



Pacini Editore & AU CNS

Regular article

Heroin Addict Relat Clin Probl 20xx; xx(x): 5-9

HEROIN ADDICTION &
RELATED CLINICAL
PROBLEMS

www.europad.org
www.wftod.org

An evaluation of community pharmacist perception of the misuse and abuse of over-the-counter co-codamol in Cornwall and Devon, UK: A cross-sectional survey

Ravina Barrett, and Dalmar Costa

University of Portsmouth, Portsmouth, UK

Summary

Background: Codeine containing preparations have the potential to cause harm and dependence. Recent UK regulatory changes to the pack-size and printed warnings have been instituted to reduce this potential. However, there is a reported increase in the misuse of codeine containing analgesics in countries where it is available over-the-counter. This is a challenge for pharmacies and pharmacists globally. **Aim:** To evaluate the perceptions of community pharmacists on the nature and management of Over-The-Counter (OTC) co-codamol (paracetamol and codeine combination preparations) misuse and abuse. **Methods:** A self-report, postal survey was developed and posted to 65 pharmacies in Cornwall and 85 pharmacies in Devon (n=150) in the UK. Qualitative and quantitative data was analysed using descriptive statistics, hypothesis testing and thematic analysis. **Results:** Most pharmacists perceived their patients and community as having some challenges with the misuse of co-codamol. Pharmacists think that co-codamol is not harmful if used as indicated. The behaviours pharmacist associated with misuse were frequent to purchase and misinformation provided by the patient during consultation. Counselling and referral are the main interventions utilised by pharmacist in such circumstances. Pharmacists who have received training on co-codamol abuse know where to refer customers. **Conclusions:** Community pharmacists face a difficult challenge when suspecting misuse. However, pharmacists believe co-codamol abuse can be reduced by increasing the public's awareness of the addictive potential of co-codamol.

Key Words: Codeine; Misuse; Over the counter; Risk reduction; Community pharmacy

1. Introduction

The inappropriate use of OTC medications is referred to as misuse or abuse, due to their potential for addiction and dependency. Misuse and abuse can sometimes be misunderstood. For the purpose of this study, the definitions are adopted from EU commissioned report [18] concerning codeine use, misuse and dependence.

The definition of 'misuse' is: 'The problematic consumption of codeine where risks and adverse consequences outweigh the benefits, and which includes use of codeine with or without prescription, outside of acceptable medical practice or guidelines, for recreational reasons, when self-medicating, with higher doses and for longer than advisable' [3].

While the definition of 'abuse' is: 'The use of drugs for nonmedical purposes is to experience their mind-altering effects, while "misuse" is applied to the use of a drug for legitimate medical purposes, but in an incorrect manner' [1]. Both definitions imply recreational use. Although these definitions are limited to codeine abuse and misuse, we use these definition as they are relevant to co-codamol use.

In the UK, there are three categories of licenced medicines for human use: 1. General Sales List (GSL) medicines, which can be readily purchased from retailers, often containing a small quantity of analgesics and other preparations (not codeine-based). 2. Pharmacy (P) medicines, which can be purchased OTC from a registered pharmacy where a registered pharmacist oversees the sale (can be codeine-based). 3.

Prescription only medicines (POM), which must be supplied only against a valid prescription. Codeine preparations are sold OTC as P medicines or on a prescription. Some examples of other commonly abused medications include benzodiazepines, z-drugs and opioid painkillers.

The misuse and abuse of OTC medicines is a worldwide problem [4, 17]; the five key groups of abuse range from laxatives, cough products, sedative antihistamines, decongestants and codeine based analgesics [4, 9]. This is due to looser regulations, greater availability and self-medication [18, 16]. The misuse of codeine containing compound analgesics (normally in combination with ibuprofen or paracetamol) is increasing in countries where it can be purchased OTC [10]. Codeine containing analgesics are commonly associated with abuse and dependence due to the addictive and euphoric properties of codeine [18].

Associated with this euphoric effect is the consequence of overconsumption of the compounded analgesic such as paracetamol. The potential health risk as a direct consequence of paracetamol overdose is hepatotoxicity [8] related to the chronic use of such products [6, 5, 8]. Similarly, when codeine is combined with ibuprofen, overdose can result in nephrotoxicity and gastric irritation. These health harms are amplified with dose escalation, which is commonly observed with chronic codeine misuse [16], because patients build tolerance to that dose of codeine and need a greater amount of codeine to generate the same euphoric effect, while sustaining damage from paracetamol and ibuprofen overdose.

The initial use of such agents is often genuine and for appropriate indicated conditions. However, eventually it is taken for non-medical reasons and borders on dependency [8, 4, 15]. Some studies suggest that codeine dependence is subtly different to other opioid dependence. It requires different types of treatment, abusers have different mental health problems, and they have more similarities to the general population [11, 13]. Similarly, individuals mainly abusing codeine, labelled themselves as 'social and economically active and different from illicit substance misusers' [4]. Additionally, individuals have described their codeine abuse as the 'blurring' between therapeutic and problematic use, whereby they think they are using it to relieve pain, while in fact they are using it to prevent opioid withdrawal symptoms [12].

Aims: The primary aim was to investigate the perceptions of community pharmacists on the misuse and abuse of OTC co-codamol (research question:

what do community pharmacists think about co-codamol misuse and abuse?)

The secondary aim was to understand how community pharmacists suspect and manage co-codamol misuse or abuse (research question: how do community pharmacists manage the phenomenon?)

2. Methods

The survey was developed from Carney et al's [2] study. This study investigated views on regulatory changes, strategies used to identify misuse of codeine and how community pharmacists managed them.

To improve internal validity and reliability, the survey instrument was piloted, and cognitive testing (read aloud) was conducted on the final instrument. The feedback confirmed that the questions were interpreted properly. Accompanying the survey was a participant information sheet, that highlighted the purpose of the study and invited participation. Taking part in the study was voluntary and anonymous. A pre-paid, self-addressed envelope was included to facilitate survey responses. Implied consent was assumed if surveys were returned. The duration of data collection was approximately 3 months from 25/11/2016.

Community pharmacies in Cornwall (n=65) and Devon (n=85) were surveyed, a sample representing approximately 60% of pharmacies in both counties. Devon had previously run a codeine awareness campaign and Cornwall had not. Community pharmacies registered on NHS choices website were targeted. Registered and preregistration pharmacists were invited to complete the questionnaire. 32 completed surveys (out of 150) were returned (response rate 21%) from Devon (20) and Cornwall (12). 56% male and 44% females responded. 59% of respondents had eight years or more practice experience. 66% of these were full-time pharmacist.

Quantitative data were analysed using SPSS [7] software and qualitative data were analysed using NVivo [14] for thematic analysis.

2.1. Ethics statement

Prior to data collection, favourable ethical opinion was received from the School of Pharmacy and Biomedical Sciences Research Ethics Committee on (Reference number: 2016.17 – 005, Date submitted: 24-10-2016). This study is in line with declaration of Helsinki-ethical principles for medical research involving human subjects.

3. Results

88% of respondents reported knowing customers who regularly purchased co-codamol, with 44% purchasing co-codamol once or twice a week. 84% of respondents did not routinely recommend co-codamol for pain relief. Of these, 38% actively avoided recommending co-codamol for pain. 94% of all responders had offered alternatives to co-codamol during an OTC sale. 91% had denied prior sales of co-codamol to individual customers. 47% of responders believe that OTC use of co-codamol is harmful. Of these, 41% believed it encouraged the risk of addictive behaviour, 28% believed there was a risk of paracetamol overdose, a similar percentage believe there was a risk of endorsing abuse, 22% believed there was a risk of liver damage with chronic high paracetamol intake. However, 72% of responders indicated that co-codamol should not be reclassified as a prescription only medicine (POM).

47% of respondents believed they served 'lower-middle-class' patients in their shop. 63% believed they knew where to refer customers for the treatment of co-codamol abuse. A Pearson chi-squared test statistic of 14.264 ($p=0.002$) rejects the null hypothesis that there is no association between perceived lower socio-economic status of patients and pharmacist's knowledge of referral.

Thematic analysis of the challenges associated with OTC co-codamol sale identified the following themes: 1. Patients, 2. Abuse, 3. Pharmacies. Patients: patients repeatedly requesting co-codamol, failed to understand the impact of their abuse on their health. Abuse: respondents reported patient abuse towards them including aggressiveness, defensiveness and abusive language and actions. Pharmacies: some respondents would rather make a supply, even when they suspect abuse to secure revenues.

Thematic analysis of how patient's health is safeguarded considering the above challenges revealed: 1. Use, 2. Patients, 3. Staff. Use: advice around safe use is given. Patients: patients are routinely questioned on their use of co-codamol. Staff: staff are locally made aware of frequent customers and the risk of abuse by individual patients.

66% of respondent had received no training on helping customers with co-codamol abuse. A Pearson chi-squared test statistic of 8.119 ($p = 0.004$) rejected the null hypothesis that there was no association between pharmacists that had received training and pharmacists who knew where to refer customers for

treatment. All respondents that received training with co-codamol abuse know where to refer customers for abuse support. Hence, Devon's public health campaign seems to have worked. 63% of all respondents would like to receive further training.

4. Discussion

Most of the responders were full-time pharmacists working in communities they perceived as upper-middle-class areas. The obstacles they face included low-level co-codamol abuse. The Pearson chi-squared test suggests that poorer communities that face challenges of co-codamol abuse/misuse are doubly disadvantaged because the community pharmacist lacks sufficient knowledge to be able to refer patients appropriately to address their addiction. Conversely, respondent working in upper-middle-class or middle-class backgrounds are more aware of appropriate referral pathways.

Pharmacist attempted to safeguard patients by asking questions and providing counselling for safe and appropriate use. They also shied away from recommending co-codamol and actively discourage its use. Many respondents had mixed opinions on the harm of OTC use of co-codamol. Most respondents concurred that OTC sale may risk 'encouraging' addictive behaviour.

Regardless of these harms, it must be stressed that respondent-pharmacists do not believe that co-codamol should be reclassified as prescription only, and many do not believe that the OTC use of co-codamol is harmful. These recommendations are in line with the recent studies that suggest raising public awareness and education is needed as the first step in combating this problem. This education should not just be for co-codamol, but include all OTC codeine containing products.

The main limitation of this study is the small sample size, where results are not generalisable. However, it provides a snapshot into current pharmacy practice. There was a high completion rate for most questions, however, responder bias is possible. Further in-depth study is warranted given the global status of the opioid epidemic.

5. Conclusions

Community pharmacists face a difficult challenge in gaining the right balance of safe co-codamol use. Community pharmacists in Devon and Cornwall believe that abuse can be reduced by raising public

awareness and training pharmacist to spot the early signs of abuse. The magnitude of this challenge remains small according to the respondent and pharmacists do not believe reclassification to POM is warranted.

Co-codamol abuse is a complex and difficult challenge, which can be reduced via policy or public health promotion. Pharmacist believed that mandatory counselling with co-codamol sale is essential. This could be achieved in several ways: having a designated 'codeine' staff, who is the single point of contact for codeine sales and is themselves additionally trained for issues around addiction. There could be barcode scanned prompts at point of sale for essential counselling with each sale. Further, local training and awareness of pharmacists and their support staff via e-learning courses could further raise awareness amongst pharmacy professionals, including local signposts for addiction support counselling services.

Patients are made aware of the risk of addiction on the packaging: in the UK, printed warning for safe use of three days as a maximum and pack sizes are restricted to a maximum of three-day supply. Further OTC opioid-analgesics awareness programs could be run by the government.

Safety as a quality can be linked to medication and their safe use. Safety, can also be linked to patient qualities and characteristics, where some patients have a greater propensity for safety versus addiction. It is this second group, which benefits most from these safer modalities exercised by pharmacy.

References

1. Albsoul-Younes A, Wazaify M, Yousef A-M, Tahaine L. Abuse and Misuse of Prescription and Nonprescription Drugs Sold in Community Pharmacies in Jordan. *Subst Use Misuse*. 2010 Jul;45(9):1319–29.
2. Carney T, Wells J, Bergin M, Dada S, Foley M, McGuinness P, et al. 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 Aug;14(4):351–69.
3. Casati A, Sedefov R, Pfeiffer-Gerschel T. Misuse of Medicines in the European Union: A Systematic Review of the Literature. *Eur Addict Res*. 2012;18(5):228–45.
4. Cooper RJ. 'I can't be an addict. I am.' Over-the-counter medicine abuse: a qualitative study. *BMJ Open* [Internet]. 2013 Jun 17;3(6). Available from: <http://bmjopen.bmj.com/content/3/6/e002913.abstract>
5. Cooper RJ. Over-the-counter medicine abuse – a review of the literature. *J Subst Use*. 2013 Apr;18(2):82–107.
6. Craig DGN, Bates CM, Davidson JS, Martin KG, Hayes PC, Simpson KJ. Overdose pattern and outcome in paracetamol-induced acute severe hepatotoxicity. *Br J Clin Pharmacol*. 2011 Feb;71(2):273–82.
7. IBM Corp. IBM SPSS Statistics for Windows. Armonk, NY; 2014.
8. Larson AM, Polson J, Fontana RJ, Davern TJ, Lalani E, Hynan LS, et al. Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study. *Hepatology* Baltim Md. 2005 Dec;42(6):1364–72.
9. Lessenger JE, Feinberg SD. Abuse of Prescription and Over-the-Counter Medications. *J Am Board Fam Med*. 2008 Jan 1;21(1):45–54.
10. McAvoy BR, Dobbin MDH, Tobin CL. Over-the-counter codeine analgesic misuse and harm: characteristics of cases in Australia and New Zealand. *NZ Med J* [Internet]. 2011 Nov 25 [cited 2017 Jan 20]; 124 (1346): 29–33. Available from: <https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2011/vol-124-no-1346/article-mcavoy>
11. Nielsen S, Cameron J, Lee N. Characteristics of a nontreatment-seeking sample of over-the-counter codeine users: implications for intervention and prevention. *J Opioid Manag*. 2011 Oct;7(5):363–70.
12. Nielsen S, Cameron J, Pahoki S. Over the counter codeine dependence, Final Report 2010. Victoria, Australia: Turning Point Alcohol and Drug Centre; 2010 Jun p. 79. Available from: http://atdc.org.au/wp-content/uploads/2011/02/OTC_CODEINE_REPORT.pdf
13. Nielsen S, Murnion B, Dunlop A, Degenhardt L, Demirkol A, Muhleisen P, et al. Comparing treatment-seeking codeine users and strong opioid users: Findings from a novel case series: Comparing codeine and strong opioid users. *Drug Alcohol Rev*. 2015 May;34(3):304–11.
14. NVivo qualitative data analysis Software. QSR International Pty Ltd.; 2015.
15. Roussin A, Bouyssi A, Pouché L, Pourcel L, Lapeyre-Mestre M. Misuse and Dependence on Non-Prescription Codeine Analgesics or Sedative H1 Antihistamines by Adults: A Cross-Sectional Investigation in France. *PLOS ONE*. 2013 Oct 3;8(10):e76499.
16. 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 Oct 1;37(5):483–8.
17. United Nations Publication. The non medicinal use of prescription drugs. Discussion paper [Internet]. 2011 [cited 2017 Jan 24]. Available from: <https://www.unodc.org/documents/drug-prevention-and-treatment/nonmedical-use-prescription-drugs.pdf>
18. Van Hout, MC. Bergin, M. Foley, M. Rich, E. Rapca, AI. Harris, R. Norman I. A Scoping Review of Codeine Use, Misuse and Dependence, final report [Internet]. CODEMISUSED Project European Commission 7th Framework Programme, EU. Brussel; 2014. Available from: http://codemisused.org/uploads/files/Van_Hout_et_al_Scoping_Report_23-03-2015.pdf

Acknowledgements

Thank you to Dr Nicola Barnes for providing editorial guidance.

Role of the funding source

This study was funded by the University of Portsmouth.

Contributors

All authors were involved in the study design, had full access to the survey data and analyses, and interpreted the data, critically reviewed the manuscript and had full control, including final responsibility for the decision to submit the paper for publication.

Conflict of interest

Authors declared no conflict of interest.

Ethics

Authors confirm that the submitted study was conducted according to the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. All patients gave their informed consent to the anonymous use of their clinical data for this independent study.

Note

It is the policy of this Journal to provide a free revision of English for Authors who are not native English speakers. Each Author can accept or refuse this offer. In this case, the Corresponding Author preferred not to use our service.

Received September 8, 2017 - Accepted February 9, 2018

