

## OVER-THE-COUNTER CODEINE: THE END OF AN ERA, AND PREPARING FOR THE CHANGES AHEAD

### Symposium presenters:

Jacinta Johnson, Jacqui McCoy, Pene Wood, Suzanne Nielsen

**Nominated chairs:** Hester Wilson (Discussant) and Suzanne Nielsen (co-chair)

*Aim:* In February 2018 codeine in Australia will become a prescription-only medication. The aim of this symposium is to explore the potential implications of the scheduling change on consumers and health care providers, including treatment providers. Treatment responses, including models of care where dependence is identified in community pharmacy settings, will be discussed. The symposium will also provide a forum for two-way knowledge sharing between presenters and symposium attendees regarding current treatment approaches with codeine dependence and potential challenges with the impending up-scheduling of codeine.

### Presentation 1. IDENTIFICATION AND TREATMENT OF CODEINE DEPENDENCE: A SYSTEMATIC REVIEW

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**Introduction and Aims:** Codeine dependence represents a significant public health issue. Strategies to identify risk profiles for developing problematic codeine use and approaches for treating codeine dependence are poorly defined. Thus, we performed a systematic review to describe what is known about identification and treatment of codeine dependence.

**Method:** Experimental or epidemiological studies that inform on the identification or treatment of codeine dependence were retrieved from Medline and Embase. Papers without empirical data were excluded. One researcher screened each abstract, subsequently; two researchers independently reviewed remaining full text papers, with discrepancies resolved via consensus. Validated tools were used to assess study quality and grade evidence for treatment studies. Data was extracted using a standardised tool.

**Results:** 2150 articles were initially identified; after excluding duplicates and reviewing against inclusion/exclusion criteria 41 papers were identified as eligible. 32 provided descriptions of codeine dependent patients that may aid in identification, no papers were specifically defined approaches for identifying codeine dependence. Numerous case reports/series described codeine dependence masked with complications of simple analgesic overuse. Eighteen papers described treatment of codeine dependence; few were interventional studies or prospective in nature. Common treatment approaches include opioid agonist treatment and psychological therapies. Meta-analysis was not possible due to heterogeneity of results.

**Discussions and Conclusions:** Significant heterogeneity of characteristics of patients with codeine dependence was evident with further research required to confirm strategies of identification of problematic use. There is some evidence for managing codeine dependence

consistent with frameworks for treating opioid dependence, including detoxification, opioid substitution therapy and cognitive behavioural therapy.

**Implications for Practice:** In the absence of larger prospective controlled clinical studies of either psychological or medication based therapies, evidence for treatment for codeine dependence must be largely assumed from other studies of pharmaceutical opioid dependent people. Medical and psychiatric comorbidities likely require integrated treatment.

## **Presentation 2: ATTITUDES IN AUSTRALIA ON THE UPSCHEDULING OF OVER-THE-COUNTER CODEINE TO A PRESCRIPTION-ONLY MEDICATION**

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**Introduction and Aims:** In December 2016, the Australian Therapeutic Goods Administration announced that over-the-counter (OTC) codeine would be available by prescription-only in February 2018. Prior to this announcement, the authors aimed to evaluate attitudes among Australian codeine consumers, pharmacists and general medical practitioners (GP) towards the proposed upscheduling of OTC codeine.

**Design and Methods:** Public Therapeutic Goods Administration submissions on codeine upscheduling were assessed, and a brief questionnaire was developed to assess the common issues raised. Participants (354 codeine consumers; 220 pharmacists; 120 GPs) completed a web-based questionnaire. Comparisons of attitudes on specific statements related to codeine upscheduling were made between consumers who were in support and those who opposed the proposal and between pharmacists and GPs. Regression models were conducted to examine correlates of attitudes towards codeine restriction.

**Results:** Most consumer, pharmacist and a third of GP respondents opposed the upscheduling of codeine. Consumers, on average, questioned whether the proposed intervention would address the intended targets of minimising codeine-related side effects and risk of codeine dependence. Like consumers, pharmacists indicated concern around whether codeine restriction would address concerns of associated harm and dependence, as well as the burden regular GP appointments would create in terms of finances for consumers and time for GPs. GPs themselves, did not support these views.

**Discussion and Conclusions:** Consumer responses identify key targets for educational campaigns when codeine is rescheduled, particularly around effective alternatives to OTC codeine. Additionally, contrasting views of pharmacists and GPs reinforce the importance of pharmacovigilance in evaluating the effectiveness of codeine restriction, once implemented.

**Implications for policy and practice:** Understanding the concerns of consumers and health professionals is important in informing key outcomes to measure in evaluating the effect of rescheduling on the community.

## **Presentation 3. MANAGING AND LINKING FREQUENT OVER-THE-COUNTER (OTC) CODEINE AND PRESCRIPTION OPIOID USERS INTO TREATMENT: A PILOT STUDY**

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**Introduction / Issues:** With the implementation of MedsASSIST pharmacists were finding it easier to identify patients who were misusing opioids. There was concern that MedsASSIST would be used as a policing tool with pharmacists refusing supply to patients or continuing to supply without intervention instead of referring them for improved management.

**Method/Approach:** To complement MedsASSIST a HealthPathway, centred on OTC codeine management for pharmacists, was developed using the current literature and subject matter experts. To encourage utilisation a quiz and CPD points were attached. These pathways were made available through the Western Vic PHN HealthPathways website, Pharmacy Guild myCPD platform and the MedsASSIST program. To accompany this a protocol was developed setting out the criteria for identification and mechanism of referral, roles of the health professionals, and required follow-up and recording. The protocol was piloted in the community pharmacy setting.

**Key Findings:** As of April 2017, 3969 pharmacies across Australia had MedsASSIST installed. Over 3000 pharmacists have accessed the HealthPathway. In total there were 3316 quizzes completed. Of these, 29% failed to meet the 80% pass mark. Questions about drug interactions and signs of dependence were most frequently answered incorrectly. From the preliminary evaluation all pharmacists found the tools relevant to their practice. Some pharmacists believe the tool has increased their confidence in selling products containing codeine though others stated despite having a tool it is still a difficult area to deal with.

The referral protocol pilot began May 2016 with data collection underway.

**Discussions and Conclusions:** Despite pharmacists having access to a clinical tool that they find relevant, regular use is limited. There is a need for pharmacist education especially around drug interactions and signs of dependence.

The referral pilot will help to answer questions around treatment options and GP pharmacist collaboration.

**Implications for practice:** The results of this study could have implications for the imminent up-scheduling of codeine and the introduction of real-time prescription monitoring.

#### **Presentation 4. TREATING OVER THE COUNTER CODEINE DEPENDENCE: 2 YEAR OUTCOMES FROM A COHORT OF PHARMACEUTICAL OPIOID DEPENDENT PEOPLE**

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**Introduction:** Few studies have directly examined treatment approaches and outcomes for codeine dependence

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**Methods:** We will present 2 year outcomes for a group of codeine dependent people (n = 23) as part of a larger cohort (n = 108) of people who have entered treatment for pharmaceutical opioid dependence.

**Results:** At cohort entry, those dependent on OTC codeine were mostly female (57%). Compared to those dependent on prescribed opioids, participants dependent on OTC codeine were significantly more likely to be employed (57% cf. 20%) and less likely to report moderate-severe depression (30% cf. 58%). Among those dependent on OTC codeine, one in five (18%) reported current chronic pain. Most (74%) reported a lifetime history of overdose. Half (52%) had entered treatment for the first time at cohort entry. At cohort entry most (21 of the 23) were in buprenorphine treatment, with most remaining in treatment at 3 months (n=19, 85%), 12 months (n=18, 82%) and 2 years later (n=13, 65%). Ongoing (past month) OTC codeine use was reported by one in three (35%) at cohort entry, a quarter at 3-months (26%), 18% at 12 months and 35% at 2 years.

**Discussion and conclusions:** This is the first study to describe long-term treatment outcomes for those that have entered treatment for OTC-codeine dependence. Good treatment retention was observed, with some ongoing codeine use despite treatment involvement. Characteristics at cohort entry demonstrate clear differences between codeine dependent people and those dependent on prescribed opioids, which may impact on treatment provision and outcomes.

**Implications for practice:** Very few studies have examined opioid-agonist treatment specifically for codeine dependence. This is the first study to report on long-term outcomes which suggest that buprenorphine treatment for codeine dependence is associated with positive treatment outcomes.

**Discussion Section (27 minutes):** Dr Hester Wilson will facilitate a discussion that aims to understand current experiences in the AOD treatment sector relating to treatment demand for codeine dependence, and answers clinical questions around approaches to treating codeine dependence.

The discussion will begin with a case –study based scenario of a person with suspected codeine dependence presenting for treatment. Symposium audience members will be asked to provide comments on specific aspects of the case presentation

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1. Are you seeing presentations like this in your services? Are you seeing presentations with codeine dependence that are very different to this case?
2. What sorts of treatment responses do you provide for codeine dependence in your services?
3. With the changes in February with codeine availability, are there things that would help support services in responding to codeine dependence?

The discussion will hope to lead to a better understanding of how services are currently responding to codeine dependence, and identify any specific strategies that could be put in place prior to the change in codeine availability in February 2018. Symposium participants may take away new information about implications of the rescheduling, and share their experience with responding to codeine dependence.

**Disclosure of interest statement:** SN is a named investigator on untied educational grants from Indivior. SN, BL, NL, RB and LD have been named investigator on untied education grants from Reckitt-Benckiser. LD, BL, NL and RB have been named investigators on untied education grants from Mundipharma. BL has received an untied educational grant from Seqirus, SN has presented a training workshop for Indivior where travel expenses have

been covered. TM has received honoraria, fees and/or provision of professional development resources from Servier, Australian and New Zealand Mental Health Association, and HealthCare.