



Original Research

The upscheduling of combination analgesics containing codeine: The impact on the practice of pharmacists

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Abstract

Background: Prior to the 1st May 2010 some combination analgesics containing codeine (CACC) were available for sale over the counter (OTC) in Australia with no requirement for input from a pharmacist. Since then the upscheduling of these medications requires the involvement of a pharmacist in all OTC CACC sales.

Objective: To explore how the upscheduling of OTC CACC has impacted the practice of community pharmacists.

Methods: A descriptive qualitative design was used, with data collected via face-to-face semi-structured interviews that were recorded and transcribed verbatim. The data were analyzed thematically via open, axial and selective coding.

Results: Pharmacists were found to monitor the supply of OTC CACC by recording sales and to intervene when they felt that the medication was being used too frequently. They perceived a number of challenges surrounding the provision of OTC CACC including; supply from other pharmacies, establishing therapeutic need, managing codeine dependent people, lacking confidence in discussing misuse with people, being unsure where to refer dependent people for help and purchaser resentment towards pharmacist involvement in all sales. People who request OTC CACC tended to be stereotyped by participants as either 'genuine' or 'misusers.'

Conclusion: A number of challenges faced by community pharmacists to ensure the safe provision of OTC CACC and to assist codeine dependent people were identified, highlighting the need for more effective ways of monitoring the use of OTC CACC and intervening in OTC codeine dependence.

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Introduction

Combination analgesics containing codeine (CACC) contain codeine in combination with either paracetamol, ibuprofen or aspirin. In some countries, including Australia, medications containing a low dose of codeine are available over the counter (OTC) from pharmacies. OTC CACC are considered to be safe when used in the recommended amounts to treat occasional pain, but excessive doses or long term use may lead to dependence, medication overuse headaches or other potentially serious medical issues.¹ Some people become dependent on codeine after commencing OTC CACC for genuine pain. Dependence can lead to an increase in the number of tablets being taken potentiating the risk of adverse effects due to prolonged high doses of the analgesic combined with codeine.^{2–4} High doses of paracetamol can lead to hepatotoxicity,⁵ whilst prolonged use of codeine/ibuprofen combinations can cause renal tubular acidosis, hypokalaemia, gastrointestinal ulceration or bleeding.^{6–10}

In Australia medicines are placed in schedules according to the appropriate level of control over access and availability needed to protect the safety and health of the public.¹¹ OTC medicines are either in Schedule 2 (Pharmacy Medicine) or Schedule 3 (Pharmacist Only Medicine). Schedule 2 medicines can only be sold in pharmacies under the supervision of a pharmacist whereas Schedule 3 medicines require the direct involvement of a pharmacist to establish that a therapeutic need exists for the medicine and provide the person with professional advice.^{11,12} New Zealand has a similar medicine classification system to Australia in which Pharmacist Only Medicines can only be supplied with the involvement of a pharmacist.¹³

Previously some OTC CACC were in Schedule 2 and were available for purchase via self selection from pharmacies without interaction with a pharmacist. On the 1st of May 2010, due to safety concerns about the harm that can occur through misuse, they were deleted from Schedule 2 and added to Schedule 3.¹⁴ From that date direct pharmacist involvement is required in all sales and pharmacists have a legal and professional responsibility to determine that a therapeutic need exists for the medication before it can be supplied. It was expected that upscheduling would reduce misuse of these medications.

When any request is made for an OTC medication a pharmacist must make a decision whether it is appropriate to supply the medication

or not. Whilst making this decision, pharmacists in Northern Ireland have been found to consider safety above all other factors and were reluctant to supply medications with the potential to be misused or abused.¹⁵ Medications perceived by pharmacists as being a concern for abuse or misuse are sedating antihistamines, laxatives and OTC CACC.^{16–18}

Community pharmacists have an important role to play in monitoring and intervening in OTC medicine misuse.¹⁷ They have been found to identify people misusing OTC medications by suspicious behavior, people asking for the product too frequently, requesting large quantities or the observation of pharmacy assistants.¹⁷ Prior to the upscheduling some pharmacists were found to use appearance as a means of identifying misuse of OTC CACC, however codeine dependent people may dress well as a means of getting easier access to OTC CACC.¹⁹ Furthermore, using frequency of supply may not be an effective means of identifying OTC CACC misuse as pharmacists lack a real-time monitoring system for OTC CACC sales thus are only aware of the sales occurring in their pharmacy.^{2,19} This implies identifying people overusing OTC CACC may not be straightforward for pharmacists.

When a pharmacist suspects a person is overusing an OTC medication they may employ strategies to reduce misuse. Most pharmacists will intervene by asking the person to seek their doctors' advice.¹⁷ Yet, pharmacists and experts in addition identify keeping the product out of sight and staff training to be the most effective ways to decrease OTC medication misuse.²⁰ Other strategies used by pharmacists include telling people that they no longer sell the product or confronting people about their overuse.^{17,21} However, some people have been found to be reluctant to talk about their misuse of OTC medications and/or unresponsive to any advice given by pharmacists.¹⁸ Similarly, both pharmacists and codeine dependent people were uncomfortable discussing codeine dependence with each other.¹⁹

Pharmacists' perceptions and practices surrounding the identification and minimization of OTC drug misuse have been reported in the literature. However, the majority of these studies were quantitative and lack the richness that qualitative research can provide. Additionally the only study providing some insight into pharmacists' experiences with OTC codeine dependent people was conducted prior to the upscheduling of OTC CACC.¹⁹ Consequently there is a lack

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