients would be required to consult with their GP:

"I was a little bit disappointed because I knew there was gonna[sic] be a decrease in sales so from a business point of view, it was disappointing. But from an ethical point of view, I could see the merit of it [be]cause we would have you know regular people coming in, yes my doctor knows about it, yes I talk to him about it so it was actually nice to be able to put it in the doctors ball park." (Participant 5).

### 2. Preparing for the codeine up-schedule

When discussing preparation for the up-schedule, pharmacists discussed how they prepared themselves and how patients were prepared by pharmacists and more broadly, they also discussed the mixed reactions from patients to the proposed change.

#### 2.1 Pharmacist preparation

There was a perception amongst some pharmacists that no training was required in the lead up to the up-scheduling of codeine "when you been put on the spot in community pharmacy you got to deal with all of the customers, how much training can you even get to do with that" (Participant 1). Despite this, most pharmacists talked about information regarding the change coming from professional associations like the Pharmaceutical Society of Australia (PSA) and the Pharmacy Guild of Australia. Manufacturers also provided information. This information and education consisted of information booklets, online modules and professional development activities "there were lots of manufacturers' stuff coming through...emails, not emails, faxes and things coming about the change but also the PSA had a module that we all did in regards to what was happening" (Participant 5). Some pharmacists undertook additional pain management courses and received specific information from their pharmacy banner group head office. Overall, all pharmacists that had received education and training indicated the level of education and training provided was adequate in preparing them for the up-schedule.

#### 2.2 Patient Preparation and response to up-schedule

A variety of strategies were used to inform patients about the up-schedule, these included advertising and signage in the pharmacy and talking to patients. Media advertising was also expressed as being helpful for preparing patients:

"leading up to it we had signage saying that things were changing...but also all the media hype was you know getting to people as well. So, I suppose people were well informed either by us or by the media, but we did see an increased amount of requests leading up to the 1st of February" (Participant 5).

When pharmacists were asked about patient reactions to the decision to up-schedule, there were mixed responses,

with some patients very accepting of the change and others less accepting. "I think most of them were, were pretty like, a few people were annoyed with it... but most people were pretty, pretty receptive to it and that, and I suppose that, they sort of understood more why we were, had been recording previously" (Participant 8). How pharmacists framed the message to patients varied, with pharmacists often removing themselves from the decision making, with one participant stating "we just tell them, this is the decision taken by the TGA, and supported by AMA [Australian Medical Association] so they probably need to go back to talk to their GP" (Participant 4).

Pharmacists believe that preparing patients early reduced the amount of hostility that was received once the up-schedule was implemented. "We kind of expected that we'd get a bit of backlash but we didn't really, yeah most people were quite okay with it" (Participant 10). "Like I know this is gonna[sic] sound cliché but we didn't really have anyone abusing or being irritated like it was quite well documented" (Participant 8). Despite this, some pharmacists reported there were a few annoyed patients, whom perceived the up-schedule to indicate "...the government thinks they can control everything and that kind of general thing" (Participant 9).

One pharmacist indicated that some patients were not happy as they were no longer able to manage their own pain "Mmmm were not happy. They weren't able to manage their own pain by themselves ...by sending it to prescription only means that I get patients now who just are in pain and can't have anything that they think is controlling their pain over-the-counter" (Participant 4). Some pharmacists took this as an opportunity to discuss with patients alternative options "So what we did when we were informing the customers of the change was that "hey, just so you know there's gonna[sic] be up-schedule, its gonna[sic] be on a script, you can't access it over-the-counter anymore" and they get "Oh no! What will I do"? Well look, you need to get your pain management looked at anyway, be reviewed anyway. So, I recommend you go and see a doctor, find a GP, you know. Really find out, come up with a plan and actually when you tell them that way, when you give them a plan, they felt a little bit more settled, they're not so stressed and it was more assuring for them that you know it's not taken off the market" (Participant 1).

### 3. Impact of up-schedule on pharmacy practice

When asked about the impact the up-schedule has had on pharmacy practice, pharmacists discussed themes such as how they were managing codeine prior to the up-schedule including the storage, recording mechanisms and their role in determining therapeutic need. They also discussed the positive impacts the up-schedule has had on practice as well as some of the challenges.

#### 3.1 Management of codeine requests and supply pre up-schedule

Most pharmacies took a similar approach when managing over-the-counter codeine containing product requests prior to the implementation of the up-schedule. Interviewed pharmacists reported codeine-containing products, including analgesics and cough and cold preparations, were

kept near the dispensary, within the professional services area as per legislative requirements in Australia. For patients to access these products, they were required to undergo a "pharmacist consult" (Participant 3), where the pharmacist is legally required to conduct "individual assessments" (Participant 2) to determine whether there is a therapeutic need. Some pharmacists also indicated that pharmacy assistants would occasionally ask some of the assessment questions such as "Who is it for, what's it for, how long have you had it" (Participant 1) and then refer onto the pharmacist to make the final decision.

All pharmacists in this study stated they recorded sales, either through the real time monitoring program (MedsAssist) or on their dispensing software, to monitor frequency of purchase and identify potential misuse. Despite this, Participant 4 indicated he had previously worked in pharmacies where using the MedsAssist program was not mandatory. "... I've worked as a locum at many pharmacies that don't record it at all, they just wave off those who were misusers of codeine for sure". In addition, Participant 1 stated their pharmacy also used the "What Stop" protocol to "assess and determine whether they would supply it". Despite using these methods to manage codeine requests, Participant 1 also indicated:

"...it was really hard to wean out the ones who really needed it. It was really hard to identify the ones who yeah who are abusing it as well".

A few pharmacists noted there was an increase in the number of requests for codeine containing products just prior to the up-schedule in anticipation that patients would find it difficult to access their GP, to obtain a prescription once it was made prescription only.

"We did see an increased amount of requests leading up to the 1st of February. You know because they knew things were changing" (Participant 5).

In situations where pharmacists suspected potential misuse of codeine containing products they would refuse supply and suggest a suitable alternative or refer the patient to their GP to discuss how to manage their pain effectively:

"...I suppose there were requests where it wasn't warranted but then that was looked at case by case as to you know, what we did with that person, whether we referred them on or we did supply it...and just referring them back to the doctor to speak about that, codeine and whether there's an alternative to the analgesic they're using." (Participant 5).

#### 3.2 Benefits to practice

Pharmacists identified that they thought the up-schedule would have an impact on their practice. However, this has not been the reality for many pharmacists. Most have not seen an increase in GPs prescribing stronger pain relief, and the volume of prescriptions for low dose combination codeine has reduced.

"... the number of scripts for codeine have dropped. Even like the over-the-counter strengths,

it's nowhere near as many as how many we were getting walking in" (Participant 6).

One participant did report that they had seen an increase in GPs prescribing products such as Panadeine Forte®.

"There's increase in the Panadeine Forte® prescriptions...I recommended one patient to have Panadeine Extra® at one point of time and he came back with a 240 tablet script from the doctor, so I don't know what to say about that" (Participant 4).

Some pharmacists believe that changes in prescribing patterns may be because many patients were not visiting their GP to have their pain management reviewed, and doctors may be being more vigilant when prescribing codeine combination products, "I think based on the scripts I've seen, it hasn't really changed very much. It hasn't pushed them to prescribe them any stronger" (Participant 1).

Since the up-schedule came into effect, pharmacists reported that recommending pain management alternatives has become easier "it's probably made it easier to recommend better products for migraines and yeah obviously referral to a doctor too...I haven't found it difficult to recommend different products from codeine... [be]cause yeah as I said the evidence just wasn't there for them anyway really" (Participant 8). There was concern expressed that as a result of the up-schedule and pharmacists recommending pharmaceutical alternatives that some patients may misuse these and experience negative side effects "...concern now is everybody's gonna[sic] end up with stomach ulcers cause they're using the anti-inflammatories, diclofenac and stuff now" (Participant 3). Recommending non-pharmaceutical therapies such as heat packs, cold packs, transcutaneous electrical nerve stimulation (TENS) machines and referral to a physiotherapist was now also common practice among pharmacists. Participant 6 expressed the importance of counselling patients, and the need to inform patients these products will not necessarily mean that they "...will be pain free but getting the pain to a level where they can manage it" and "that it might be unrealistic to expect to be completely pain free".

Pharmacists communicated that the up-schedule was generally useful in encouraging patients to visit their GP and discuss how to effectively manage their pain. Participant 7 expressed "pain is actually managed I guess more appropriately" and that consultation with the GP provides the option to trial new things. "I'd say that yeah pain is obviously managed better potentially in different ways now". Pharmacists also believed that "a lot of people, like obviously were just using it as it's easily accessible and their underlying pain was never actually managed by the doctor".

### 3.3 Challenges for practice

Pharmacists discussed a number of challenges post up-schedule. These include limited ability to assist people with short-term pain, concerns about side-effects and misuse of alternatives and they also discussed the challenges of identifying misuse; something that was also seen as a challenge prior to the up-schedule. Pharmacists discussed

that the recent up-schedule had limited their ability to assist people with severe or short-term pain. Participant 10 stated that "there's been just a few cases where people have come in and it's been difficult to give them any pain relief cause they might not be able to take anti-inflammatories and they've tried Panadol® [paracetamol] and you know sometimes it just leaves us a little bit limited, but those cases are not very common".

An additional challenge experienced by pharmacists has been the supply of codeine products, with some pharmacists reporting that there were wholesale supply issues when codeine was first up-scheduled "...even when someone had a script, they couldn't necessarily get the product" (Participant 8). Supply issues were also a challenge prior to the up-schedule and are linked to patients negative reactions to the up-schedule, "well initially people were annoyed and they were also annoyed because I think mid-January a lot of the manufacturers weren't able to supply as well, even though it was still S3, we couldn't supply it because there was no stock. So that was frustrating for people" (Participant 5).

A further challenge expressed by pharmacists was that of identifying people misusing codeine. Identifying misuse was identified as a challenge both pre and post up-schedule. While a few were confident if patients were regular customers or there were obvious signs such as "...from their behaviour, they tend to over describe what they need it for" (Participant 9), a number of pharmacists indicated it could be difficult, but that there was an opportunity to refer patients back to the GP "a bit of a difficult one, it's hard to distinguish people that are, have a genuine need for it and those that, might be misusing it, but yeah it's a really difficult area" (Participant 10). Pharmacists indicated if they suspected someone was misusing or dependent on codeine products, they would refer them to their doctor for assessment. "It's certainly referral back to the doctor or it you've got a patient, getting large amounts through prescription, obviously your first point of call is to contact the prescriber" (Participant 8). There was recognition from one participant that the up-schedule had made it more difficult to identify misuse of codeine, as they may no longer be the patients "first point of call" (Participant 9).

## DISCUSSION

There are numerous studies emerging investigating the impact and changes seen post up-scheduling of codeine containing analgesics in Australia in 2018, from being available without a prescription over-the-counter in pharmacies to only being available on a prescription. As the majority of these studies are quantitative in nature this study aimed to explore in more depth some of the perceptions and experiences of Pharmacists in Victoria and South Australia. Using both quantitative and qualitative data from pre and post the up-schedule it was identified that pharmacists had varying perceptions about the changes, what they did to prepare and the impacts they felt it had or would have on their practice.

Some pharmacists in this study expressed a negative perception towards the up-schedule as they believed it would limit their patients' ability to access effective pain relief. They suggested it may be difficult for patients to visit

their doctor to obtain a prescription. Disadvantages similar to this were identified by Mishriky *et al.* and McCoy *et al.* including fewer analgesic options, and increased burden for patients, General Practitioners, and the health system.<sup>17,18</sup>

However, evidence from an overview of Cochrane reviews of non-prescription (over-the-counter) oral analgesics for acute pain disputes the notion low dose codeine provides more effective pain relief than other readily available alternatives.<sup>19</sup> They identified combinations of ibuprofen plus paracetamol worked in 7 out of 10 people, and fast acting ibuprofen formulations 200 mg and 400mg, ibuprofen 200 mg plus caffeine 100 mg, and diclofenac potassium 50 mg worked in over 5 out of 10 people. Paracetamol plus aspirin at various doses worked in 1 out of to 4 out of 10 people and they found no information on many of the commonly available combinations containing low doses of codeine. Most of these alternative medicines are available in a pharmacy without a prescription.

Although there were concerns that pharmacists would not be able to provide options for managing pain without access to codeine containing analgesics over-the-counter, there were mixed views both within this study and from other research about the perceived efficacy of analgesics containing codeine thus their benefit as an analgesic option. Prior to the up-schedule the quantitative questionnaire used in this study identified that a significant proportion of pharmacists rated the perceived efficacy of over-the-counter combination products containing codeine as high. Post the up-schedule pharmacists in the qualitative interviews indicated that the evidence for low dose codeine is weak and that low doses of codeine (8 mg & 15 mg) are not considered effective doses to provide an adequate therapeutic effect. This was re-iterated by Mishriky *et al.*<sup>17</sup> This may reflect increased education and awareness around the efficacy of codeine provided during the up-schedule process.

Many pharmacists in this study understood the reasons behind the up-scheduling of codeine containing analgesics, in particular the increasing rates of misuse and related harm from these products. However, they did not believe this was the most effective way to address codeine misuse, this has also been identified as a theme by other studies.<sup>17,18</sup> The Mishriky *et al.* study identified that pharmacists felt the up-scheduling of codeine did not solve the wider codeine misuse issue as patients have simply gone from “pharmacist shopping” to “doctor-shopping”, and escalation to inappropriate use of other medicines or stronger opioids.<sup>17</sup> This was not the findings of the current study in which pharmacists felt that despite concerns before up-scheduling, sales of over-the-counter codeine products were not being translated into an increase of prescriptions for either low dose codeine preparations, higher dose codeine preparations, or other opioids. Middleton & Nielsen further confirm this with their analysis of Pharmaceutical Benefits Scheme data post the 2018 up-schedule.<sup>20</sup> They found rescheduling of codeine to remove non-prescription supply did not have an immediate effect on the prescription rates of codeine, and there were no significant changes in these rates in the months following. The data showed decreasing trends for codeine and most other Schedule 8 prescription opioids, with no increase in

any prescribed opioids associated with codeine up scheduling.

Pharmacists interviewed raised concerns about “Dr. shopping” but this has been somewhat mitigated with the introduction of real time prescription monitoring (RTPM) in Victoria, joining Tasmania, with the other states also now following suit. As at the time of writing RTPM is only mandatory in Victoria, it therefore would be interesting to compare the thoughts of Victorian and South Australian pharmacists at this point in time and whether the introduction of real time prescription monitoring has had an impact on the practice of pharmacists in this post up-scheduling era.

Regardless of the lack of success from the first codeine up-scheduling in 2010, there appears to have been some success with the further measure in 2018. A 2020 study by Cairns *et al.* looking at data from a New South Wales poisons information Centre and national sales data, found that the further codeine re-scheduling to prescription only in Australia appears to have reduced codeine misuse and sales and has successfully reduced use and harm from codeine.<sup>21</sup> They also report no evidence for substitution with high-strength codeine products or other pharmaceutical opioids in the poisoning data.

It appears from the data in this study that preparation had an influence over outcomes experienced by some pharmacists, including the use of “borrowed protection”. That is, putting the onus back on the government which took the blame and responsibility from the pharmacist allowing an opening for conversations about alternative options. Pharmacists believe that preparing patients early reduced the amount of hostility that was received once the up-schedule was implemented. This was surprising, as media hype, prior to the up-schedule suggested that pharmacists were likely to receive a lot of backlash from the community regarding the up-schedule.<sup>22</sup> These findings highlight that preparing the public, as well as practitioners in advance of any changes to pharmaceutical scheduling, is an important factor in the implementation of such changes.

There appears to be a mixed response in all studies to date investigating the impact of the codeine changes on the practice of Pharmacists in Australia.<sup>17</sup> Pharmacists in this study appeared torn between the potential business and professional impacts with regard to scope of practice and reputation, of the change, versus the improved person centered care and safety aspects of the up-schedule. These included removal of opportunities for pharmacists to help people using their professional judgment such as the ability to identify misuse and the opportunity to intervene. Despite this, pharmacists have the opportunity to intervene if they suspect misuse when they are presented with prescriptions for codeine containing products or other opioids and there is opportunity for improved collaboration with prescribers of these medications.

There is also opportunity for pharmacists to undertake chronic pain interventions and improve chronic pain health outcomes as discussed in the narrative from Mishriky *et al.* International studies investigating the effectiveness of pharmacist-driven interventions have demonstrated that there are benefits of pharmacists going beyond standard

primary care practice for chronic pain management but further work is still required in the Australian context where research around the application of pharmacist-driven chronic pain interventions is lacking.<sup>23</sup> The recent Chronic Pain MedsCheck trial in Australia which ended February 2020, may provide further information about the role of Australian pharmacists in this space.<sup>24</sup>

There was an indication by some pharmacists that the impact of up-scheduling on the pharmacy business was of concern. There were fears about a decrease in sales, loss of business and the corresponding impact on the business financially. This could be influenced by bias towards self-preservation. Further work should be done analyzing actual figures to see if there was a loss in sales overall or if sales transferred to other products such as alternative analgesics or pain management options including rubs, heat or ice packs. As mentioned above, data show these sales have not been transferred to prescription opioid medications, but researchers have not investigated other prescription medications such as pregabalin, non-steroidal anti-inflammatory drugs and paracetamol which potentially still contribute business to the pharmacy.

Some pharmacists interviewed for this study were relieved to have the pressure of having to determine if supply was warranted taken from them. This was identified as an issue by Hamer *et al.* when codeine containing analgesics were first up-scheduled in Australia from a Pharmacy Medicine to a Pharmacist Only Medicine in 2010.<sup>9</sup> They found that pharmacists found it challenging to establish a therapeutic need, in particular due to the subjective nature of pain. There were also concerns regarding the lack of time to have detailed consultations with people about their use of these products. Since the up-schedule came into effect, pharmacists reported that recommending pain management alternatives had become easier and was generally useful in encouraging patients to visit their GP and discuss how to effectively manage their pain.

A strength of this study was its mixed-methods approach to gain insights into the perceptions of pharmacists post the 2018 up-scheduling of OTC codeine containing analgesics in Australia. However, this is limited by the fact that the participants in the qualitative phase were only practicing in South Australia and Victoria therefore the results may not

be generalisable to all Australian pharmacists. A further limitation was the timing of the study. As the study was conducted just after implementation it may not be a true reflection of the longer-term impacts. Additionally, further information around whether participants were pharmacy owners or employees within the pharmacy would have been beneficial to determine if the perceived impacts, from a business perspective, were different and this could be the focus of future research.

## CONCLUSIONS

Overall pharmacists expressed diverse perceptions, preparedness and impact on practice regarding the up-scheduling of low dose codeine products. Many pharmacists indicated that the up-schedule had not affected their practice to a great degree. This study was completed during 2018, just post the up-schedule. As a number of the perceptions expressed have proven not to be backed by the emerging evidence, further research should be conducted to gauge if and how these perceptions have changed over time. Further research could also be conducted to identify whether pain is being managed more effectively post codeine up-scheduling and if so how and why. A strength of this study was the ability to explore more in depth the perceptions of the up-schedule and reasoning behind these perceptions.

## ACKNOWLEDGMENTS

The researchers would like to acknowledge all the pharmacists who gave up time during work hours to be interviewed as part of this study.

## CONFLICT OF INTEREST

There are no conflicts of interest to declare.

## FUNDING

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## References

1. Tobin CL, Dobbin M, McAvoy B. Regulatory responses to over-the-counter codeine analgesic misuse in Australia, New Zealand and the United Kingdom. *Aust N Z J Public Health*. 2013;37(5):483-488. <https://doi.org/10.1111/1753-6405.12099>
2. Frei MY, Nielsen S, Dobbin MD, Tobin CL. Serious morbidity associated with misuse of over-the-counter codeine-ibuprofen analgesics: a series of 27 cases. *Med J Aust*. 2010;193(5):294-296. <https://doi.org/10.5694/j.1326-5377.2010.tb03911.x>
3. Nielsen S, Van Hout MC. Over-the-Counter Codeine-from Therapeutic Use to Dependence, and the Grey Areas in Between. *Curr Top Behav Neurosci*. 2017;34:59-75. [https://doi.org/10.1007/7854\\_2015\\_422](https://doi.org/10.1007/7854_2015_422)
4. Ostapowicz G, Fontana RJ, Schiødt FV, Larson A, Davern TJ, Han SH, McCashland TM, Shakil AO, Hay JE, Hynan L, Crippin JS, Blei AT, Samuel G, Reisch J, Lee WM; U.S. Acute Liver Failure Study Group. Results of a prospective study of acute liver failure at 17 tertiary care centers in the United States. *Ann Intern Med*. 2002;137(12):947-954. <https://doi.org/10.7326/0003-4819-137-12-200212170-00007>
5. Mill D, Johnson JL, Cock V, Monaghan E, Hotham ED. Counting the cost of over-the-counter codeine containing analgesic misuse: A retrospective review of hospital admissions over a 5 year period. *Drug Alcohol Rev*. 2018;37(2):247-256. <https://doi.org/10.1111/dar.12595>
6. Nielsen S, MacDonald T, Johnson JL. Identifying and treating codeine dependence: a systematic review. *Med J Aust*. 2018;208(10):451-461. <https://doi.org/10.5694/mja17.00749>



7. Carney T, Wells J, Bergin M, Dada S, Foley M, McGuinness P, Rapca A, Rich E, Van Hout MC. A Comparative exploration of community pharmacists' views on the nature and management of over-the-counter (OTC) and prescription codeine misuse in three regulatory regimes: Ireland, South Africa and the United Kingdom. *Int J Ment Health Addict*. 2016;14(4):351-369. <https://doi.org/10.1007/s11469-016-9640-z>
8. Therapeutic Goods Administration. Codeine information hub: Codeine use can be harmful. Therapeutic Goods Administration; 2018; Available at: <https://www.tga.gov.au/codeine-information-hub-codeine-use-can-be-harmful> (accessed May 2, 2020).
9. Hamer AM, Spark MJ, Wood PJ, Roberts E. The upscheduling of combination analgesics containing codeine: the impact on the practice of pharmacists. *Res Social Adm Pharm*. 2014;10(4):669-678. <https://doi.org/10.1016/j.sapharm.2013.08.004>
10. Australian Institute of Health and Welfare. National Drug Strategy Household Survey detailed report 2016. Drug statistics series no. 31. Cat. no. PHE 214 Canberra: AIHW; 2017; Available at: <https://www.aihw.gov.au/reports/illicit-use-of-drugs/ndshs-2016-detailed/contents/table-of-contents> (accessed May 2, 2020).
11. Australian Institute of Health and Welfare. National Drug Strategy Household Survey detailed report 2013. Drug statistics series no. 28. Cat. no. PHE 183. Canberra: AIHW; 2014; Available at: <https://www.aihw.gov.au/reports/illicit-use-of-drugs/ndshs-2016-detailed/contents/table-of-contents> (accessed May 2, 2020).
12. Cairns R, Brown JA, Buckley NA. The impact of codeine re-scheduling on misuse: a retrospective review of calls to Australia's largest poisons centre. *Addiction*. 2016;111(10):1848-1853. <https://doi.org/10.1111/add.13450>
13. Roberts DM, Nielsen S. Changes for codeine. *Aust Prescr*. 2018;41(1):2-3. <https://doi.org/10.18773/austprescr.2018.006>
14. Therapeutic Goods Administration. Final decision on re-scheduling of codeine: frequently asked questions. Therapeutic Goods Administration; 2016; Available at: <https://www.tga.gov.au/final-decision-re-scheduling-codeine-frequently-asked-questions> (accessed May 4, 2020).
15. Chan V, Tran H. Purchasing Over-the-counter medicines from Australian pharmacy: What do the pharmacy customers value and expect?. *Pharm Pract (Granada)*. 2016;14(3):782. <https://doi.org/10.18549/pharmpract.2016.03.782>
16. QSR. NVivo qualitative data analysis software. 12 ed. Melbourne: QSR International Pty Ltd.; 2018.
17. Mishriky J, Stupans I, Chan V. Pharmacists' views on the upscheduling of codeine-containing analgesics to 'prescription only' medicines in Australia. *Int J Clin Pharm*. 2019;41(2):538-545. <https://doi.org/10.1007/s11096-019-00804-8>
18. McCoy J, Bruno R, Nielsen S. Attitudes in Australia on the upscheduling of over-the-counter codeine to a prescription-only medication. *Drug Alcohol Rev*. 2018;37(2):257-261. <https://doi.org/10.1111/dar.12568>
19. Moore RA, Wiffen PJ, Derry S, Maguire T, Roy YM, Tyrrell L. Non-prescription (OTC) oral analgesics for acute pain - an overview of Cochrane reviews. *Cochrane Database Syst Rev*. 2015;2015(11):CD010794. <https://doi.org/10.1002/14651858.cd010794.pub2>
20. Middleton M, Nielsen S. Changes in Australian prescription opioid use following codeine rescheduling: A retrospective study using pharmaceutical benefits data. *Int J Drug Policy*. 2019;74:170-173. <https://doi.org/10.1016/j.drugpo.2019.08.008>
21. Cairns R, Schaffer AL, Brown JA, Pearson SA, Buckley NA. Codeine use and harms in Australia: evaluating the effects of re-scheduling. *Addiction*. 2020;115(3):451-459. <https://doi.org/10.1111/add.14798>
22. Haggan M. Review codeine: Patients taken by surprise. *Austral J Pharm*. 2018;99:26.
23. Mishriky J, Stupans I, Chan V. Expanding the role of Australian pharmacists in community pharmacies in chronic pain management - a narrative review. *Pharm Pract (Granada)*. 2019;17(1):1410. <https://doi.org/10.18549/pharmpract.2019.1.1410>
24. Australian Government Department of Health. Chronic Pain Medscheck Trial . Available at: <http://6cpa.com.au/chronic-pain-medscheck-trial/chronic-pain-medscheck-trial/> (accessed May 4, 2020).