



Original Research

Managing inappropriate use of non-prescription combination analgesics containing codeine: A modified Delphi study



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A B S T R A C T

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Background: Misuse and/or dependence upon non-prescription combination analgesics containing codeine (NP-CACC) can result in serious physiological and psychological harms.

Objective: To explore pharmacists' and other health care professionals' ideas and views on strategies for managing NP-CACC misuse and/or dependence in a community pharmacy setting.

Methods: A 3-iteration modified Delphi study was conducted to gain the consensus view of panelists. Forty experts within the fields of pharmacy and drug misuse and/or dependence agreed to be on the panel. Questionnaires explored opinions on issues and possible strategies that could be used to manage NP-CACC misuse and/or dependence. Responses from the first-round questionnaire were summarized and reported back to panelists through the second-round questionnaire for further reflection and evaluation using a 6-point, Likert-type scale. Strategies included in the third-round questionnaire had agreement by more than 80% of panelists. Panelists provided feedback on effectiveness using a 6-point, Likert-type scale for impact.

Results: The response rates for the 3 rounds were 65%, 67.5% and 55%, respectively. Panelists provided 54 strategies in round 1. In round 2 there was consensus agreement with 31 of these strategies. In round 3 there was consensus that 21 strategies were expected to be effective (>80% of panelists expected the strategy to be effective, median above Somewhat Effective (4), IQD ≤1). Of these, 8 were expected to have the most impact if implemented into clinical practice (chosen by 5 or more panelists in their Top 5 for impact). The strategies identified as effective and likely to have the most impact on NP-CACC misuse/dependence in a community pharmacy setting were: utilization of a national real-time database to monitor product sales to aid identification of at-risk people (100% effectiveness, rank 1 for impact); development of a referral pathway for management of people whom pharmacists have identified as at-risk (95.2% effectiveness, rank 2 for impact), and training to improve pharmacist communication with people (95% effectiveness, rank 2 for impact).

Conclusions: The high level of consensus achieved indicates that the strategies generated represent useful approaches which could be utilized to manage NP-CACC misuse and/or dependence within community pharmacy in the future.

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Introduction

Combination analgesics containing codeine (CACC) are indicated in the treatment of mild to moderate pain as alternatives to single ingredient non-opioid analgesics. In a number of countries, including Australia and New Zealand, these products are available

without prescription when they contain 8 mg–15 mg of codeine phosphate, which is an opioid analgesic, in combination with a non-opioid analgesic (paracetamol/acetaminophen, ibuprofen or aspirin).¹ In Australia these products are stored behind the counter where consumers are unable to self-select and a pharmacist is legally required to determine therapeutic need prior to any sale. Non-prescription CACC (NP-CACC) is safe for the majority of people for short-term use (3–5 days). Longer-term use requires referral for further investigation and alternative treatment.² The codeine contained in NP-CACC exposes them to use for purposes other than

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indicated, such as self-medicating for mental health conditions, recreational purposes (misuse) and physical or psychological dependence.^{3,4} Overuse is an increasing concern for pharmacists, other health professionals and the Australian government because of the morbidity and toxicity associated with codeine misuse and dependence. The overall rate of codeine-associated deaths more than doubled from 3.5 per million in 2000, to 8.7 per million in 2009, although only 7.8% of the deaths were attributed to codeine toxicity alone.⁵ The increase in reports of codeine-related toxicity and morbidity has led to a call by some medical and government groups to have non-prescription codeine products made available via prescription only.⁵

Misuse of NP-CACC obtained from community pharmacies in Australia and the United Kingdom (UK) is thought to be common. Pharmacists have reported suspicion of misuse and/or dependence of CACC sold within their pharmacy.^{7–10} The risks associated with codeine misuse include respiratory depression, cardiac arrest, medication-overuse headache and withdrawal symptoms. Dependence on the codeine component of CACCs can lead to their increased consumption, which may consequently lead to adverse effects associated with high doses of the accompanying non-opioid analgesic (paracetamol/acetaminophen, ibuprofen or aspirin).¹¹ Supra-therapeutic doses of paracetamol/acetaminophen are known to lead to hepatotoxicity, whilst sustained consumption of large quantities of ibuprofen and/or aspirin may induce hypokalemia, renal tubular acidosis and gastric ulceration.^{11–13} Concerns about inappropriate use of NP-CACC products has led to calls for changes to Australian legislation; consequently on May 1st 2010, these medications were up-scheduled, which resulted in all NP-CACC being moved from where consumers could self-select to being kept behind the counter, and a pharmacist being required to determine therapeutic need for every sale. Recently, it has been recommended that all Australian products containing codeine be rescheduled so they can only be obtained with a prescription from a doctor.⁵ This was to be implemented on June 1st 2016, but following submissions from pharmacy groups, the pharmaceutical industry and key consumer groups, a final decision was deferred until June 2016.¹⁴

Following up-scheduling of NP-CACC in 2010, Australian pharmacists were required to establish therapeutic need, which prompted increased monitoring of NP-CACC purchases by pharmacists and an increased awareness of people who may not be using the product as prescribed.⁸ Prior to this, pharmacist management of inappropriate use of NP-CACC had been reported as needing improvement, particularly with regard to: identification of an issue, communication with the patient, referral and treatment.¹⁵ Identification of people misusing and/or dependent upon NP-CACC can be difficult for pharmacists, partly due to the ability for people to shop around pharmacies, and no mechanism to record NP-CACC sales across multiple pharmacies.^{7,8} Furthermore, pharmacists experience difficulty communicating product risks or addressing suspected dependence with people, possibly due to concerns about aggressive behavior if misuse and/or dependence is raised.¹⁵ Additionally, it has been identified both in Australia and abroad that once a pharmacist has recognized that there is an issue, they are unsure of the best treatment strategies for these people or the appropriate referral pathways.^{7,15,16}

Misuse of NP medications appears to also be a concern for pharmacists in the UK. Intervention strategies used or seen as desirable by UK pharmacists to manage NP medication misuse include: suggesting patients seek the advice of GPs, better communication between primary health care professionals, sharing information amongst pharmacies, access to up-to-date local and national information about non-prescription drug misuse and developing an 'early warning system'.^{10,17} While

restricting access to medications that were being misused was reported as an important first step, support or counseling were considered likely to be more beneficial for more chronic cases of misuse. Training involving dealing with the problem of non-prescription medication misuse and other sensitive issues coupled with support from training organizations has been identified as a means of reducing inappropriate non-prescription medication sales in pharmacies.^{10,17} A community pharmacy harm minimization model has been trialed in Ireland for abuse or misuse of a small range of NP medicines [opioid (predominantly kaolin and morphine mixture), antihistamine or laxative].^{18,19} Pharmacists were asked to identify and recruit people they thought were misusing or abusing NP medicines. Then, depending on the medication involved, offer treatment or refer the person. Pharmacists raised the topic of inappropriate use with less than half (46%) of the people they identified as abusing or misusing one of the study medicines. Of the patients with whom pharmacists spoke, only 20% agreed to stop using the product and/or use a safer alternative; none of these patients completed the outcome component of the study.¹⁸ These UK studies have focused on NP medicines as a group and some of the strategies used could be applicable to NP-CACC.

Australian pharmacists have made suggestions for the appropriate management of NP-CACC requests. Suggestions include a real-time monitoring system, further pharmacist training in communication skills, greater collaboration with doctors and the development of effective programs to refer over-the-counter (OTC) CACC-dependent people for assistance, including pharmacy based programs.^{8,20} These are similar to the strategies identified for misuse of OTC medications in general in the UK, where there was also a call for greater consistency in the management of OTC misuse and the need for the development of nationally recognized guidelines for pharmacists.^{10,17} Previous studies gathered information from individuals but there is a need to explore wider views and reach agreement on the way forward for the management of misuse and/or dependence on codeine. This study aimed to explore and obtain consensus on potential specific strategies for managing NP-CACC misuse and/or dependence that would be expected to be effective and have impact if they were implemented in an Australian community pharmacy setting.

Methods

A 3-iteration modified Delphi survey was chosen to explore potential strategies for the management of NP-CACC misuse and/or dependence in a community pharmacy setting. The Delphi survey technique is an anonymous structured group communication process; it involves a 'panel of informed individuals,' or experts, undertaking a multi-faceted exploration of the topic of interest and establishing consensus opinion.²¹ The first-round questionnaire usually consists of open-ended questions to canvass opinions on a particular topic. Subsequent questionnaires are then built upon responses to the previous questionnaire. Group responses are summarized and returned to panelists who may modify their contribution in light of newly-shared opinions.²² This anonymous process enables the generation of a diverse and comprehensive range of opinions, whilst avoiding domination by individuals who may sway the responses of others. The process usually concludes when stability of opinion (consensus) is reached. However, in modified Delphi-surveys a pre-determined number of 'rounds' is used, which has been shown to be an effective and feasible means of gathering data in a timely and efficient manner.²³ Pilot testing of questionnaires with a small group of individuals prior to release has been recommended.^{22,24}

Purposive sampling was used. A panel size of 40 was chosen to

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