

**ORIGINAL ARTICLE**

## **Over-the-counter medicine abuse – a review of the literature**

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### **Abstract**

*Background:* The sale of over-the-counter (OTC) medicines from pharmacies can help individuals self-manage symptoms. However, some OTC medicines may be abused, with addiction and harms being increasingly recognised. This review describes the current knowledge and understanding of OTC medicine abuse.

*Approach:* Comprehensive search of international empirical and review literature between 1990 and 2011.

*Findings:* OTC medicine abuse was identified in many countries and although implicated products varied, five key groups emerged: codeine-based (especially compound analgesic) medicines, cough products (particularly dextromethorphan), sedative antihistamines, decongestants and laxatives. No clear patterns relating to those affected or their experiences were identified and they may represent a hard-to-reach group, which coupled with heterogeneous data, makes estimating the scale of abuse problematic. Associated harms included direct physiological or psychological harm (e.g. opiate addiction), harm from another ingredient (e.g. ibuprofen-related gastric bleeding) and associated social and economic problems. Strategies and interventions included limiting supplies, raising public and professional awareness and using existing services and Internet support groups, although associated evaluations were lacking. Terminological variations were identified.

*Conclusions:* OTC medicine abuse is a recognised problem internationally but is currently incompletely understood. Research is needed to quantify scale of abuse, evaluate interventions and capture individual experiences, to inform policy, regulation and interventions.

**Keywords:** *Over-the-counter, abuse, medicines*

### **Background**

The mechanisms by which individuals can obtain medicines include not only their traditional prescribing by doctors, but also the ability to purchase medicines directly. The most obvious example of this is the community or retail pharmacy, where the metonymic term over-the-counter (OTC) originates and is used to describe such medicines. Such availability has been argued to offer benefits in terms of convenient access to, and choice of, medicines as well as involving individuals as active participants in their own health and the treatment

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of illness (Bond & Bradley, 1996; Nettleton, 2006). The range of medicines available is often more restrictive compared to prescribed medicines, and there are often limitations to indications and doses, although there has been a trend towards increasing deregulation of medicines from prescription to OTC supply and most recently availability from Internet pharmacies (Bessell et al., 2003). There has been a tendency for the public to perceive OTC medicines to be safer than prescription medicines (Bissell et al., 2001; Hughes et al., 2002; Raynor et al., 2007), but it has been recognised that OTC medicines have the potential for harm as well as benefit (Lessenger & Feinberg, 2008). This may result in what has been variously referred to as the misuse or abuse of OTC medicines and their potential to cause addiction and dependency. A number of specific OTC medicines and therapeutic groups have been implicated and in a recent review for doctors, for example, Lessenger and Feinberg (2008) suggested medicines such as stimulants, laxatives, sedatives and dissociative substances such as dextromethorphan as being liable to abuse. They noted that in relation to abused drugs, “the literature is sparse about OTC medicines” and their review tellingly omits opiate-based OTC analgesics. The latter are available for purchase in many countries and combine codeine or dihydrocodeine with either ibuprofen or paracetamol and have led to particular concerns about addiction and also gastric or hepatic damage, respectively (Reay, 2009; Frei et al., 2010).

As Lessenger and Feinberg (2008) noted, there is a relative lack of literature relating to OTC medicines that may be abused, and only one previous review has been undertaken (Reed et al., 2011); this was limited only to codeine-based OTC medicines and certain prescribed medicines and focused mainly on the context for England but similarly concluded that there was little current OTC evidence relating to the prevalence of misuse and dependence and treatment. The aim of this article, therefore, is to undertake a comprehensive review of the international empirical and other relevant literatures, to describe current knowledge and understanding about the range of OTC abuse. Specific objectives were to identify the different types of OTC medicines implicated, the scale of OTC abuse, the characteristics of those affected, harms associated with OTC medicine abuse and also approaches to dealing with it in terms of policy and interventions.

### **Review strategy**

A thematic literature review approach was adopted, since there were a range of questions identified which a systematic review would have been inappropriate for, and also because including both review and empirical literature was considered advantageous in mapping out the breadth of understanding in this area.

Initial searches were conducted using ISI Web of Science, CINAHL, EMBASE and Medline together with specific searches of journals such as the *Pharmaceutical Journal* using combinations of the following terms: “over the counter”, “OTC”, “medicine”, “drug”, “misuse”, “abuse”, “addiction”, “dependency” and “non-prescription”. Additional searches were then undertaken based on identified medicines, and these included “codeine”, “pseudoephedrine”, “dextromethorphan”, “antihistamine”, “laxative” and also specific products, such as “Nurofen Plus” or “Coricidin”, for example, as they were identified in the literature. Reference lists of included publications were also checked and further searching was undertaken as a result. Additional grey literature was explored by strategies such as extensively contacting researchers in the field, to identify current research and non-peer-reviewed research publications. Additional non-peer-reviewed journal literature such as official organisation documents were also identified by searching OpenSIGLE, key organisations such as the Royal Pharmaceutical Society of Great Britain, the Medicines

and Health Care products Regulatory Authority and the Proprietary Association of Great Britain together with more general searches of common search engines such as Google. Searches were undertaken for publications from 1990 to 2011 and inclusion criteria included publications published in English, empirical, review or opinion pieces. Exclusion criteria included non-English language publications and reference exclusively to prescribed or illicitly obtained medicines. Prescribed medicines were specifically excluded since, whilst this represents an important category, it covers very different mechanisms of governance.

### **Literature review findings**

A total of 53 publications were identified, including 25 empirical studies, 11 case reports, 11 reviews articles, 1 book chapter, 1 doctoral thesis, 1 parliamentary enquiry and 3 key publications from organisations. The empirical studies represented 10 countries, with the United Kingdom (England, Wales, Scotland and Northern Ireland) being the most studied, followed by the United States (Table I). The earliest identified study was conducted in 1996. A range of methods had been used in empirical studies, with various scales of surveys being most commonly used, as well as primary data collection of treatment centres and secondary data collection of emergency department presentations. Qualitative methods were identified in only two empirical studies and several studies reported on findings from pilot stages only (Fleming et al., 2004; Sweileh et al., 2004; Orriols et al., 2009). The findings are now described in more detail, organised in relation to the objectives described earlier – types of medicine implicated, scale of OTC abuse, associated harms, characteristics of those affected and approaches to dealing with OTC abuse – with an additional theme relating to terminology also being included.

#### *Medicines implicated in OTC abuse*

OTC medicine abuse was identified in many countries and although implicated products varied, five key groups emerged: codeine-based (especially compound analgesic) medicines, cough products (particularly dextromethorphan), sedative antihistamines, decongestants and laxatives. This variation may be related to both geographical variation and methodological and study design factors.

Geographical variation was evident and different products were subject to abuse in different countries. This appeared to be associated with variation in the availability of products, such as codeine-based analgesic or cough medicines in several countries but not in the United States, for example; specific trends, such as adolescent dextromethorphan abuse in the United States; and variation in regulation, such as availability of prescription medicines for purchase in some countries. In Jordan, for example, antibiotics and benzodiazepines were commonly cited by pharmacists as being abused, as regulations restricting their supply were not always enforced (Albsoul-Younes et al., 2010). Despite such international variation, common themes emerged and this Jordanian study typified several others in identifying five key groups of non-prescription medicines that were implicated in OTC abuse namely: sympathomimetic decongestants, cough products, analgesics, antihistamines and laxatives (see Table II). These reflected a similar categorisation made by Matheson et al. (2002) and MacFadyen et al. (2001), who identified Nytol (a brand of diphenhydramine, an antihistamine) as the product of misuse most suspected by pharmacists in Scotland, and, like Hughes et al. (1999b), these were broadly similar to the methodological design of studies such as Orriols et al. (2009), who grouped their survey of pharmacy customers into whether they purchased codeine (an analgesic), dextromethorphan (a cough suppressant),

Table I. Summary of empirical studies

Authors	Study aims	Design	Sample	Participants	Results
Paxton and Chapple (1996)	To establish the number and kinds of people affected by OTC medicine misuse, medicines involved, pharmacists' concerns and policies.	Postal questionnaire (no details provided).	All 60 pharmacies in Northumberland, England in 1994.	39 pharmacists (65%) responded.	69% of pharmacists considered there to be some form of OTC medicine misuse in their pharmacies. Female customers were perceived to be more likely to misuse, and Gee's linctus, codeine linctus or tablets, kaolin and morphine and laxatives were the most commonly cited medicines involved. Most pharmacists had 'concerns' about OTC misuse and 62% of pharmacists reported having associated policies including pharmacist interviews, not displaying medicines and refusing sales. Around 2/3 of pharmacies did not communicate with other pharmacies.
Mattoo et al. (1997)	To study socio-demographic and clinical profiled of patients seeking treatment for codeine-based cough medicines in India.	Observational case series; semi-structured interview. No pilot stated.	Patients seeking treatment in hospital addiction centre in Chandigarh in 2004–2005.	All 46 eligible patients identified from the total of 126 opioid abusers participated.	Participants with codeine-based cough medicine dependency were all male, from mainly urban backgrounds (80%) and have completed school education (85%). Initial use was most common through friends (89%) with 11% citing pharmacists or doctors as the source of their supply. Curiosity was the most common reason given for initial use (63%), followed by substitution due to non-availability of another medicine (22%) and treatment of symptoms (15%). Participants reported a range of pleasurable effects, including alertness, cheerfulness and subsequent drowsiness; 92% experienced withdrawal symptoms.

Table I. (Continued)

Authors	Study aims	Design	Sample	Participants	Results
Hughes et al. (1999b)	To investigate the abuse of OTC products in Northern Ireland.	Cross-sectional postal questionnaire. One follow-up mailing piloted, with minor amendments made.	All 509 Northern Ireland community pharmacies in 1997.	253 responses (49.7% response rate).	112 different OTC products identified by pharmacist respondents as being abused in Northern Ireland, with a mean of 6.8 products noted per pharmacist. Opioids were the most common group mentioned (on 878 occasions) and Kaolin & Morphine mixture was the most commonly named product (81.4%, $n = 206$ ). Antihistamines were the next most frequently identified (364 times), followed by laxatives. Clients suspected of abusing in the last 3 months ranged from 0 to 700, with a median estimate of 10 and a mode of 6; 55% of such clients were considered regular. No statistical link to pharmacy location and extent of OTC problem. Hiding products, contacting other pharmacies were reported as strategies to deal with the problem and when asked about pharmacists' role in OTC abuse, 67.2% considered referral to a GP appropriate, 40.3% to a drug and alcohol team appropriate and 64.4% felt pharmacists should be involved in a dedicated harm-reduction programme.
Hughes et al. (1999a)	To assess the attitudes of GPs regarding the appropriateness of OTC medication use by their patients.	Cross-sectional postal survey. No pilot stated.	Stratified random sample of 500 GPs in Northern Ireland. One repeat mailing.	202 GPs responded (40.7%).	Majority of GPs (97%) believed OTC medicines were valuable for self-limiting conditions; 91% were concerned about abuse/misuse potential of OTC medicines; and 73.3% felt these consequences were as severe as prescription problems. Almost 80% of GPs felt they required training in such issues; increased communication between health care professional was identified.

Table I. (Continued)

Authors	Study aims	Design	Sample	Participants	Results
MacFadyen et al. (2001)	To explore the type of OTC medicines being abused and pharmacist attitudes, management and training needs.	Cross-sectional postal survey, 2 reminders and 1 follow-up survey sent in 1998. Survey informed by unreported qualitative study.	All 110 pharmacies in one region of Scotland.	86 responses obtained (79%).	58% reported occasional and 31% frequent misuse, with more problems reported in urban than in rural pharmacies. Perceived prevalence of misuse varied with 45% reporting only 1–2 patients per typical week, 21% reporting 3–4; estimated mean was 5.63. Nytol (79%), laxatives (58%), paracetamol and codeine products (55%) commonest products involved. Frequent requests (100%), counter-assistant concerns (78%), particular products (64%) and suspicious behaviour (45%) identified as alerting factors by pharmacists. Interventions always or often made by 72% of pharmacists, using information provision, removing products from sight, communicating with other pharmacies and medical referrals. More support wanted.
Matheson et al. (2002)	To identify 5-year trends in local misuse of OTC medicines.	Two cross-sectional postal surveys in 1995 and 2000.	1091 and 1162 Scottish community pharmacists.	864 (79.1%) in 1995 and 969 (83.4%) in 2000.	Extent and pattern of misuse unchanged over period – 67.8% ( $n = 586$ ) in 1995 and 68.5% ( $n = 669$ ) of pharmacists considered there to be OTC abuse in their area. Nytol remained commonest product and was cited by around half of all pharmacists, then Feminax and Kaolin and morphine. Hiding products, registers of sales, increased pharmacist intervention identified as sales policies.

Table I. (Continued)

Authors	Study aims	Design	Sample	Participants	Results
Pates et al. (2002)	To investigate pharmacist perceptions of OTC misuse, identify products used, alerting factors and strategies used.	Survey of all pharmacies in Welsh health authority in 2000.	180 community pharmacies.	161 (89%) responded.	66% of pharmacists believed there was current OTC misuse, 19% disagreed; mean of 4.5 attempts to misuse OTC product per pharmacy identified in previous month. Opioids most commonly suspected (57%, $n = 217$ ), then sleep aids (16%, $n = 61$ ) and laxatives (10%, $n = 37$ ). Frequency of request (85%, $n = 59$ ), customer behaviour/state (11%, $n = 18$ ) or appearance (11%, $n = 18$ ) identified as alerting factors. Refusals or out of stock excuses commonest strategy (63%, $n = 66$ ), then counselling (32%, $n = 33$ ). Referral to GP, removing stock, monitoring or limiting sales also mentioned.
McBride et al. (2003)	To explore expert views on OTC abuse, current, future strategies and best practice.	Modified three-stage Delphi design using postal survey.	164 international experts.	109 (66%) recruited and 47 completed all stages.	Consensus reached in key areas such as improving staff training, access to information, and concerns about non-pharmacy and Internet supplies and commercial pressure. Improved coordination and communication essential to implementation. Barriers included staff changes, time pressures, gaining full cooperation, lack of deterrence to those addicted and industry factors.
Myers et al. (2003)	To provide community-level surveillance information of OTC and prescription medicine misuse.	Retrospective study of patients attending substance abuse centres over 6 months periods (1998–2000) using form to collect patient data, drugs used and use patterns.	9063 forms collected from 23 centres in Cape Town, South Africa.	N/A	710 (7.8%) of cases included OTC, prescription or unspecified medicines. Of these, 239 (33.7%) used medicines as primary drug of abuse, and OTC specific use of codeine was identified in 17 cases (29.8%) of these. With 25 (43.9%) being from prescription and 15 (26.3%) being unspecified.

Table I. (Continued)

Authors	Study aims	Design	Sample	Participants	Results
Akram and Roberts (2003)	To determine how pharmacists respond to requests for over-the-counter (OTC) medicines by patients on a methadone maintenance programme.	Cross-sectional postal survey.	All 213 community pharmacists in Glasgow health board, Scotland.	153 of 167 pharmacists providing methadone responded (92%).	Methadone patients sought advice on colds, GI problems and headaches most frequently, and requested codeine/paracetamol analgesics, other analgesics and antacids most frequently. 62% of pharmacists ( $n = 93$ ) had refused sales, with Nytral (diphenhydramine) the most common, but also codeine-containing analgesics and codeine linctus. Night Nurse, Sudafed and Benlylin also denied. 15% ( $n = 23$ ) of pharmacists had supplied abusable product to avoid problems/trouble. Pharmacists perceived methadone patient requests not to be genuine on occasion.
Fleming et al. (2004)	Develop and pilot a harm-minimisation model for identification and treatment of OTC medicine abuse/misuse by community pharmacists.	Observation of model developed using expert conference discussion local stakeholders consultation; records analysed from participating pharmacies trained in using model.	Two pharmacies.	N/A	18 clients identified during 1 month of pilot (10 in one pharmacy, 8 in the other), of whom 3 were already known to the pharmacist as being suspected of abusing medicines. 14 were challenged and some success reported in initiating change; no clients were successfully enrolled into the harm-minimisation scheme.
Hughes et al. (2004)	To estimate the amount of misuse of and dependence on nicotine gum in OTC setting.	Cross-sectional telephone survey, eliciting views on past and current use of nicotine gum in first study and questions based on dependency diagnostic criteria from DSM-IV and ICD-10. No pilot mentioned.	Public and pharmacy customers in five US states in 2000 approached via adverts.	In first part of study, 351 contacts led to 266 participants. In second study, 139 contacts led to 100 participants.	Around half (46%) of respondents in study 1 had used gum longer than 3 months; 20% of those using gum for more than 90 days attributed use to addiction. In study 2, 66% of respondents met DSM-IV dependency criteria and 74% the ICD-10 criteria. Overall incidence of dependence of nicotine gum was estimated as 0.7–1.4% using data from another study.



Table I. (Continued)

Authors	Study aims	Design	Sample	Participants	Results
Agaba et al. (2004)	Use and abuse of analgesics in Nigeria.	Cross-sectional community survey using structured face-to-face interview. Pretested in pilot.	Two-stage random sampled using residents of Zawan B ward district of Jos, Nigeria.	600 subjects enrolled, but 80 invalid responses.	312 (60%) of participants reported regular (twice a week for 2 months or greater) use of analgesics; 76% obtained by self-medication. Commonest indications were for rheumatical complaints (89%) and headache (67%). Paracetamol commonest medicine (58%), with 28.9% reporting compound analgesic use. Analgesic abuse (defined in study as cumulative lifetime use of > 5000 doses) was identified in 22.6% of participants.
Sweileh et al. (2004)	To obtain information from Palestinian community pharmacists about perceptions of OTC medicine abuse, suspected customer types and solutions.	Questionnaire, section related to demographics and customers suspected of abuse.	All 111 pharmacies in Nablus district, Palestine.	97 valid responses obtained.	2/3 of respondents perceived an increase in suspected OTC misuse or abuse due to instability in region, and that majority were not regular customers. 80% of pharmacists identified antitussives as being of misuse/abuse potential, 70% identified analgesics, 41% antihistamine problems and 67% laxative misuse/abuse. Male customers were perceived more likely to abuse or misuse OTC medicines in all categories except laxatives and the 20–40 age range was most commonly identified. Informing the customer's doctor, hiding products and informing customers of abuse potential were identified as strategies to reduce problem.
Wazaify et al. (2005)	To investigate general public's opinion and perceptions of OTC medicines.	Cross-sectional survey using structured interviews.	1000 members of public interviewed in 10 shopping centres over 10 weeks in 2002.	N/A	OTC purchases were cited by 11.3% of participants as reason to visit pharmacy. 76.4% of participants reported painkillers as always being kept in stock at home; 14.7% of participants strongly agreed; and 65.2% agreed that some OTC medicines could cause dependency or addiction if take over time. Almost 1/3 ( $n = 298$ ) reported having personally encountered OTC abuse (based on personal experience, knowledge or observation). Younger participants were more likely to report this. Paracetamol ( $n = 106$ ) was the most reported medicine liable to abuse, followed by Paracodol ( $n = 37$ ) and co-codamol ( $n = 30$ ).

Table I. (Continued)

Authors	Study aims	Design	Sample	Participants	Results
Bryant-Waugh et al. (2005)	To determine the availability of laxatives and pharmacists' and other retailers' awareness and responses to laxative misuse.	Cross-sectional survey of retailers (pharmacies, supermarkets, health food shops) of laxatives near to eating disorder treatment centre.	293 retailers sent survey by post. No date specified.	53 retailers (18.1%) responded.	20 retailers (37.7%) reported selling laxatives, including all pharmacy respondents but only 1 of 31 conveniences or newsgagent categorised retailers. Awareness of abuse potential varied and was not limited only to pharmacies. Only 3 pharmacies had a protocol for supervising sales of laxative, but 18 retailers had at least one policy and these included age restrictions, limiting quantities sold and involving the pharmacist routinely. Responses to suspected misuse involved limiting supply rather than advice.
Wazaify et al. (2006)	To develop a harm-minimisation model for identification and treatment of OTC medicine abuse/misuse by community pharmacists.	Retrospective study of all queries and sales of OTC medicines recognised as having abuse potential (opioid, antihistamine, laxative).	Eight pharmacies in Belfast.	N/A	Over 7 weeks, average of 6.8 clients per pharmacy suspected of abuse, and 4.8 of misuse. Opioids ( $n = 25$ ), most commonly identified (and were most often requested by male clients), then antihistamines ( $n = 11$ ) and laxatives ( $n = 5$ ) (all requested by women). More than half (58.5%) of clients were regarded as strangers rather than regular customers.
Steinman (2006)	To estimate the prevalence of adolescent misuse of OTC drugs, identify misuse of other substances and demographic/psychosocial characteristics of OTC misuse.	Census of students in US county using survey in 2003. Focus groups used to address validity. Frequency of OTC medicine misuse assessed with one question.	39,345 students.	4.7% of students reported misusing OTC drugs occasionally (which included responses to either one or twice a year as used, but not in past year), with a further 2.1% reporting misuse in the previous month. Females misused OTC medicines more than males, as were those who also reported using alcohol and other illicit drugs. Depressive effect and violent behaviour were positively associated with OTC misuse, and Native American youths reported the highest level of OTC misuse, with African Americans reporting the lowest.	

Table I. (Continued)

Authors	Study aims	Design	Sample	Participants	Results
Ajuoga et al. (2008)	To investigate the use and misuse of OTC medicine in HIV-infected patients and determine related adverse drug events (ADE).	Cross-sectional self-administered pre-piloted, questionnaire (demographic and attitudinal data) and semi-structured interview (on medicine use, frequency, side effects). Expert panel judged on abuse.	HIV-infected adult patients at Houston, US hospital. Convenient sample of every third clinic patient having prescription filled.	215 patients responded from 338 approached (63.6%).	Analgesics/antipyretic OTC medicines were the most commonly used (64.2%) and non-steroidal anti-inflammatory the most common type. 80 (37.2%) respondents misused OTC medicines on 149 reported occasions, as judged by the panel, by duration (46.3%, $n = 69$ ), dose (45.6%, $n = 68$ ) and condition (8.1%, $n = 12$ ) misuse, respectively. 16.7% ( $n = 36$ ) of participants reported ADEs.
Orriols et al. (2009)	To explore the feasibility of pharmacoepidemiological methods and to investigate misuse of self-medicated drugs.	Cross-sectional pilot survey of patients requesting medicines from pharmacies assigned into one of five therapeutic groups (codeine, dextromethorphan, pseudoephedrine, antihistamines and control).	74 pharmacies (from 228 solicited in one French region) distributed 817 surveys over 2 months in 2007.	530 participated (64.9%) with 491 valid surveys.	48.9% ( $n = 240$ ) of patients had used the medicine in previous month, with 49.2% having informed their doctor of such use; 38.8% had started use on medical advice, 27.5% on pharmacist advice. Of those who used codeine-based products in the last month, 15% (8/53) were misusing, 7.5% (4/53) were abusing and 7.5% (4/53) were dependent – all statistically significant. No abuse identified for dextromethorphan, one case for pseudoephedrine, and none for antihistamines.
Björnsdóttir et al. (2009)	Mapping Icelandic people's definitions of drugs/medicines.	Focus groups.	Members of the public in Iceland, identified as rural/urban dweller, and lay/educated (teaching, ICT, midwifery).	42 participants in 8 focus groups; 4 lay, 5 urban, 4 rural, 4 professional.	Slight variation in definitions of medicines emerged but participants recognised categories such as OTC, prescription, illicit, vitamin/herbal although often chose to conflate drugs as being from any source. Some participants expressed concern about side effects and abuse and misuse potential of medicines, including OTC medicines. More information about medicines was suggested as being needed. The Internet was identified as a source of medicines but rejected, and considered suitable for information in the main.

Table I. (Continued)

Authors	Study aims	Design	Sample	Participants	Results
Nielsen et al. (2010)	To understand who is at risk of developing dependence to OTC codeine, and how products are used.	On-line survey of codeine users, qualitative interviews with codeine-dependent people and key experts.		800 valid survey responses (from 909 respondents), 20 interviews with codeine-dependent people and 14 key experts.	17% ( $n = 138$ ) survey respondents were codeine-dependent, and around 3/4 had not sought help. Doses at 10 times the recommended maximum were reported. Interviews suggested three types of codeine user: therapeutically dependent on doses not above recommended maximum, recreational users and high-dose-dependent users. Participants viewed OTC medicines as different to other drugs, and themselves as different from other drug users. Key experts perceived older females to be typical, pharmacists used appearance to describe those affected and barriers to treatment involved user's lack of insight. Raising awareness, training pharmacists and over-coming barriers to treatment recommended.
Albsoul-Younes et al. (2010)	To investigate abuse/misuse of prescription and non-prescription drugs in pharmacies in Jordan.	Cross-sectional survey using structured questionnaire in 2005–2006.	Random sample of 405 pharmacies in Jordan.	N/A	Most respondents (94.1%) suspected some abuse/misuse in their pharmacy, with decongestants, cough/cold products, benzodiazepines and antibiotics most commonly cited. Current controls are ineffective.
Major and Vincze (2010)	Survey self-reported use of OTC medicines and understanding of abuse potential amongst people who visit Hungarian pharmacies.	Structured face-to-face questionnaire of 25 questions. No details given. Piloted with 50.	2000 surveys distributed at 25 geographically varied Hungarian pharmacies in 2008.	1486 completed surveys and 65 returned not valid.	81.7% of respondents thought OTC medicines could be abused and more than half (782) were not able to suggest solutions: 1089 named at least one product or category, 180 named 2 and 45 named 3. Most frequently identified were painkillers, sleep aids and cough medicines. Almost 1/3 of respondents identified specific brands. 536 respondents reported having personally encountered OTC medicine abuse; women were statistically more likely to identify weight loss medicines.

Table I. (Continued)

Authors	Study aims	Design	Sample	Participants	Results
Gonzales et al. (2010)	To examine treatment admission patterns to addiction system for primary abuse of prescription and OTC drugs, differentiating between adolescents and adults.	Cross-sectional descriptive study using data captured for all treatment admissions to public addiction services. Data included drug use and demographic information.	216,716 admissions were identified in this period for individuals aged 12 or over in California, USA, in 2006–2007.	N/A	Prescription and OTC medicines accounted for 6841 (3.2%) of admissions, with adolescents (12–18-year-olds) accounting for 1.5% of overall admissions. OTC medicines represented 1.9% ( $n = 139$ ) of total of prescribed and OTC medicine admissions and were statistically more likely to be reported by adolescents, who were more likely to cite 'self' for referral to treatment than older clients, who cited 'others' more often.

Note: OTC, over-the-counter; GP, general practitioner.

Table II. Examples of medicines/therapeutic groups implicated in OTC abuse

Medicine/therapeutic group	Countries identified
Codeine or other opiate containing products (compound analgesics, cough medicines)	Australia, France, Jordan, India, Hungary, Palestine, UK, South Africa
Non-opiate cough medicines (e.g. dextromethorphan)	France, Hungary, USA
Sedative antihistamines (e.g. diphenhydramine)	France, Hungary, Jordan, UK, USA
Decongestants (e.g. pseudoephedrine)	France, Jordan, UK, USA
Laxatives	France, Jordan, UK
NRT	USA

Note: OTC, over-the-counter; NRT, nicotine replacement therapy; GP, general practitioner.

pseudoephedrine (a decongestant) or an antihistamine. Cough products (and especially dextromethorphan) appeared to be the focus of several studies and data from the United States (Steinman, 2006; Levine, 2007; Peters et al., 2007; Substance Abuse and Mental Health Services Administration, 2008; Ford, 2009).

Methodologically, studies varied as to whether they focused on a particular product or sought to capture the range of products involved. It was also apparent that sampling influenced the emergent data, and, for example, studies that used pharmacists appeared to generate more detailed and varied descriptions of medicines that may be abused or misused (Hughes et al., 1999b; Matheson et al., 2002) compared to patient/customer/public accounts (Wazaify et al., 2005; Ajuoga et al., 2008; Major & Vincze, 2010), reflecting pharmacists' knowledge of products and brands.

*Scale of OTC medicine abuse.* Attempts to describe the extent of OTC medicine abuse have been made using a variety of methods and data sources, which were often geographically related, but reflected heterogeneous participant groups and data. These included pharmacists' perceptions of abuse (often in UK studies), data from drug treatment centres and poisons centres (e.g. in the United States), sales of codeine-containing medicines, perceptions of members of the public and self-reported abuse from specific groups such as US adolescents and gym users. The heterogeneous nature of these data sources makes assessing the international scale of OTC medicine abuse difficult to determine and making comparisons between countries difficult.

Data relating to the United Kingdom have been obtained from various sources. One of the most frequently referred to in the literature (Phelan & Akram, 2002; Ford & Good, 2007; Reay, 2009) involved the data reported from the UK-based on-line support group, *Overcount*, indicating the number of individuals who have registered with the site. This figure had been quoted as ranging from "more than 4000" (Ford & Good, 2007) to 16,000 (Reay, 2009), but specific details of the data were not provided in either source and no further information about it were identified in this review. Several UK studies have explored the experiences and perceptions of pharmacists in relation to OTC medicine misuse and abuse and estimates of the extent of the problem were presented as a result. The earliest identified study involved a postal survey of pharmacists in a county in England (Paxton & Chapple, 1996), which reported that 69% of pharmacists considered there to be some form of OTC medicine misuse in their pharmacies. Matheson et al. (2002) reported on two postal surveys of pharmacists in Scotland undertaken in 1995 and 2000, which reported pharmacists' belief that OTC product misuse was occurring in their area as 67.8% and

68.5%, respectively. Also involving Scottish pharmacists and a postal survey, MacFadyen et al. (2001) reported that 31% of pharmacists perceived there to be frequent misuse and 58% perceived occasional misuse. This study also estimated that a mean of 5.6 patients were suspected of misusing medicines for each pharmacy in an “average week”, with the maximum being 40 in one pharmacy. In Wales, Pates et al. (2002) also used a postal survey design and reported that 66% of respondents believed the presence of a problem in their area. In Northern Ireland, Hughes et al. (1999b) reported that pharmacist estimates of abuse in the previous 3 months ranged from 0 to 700, with a median of 10 and a mode of 6. Wazaify et al. (2006) reported that six pharmacists identified 196 clients suspected of OTC abuse/misuse over 6 months. Geographically, urban pharmacies were associated with more suspected abuse than rural ones in two Scottish studies (MacFadyen et al., 2001; Matheson et al., 2002) and Mattoo et al. (1997) reported that of those attending a clinic in India for addiction to codeine cough syrups, 80% were urban residents. Others studies identified no difference (Hughes et al., 1999b).

Data relating to the United States have been reported from a range of sources, ranging from specifically collected national level data, to surveys of specific groups, such as gym users, nicotine gum users and high school students. The Annual National Survey on Drug Use and Health (NSDUH) has provided data relating to specific issues such as, for example, abuse of OTC cough medicines amongst adolescents (Substance Abuse and Mental Health Services Administration, 2008), which revealed that in 2006 around 3.1 million people aged 12–25 stated that they had used an OTC cough and cold medicine to “get high” for a non-medical reason. This appeared to involve dextromethorphan, a cough suppressant, in 140 different products. Emergency department admissions were used by the Drug Abuse Warning Network (DAWN) to provide national-level data relating to the involvement of dextromethorphan in admissions (Substance Abuse and Mental Health Services Administration, 2010). This revealed that for 2004 0.7% ( $n = 12,584$ ) of all emergency department admissions involved dextromethorphan and that the rate of visits was significantly higher amongst adolescents (aged 12–20) than other age groups. The third national-level data collected in the United States involved that collected in the treatment episode data set (TEDS) for treatment admissions by the Drug and Alcohol Services Information System (DASIS) (Substance Abuse and Mental Health Services Administration, 2004). Data from 2002 revealed that, as primary sources of abuse, only 4% of the 1.9 million admissions related to prescription or OTC medicines, which were described as including cough products, aspirin, sleep aids, diphenhydramine and other antihistamines. Of these, OTC medicines accounted for only 1% ( $n = 600$ ) of admissions, and the authors noted that:

OTC medications are relatively rare as primary substances of abuse. They are more commonly noted as secondary or tertiary substances of abuse upon admission. (Substance Abuse and Mental Health Services Administration, 2004)

A more recent study from the United States also used drug treatment admissions (Gonzales et al., 2010), but reported on the state of California only. Prescription and OTC medicines in this study accounted for 6841 (3.2%) of admissions, with adolescents (12–18-year-olds) accounting for 1.5% of overall admissions. As in the above national-level study, the Californian study found OTC medicines to be relatively low, representing only 1.9% ( $n = 139$ ) of the total prescribed and OTC medicine admissions. These were found to be statistically more likely to be reported by adolescents, who were more likely to cite “self” for referral to treatment than older clients, who cited “others” more often. The authors identified methodological concerns about the recording of such data, noting that OTC and

prescription medicine recording by treatment staff was inconsistent, and may be due to not only the relatively recent inclusion of such data but also two further factors:

First, new prescription and OTC medications come on the market frequently. Second, there is wide variability in prescription and OTC drugs in relation to brand names, generic names, chemical names, and street names, which can change over time. (Gonzales et al., 2010)

Steinman (2006) focused on the adolescent US population and surveyed 39,345 high school students in one county and reported 4.7% as having occasionally misused OTC medicines, with 2.1% reporting use in the past month; the study did not explore the types of product involved. Hughes et al. (2004) identified 20% of those using nicotine replacement therapy (NRT) gum for more than 90 days as being addicted, and Ajuoga et al. (2008) identified 37.2% of HIV positive patients as misusing OTC products. Kanayama et al. (2001) used data from a survey of gym users and national data on fitness club membership to estimate a national incidence of 1.5 million individuals using adrenal hormones and 2.8 million using ephedrine.

The situation in Jordan was studied by Albsoul-Younes et al. (2010), who adopted similar methods to UK studies, and found that 94.1% of pharmacists suspected some abuse or misuse of OTC products, and a mean estimate of “abusers” in the last 3 months per pharmacy to be 18.6 for regular, and 15.4 for new customers. From a total of 710 patients attending treatment clinics in Cape Town, South Africa in a 6-month period, Myers, Siegfried and Parry (2003) identified 17 cases involving OTC codeine abuse.

Wazaify et al. (2005) surveyed members of the public in Northern Ireland and described almost one-third of participants as having personally encountered OTC abuse (based on either personal experience, knowledge or observation). The most recent study identified (Nielsen et al., 2010) involved an on-line survey of 909 Australian individuals who used codeine and identified 138 (17.3%) as being “likely to be codeine dependent” using a severity of dependence scale. Two studies sampled pharmacy customers: in France, Orriols et al. (2009) questioned 53 pharmacy customers using surveys about their codeine use in the previous month and identified 15% as misusing, 7.5% as abusing and 7.5% as being dependent. Major and Vincze (2010) randomly surveyed pharmacy customers in Hungary and reported that almost one-third had personally experienced OTC abuse. With a specific focus on analgesic use, Agaba et al. (2004) randomly sampled an area in Nigeria and reported analgesic abuse in 22.6% of respondents. They collected data on patients’ self-reported weekly use and overall duration and defined abuse as being a cumulative lifetime use exceeding 5000 “pills”.

OTC medicine sales data were identified in two reviews. Almarsdóttir and Grimsson (2000) used secondary data and reported on a significant rise in codeine sales between 1993 and 1998 in Iceland and attributed this not to the hypothesised influence of legislative changes but to an increased Western consumption of medicines generally or more specifically OTC codeine abuse reporting by treatment centres. Reed et al. (2011) reported on national UK sales data relating to codeine-containing OTC medicines from a trade association. Data indicated that 21.4 million packs of codeine-containing OTC medicines were sold during 2008. This represented an increase from 19.5 million packets in 2006 but trends were not identifiable due to the limited data available.

Who is addicted to OTC medicines? Data relating to those who may be addicted to OTC medicines were obtained from several different sources. Several studies relied on the



perceptions of pharmacists, whilst others relied on sampling the public, pharmacy customers or those suspected of actual abuse. Several studies analysed the case reports obtained from addiction centres. Overall, there was no consensus as to who may be affected by OTC medicine abuse. Amongst the first type, Akram (2000) summarised several early UK studies as involving “middle-aged females”, whereas Albsoul-Younes et al. (2010) reported that Jordanian pharmacists perceived the majority of abusers to be 26–50-year-old males. Similarly, Sweileh et al. (2004) reported pharmacists as perceiving males to be more likely products than females in all categories except laxatives, in the 20–40-year-old age range. Other studies provided more equivocal pharmacist perceptions, and Pates et al. (2002) noted that 54% of pharmacists considered all types of people to be suspected of OTC misuse, although female customers were more likely to be suspected of abusing or misusing laxatives. Of the remainder, there was variation in the ages suspected and Ajuoga et al. (2008) found no association between OTC product misuse amongst HIV positive US patients and age, gender, ethnicity or education status.

Some studies, however, did include designs that permitted the collection of demographic data. Myers et al. (2003), for example, examined details of patients attending a drug treatment centre in Cape Town, South Africa. It should be noted that in this study, although some data pertained to an OTC-specific medicine (codeine), the main findings did not present OTC medicines and those on prescription separately. This was also the case for data collected in the United States by the DAWN (Substance Abuse and Mental Health Services Administration, 2010). Steinman (2006) reported that female students misused OTC medicines more than males, and misuse was also higher amongst older white students and Native American youths. Agaba et al. (2004) reported those abusing analgesics to be slightly older than those who did not abuse. Nielsen et al. (2010) compared codeine-dependent users and codeine users and, although not reporting any statistical data, found the former to be younger, with lower educational level, less likely to be in full-time employment but more likely to have used illicit substances and had family history of alcohol or drug problems.

Harms related to OTC medicine abuse. A range of problems and harms associated with OTC medicine abuse were identified and these comprised three broad categories (Fig. 1). First, there were direct harms related to the pharmacological or psychological effects of the drug of abuse or misuse. Second, there were physiological harms related to the adverse effects of another active ingredient in a compound formulation. Both these types of harm led to concerns about overdoses and presentation at emergency services. Third, there were those harms related to other consequences, such as progression to abuse of other substances, economic costs and effects on personal and social life. Direct harms included addiction and dependence to an opiate such as codeine (Mattoo et al., 1997; Orriols et al., 2009; Nielsen et al., 2010). Other direct problems included convulsions and acidosis due to a codeine and antihistamine (diphenhydramine) containing antitussive medicine (Murao et al., 2008) and tachycardia, hypertension and lethargy due to abuse of Coricidin cough and cold tablets (dextromethorphan and chlorphenamine) (Banerji & Anderson, 2001). Lessinger and Feinberg (2008) produced a comprehensive list of physical findings of nonmedical use of abused OTC products, noting agitation with nicotine gum, caffeine and ephedra, priapism with ephedrine and pseudoephedrine, psychiatric effects with dextromethorphan, euphoric psychosis with Coricidin and chlorphenamine and gastrointestinal disturbances with laxatives. Also within this category of direct harms were concerns raised about chronic rebound headache associated with repeated use of analgesics.

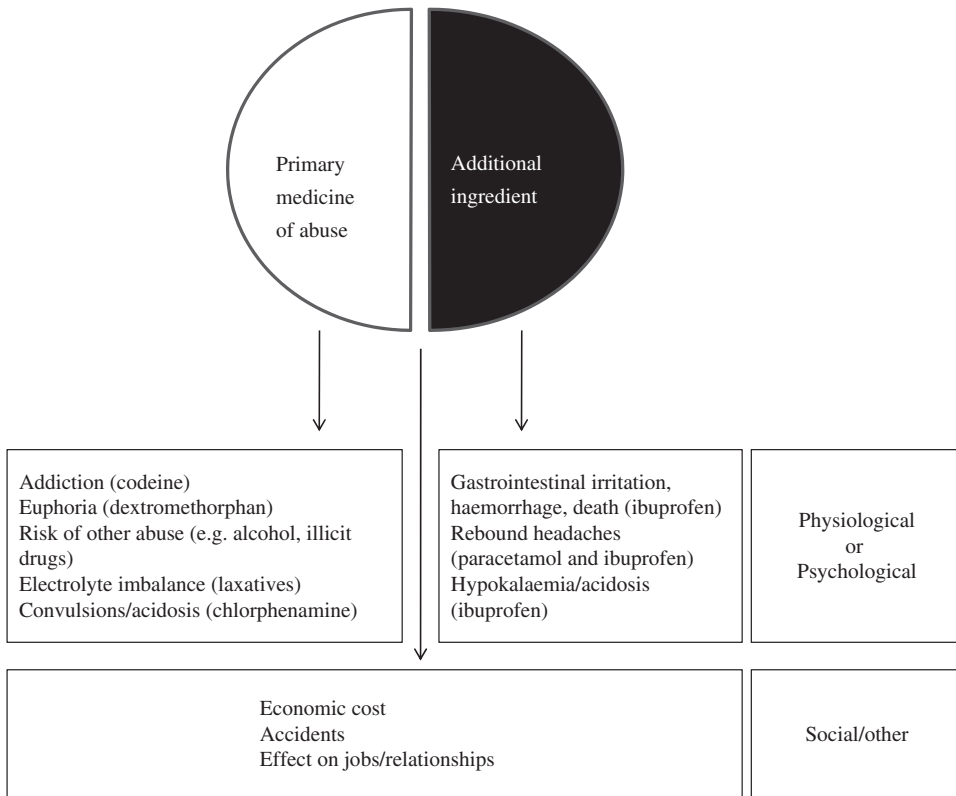


Figure 1. Examples of types of harm associated with OTC medicine abuse.

In relation to harms from other ingredients, two analgesic combination products – paracetamol and codeine (co-codamol) and ibuprofen and codeine – were considered problematic, with ibuprofen-containing medicine being particularly highlighted (Chetty et al., 2003; Dyer et al., 2004; Lambert & Close, 2005; Ford & Good, 2007; Dobbin & Tobin, 2008; Dutch, 2008; Ernest et al., 2010; Frei et al., 2010; Robinson et al., 2010). Dutch (2008) and Ford and Good (2007) reported on two hospital and three primary care presentations, respectively, of patients who had used a combination analgesic containing ibuprofen and codeine. Ford and Good (2007) noted the side effects relating to ibuprofen and Dutch (2008) reported both patients having perforated gastric ulcers. Hypokalaemia secondary to renal acidosis was identified as a result of abuse of this combination product (Chetty et al., 2003; Dyer et al., 2004; Lambert & Close, 2005; Ernest et al., 2010). Dobbin and Tobin (2008) reported on 77 cases reported through personal networks of one of the authors where harm and dependence to ibuprofen and codeine OTC products had occurred. They identified similar clinical presentations as noted above and one death.

In relation to other consequences, several studies have referred to the association of OTC medicine abuse and the use of illicit substances (Levine, 2007; Reay, 2009) or obtaining codeine supplies from “street” supplies (Sproule et al., 1999). Tinsley and Watkins (1998) reported on seven patients with dependence (according to DSM-IV criteria for amphetamine-like abuse) to ephedrine or pseudoephedrine and reported adverse social consequences in relation to losing jobs, family-marital stresses, relapse into alcohol misuse, motor vehicle violations and accidents.

Interventions and support. A range of strategies were identified that were aimed at minimising the harm associated with OTC medicine abuse, and supporting and treating affected individuals, although there was no evidence of any associated evaluation of these. Strategies ranged from pharmacy-based approaches reported by pharmacists in their actual work, to suggested interventions such as increasing awareness of the problem, providing additional training, to allowing pharmacists to provide treatment withdrawal programmes.

Many empirical studies that surveyed pharmacists sought their practical strategies and a number of common approaches emerged (Matheson et al., 2002; Pates et al., 2002; Albsoul-Younes et al., 2010). These included removing products from sight, claiming products were not in stock or not stocked anymore, alerting or counselling customers to the abuse potential of products, refusing sales, suggesting customers contact their doctor and supplying only limited amounts. A Delphi survey of experts in the field of addiction and OTC medicines also identified similar strategies (McBride et al., 2003), as well as broader strategies based on raising public awareness, establishing an official body to monitor Internet sales, limiting advertising and making warnings on packets more visible. Fleming et al. (2004) developed a harm reduction model that comprised a manual and treatment algorithms for involving a customer's doctor, the appropriate signposting for opioid, laxative and antihistamine abuse. Lack of pharmacist confidence and general practitioner (GP) engagement and competing work demands were identified as barriers. Wazaify et al. (2006) reported that the same model led to some clients agreeing to stop using a medicine, using an alternative and being referred to their doctor for prescribing. No clients were recruited to enable collection of quality of life data. Raising awareness was recognised as being necessary amongst both the public (McBride et al., 2003; Reay, 2009) and health care professionals such as doctors (Williams & Kokotailo, 2006; Lessenger & Feinberg, 2008; Reay, 2009). A harm reduction strategy was proposed by Temple (1996) whereby pharmacists would set a contract with individuals experiencing OTC medicine abuse to have regular supplies of medicines, reducing over time and involving detailed record keeping and adequate communication between pharmacies and involving drug team coordinators.

The All Party Parliamentary Drug Misuse Group (APPDMG) in the United Kingdom (Reay, 2009) concluded that increased recognition and support were needed for the voluntary groups that provided support for those with an OTC problem. Two specific websites – Overcount and CodeineFree – were identified and considered to provide a valuable service that was not formally recognised (Reay, 2009).

Definitions and terminology. Considerable terminological variation was apparent in the identified literature. Some literature referred only to the term “misuse” and appeared to use this generically, to describe all forms of problematic OTC medicine use in pharmacies (MacFadyen et al., 2001; Matheson et al., 2002; Pates et al., 2002; Myers et al., 2003; Ajuoga et al., 2008). As Akram (2000) noted, however, this is unfortunate because it does not distinguish between misuse and abuse as separate problems, although some attempts to do this were identified in the literature:

Misuse is defined as using an OTC product for a legitimate medical reason but in higher doses or for a longer period than recommended, e.g. taking more of a painkiller than recommended to treat headache. Abuse is the non-medical use of OTC drugs, e.g. to experience a ‘high’ or lose weight. (Wazaify et al., 2005, p. 170)

According to Fleming et al. (2004), misuse applied to potentially all medicines, whereas abuse related to specific medicines, such as laxatives, antihistamines and codeine-based products. There was no mention in the literature of the transition between misuse and

abuse, as has been recognised in the medical prescribing situation of involuntary addiction (Reay, 2009). Further distinctions were identified within these broad categories and, for example, with misuse, it was argued to be possible to view this as resulting from using a medicine at a higher than recommended dose, or using it to treat symptoms for which the medicine is not indicated (Abbott & Fraser, 1998); with OTC medicine abuse, a distinction has also been made between sole OTC medicine abuse and substitution, where an individual is dependent on another medicine, often an illicit drug, and uses an OTC product when the other is unavailable (Abbott & Fraser, 1998; Temple, 2003).

Several studies did draw upon the wider literature relating to clinical classification such as DSM-IV (American Psychiatric Association, 2000) or ICD-10 (World Health Organisation, 1992) in specifically contrasting the terms abuse and dependence or “pharmacodependence” (Orriols et al., 2009) and misuse and dependence (Hughes et al., 2004). Several studies used the word “dependant” in relation to some use of the word codeine (Tinsley & Watkins, 1998; Orriols et al., 2009). The term “addiction” was identified in some literature (Hughes et al., 2004; Reay, 2009), but was infrequently used overall and, as Reay (2009) noted, this may have occurred due to the perceived stigmatising effect that the term and that of “addict” might have on those affected. One mixed methods study (Nielsen et al., 2010) used the DSM-IV definition of dependence (but not abuse) as inclusion criteria for their qualitative interviews with codeine-dependent individuals and described some users having “therapeutic dependence” to doses at or less than the maximum, often over a prolonged period.

An additional and significant definitional point concerned the terms used to describe not only the condition but the actual individual themselves, who were affected by OTC medicine problems. Within the empirical literature, this related partly to the study design and sample and included the use of the word “patient” in studies where the participants were those attending hospitals to seek treatment (Mattoo et al., 1997; Myers et al., 2003) and the term “client” in a study which studied a pharmacy-based intervention (Fleming et al., 2004). Two studies referred to those affected by OTC medicine abuse and/or misuse as “customers” (McBride et al., 2003; Albsoul-Younes et al., 2010) reflecting the commercial nature of OTC medicine sales, although Albsoul-Younes et al. (2010) also used the term “abusers” uniquely. One further definition offered was that relating to individuals who “manage their drug use as part of their normal daily routine” and were termed “recreational users”, to describe a heterogeneous group of individuals who may be abusing anabolic steroids, and “soft drugs” such as cannabis or LSD, or OTC medicines (Scottish Specialist in Pharmaceutical Public Health, 2004).

## Discussion

This review of the literature has revealed a number of themes and data to inform understanding of OTC medicine abuse. However, what is perhaps most apparent is the extent of the *omissions* in the extant literature, particularly as they relate to the lack of:

- qualitative methods that may be appropriate for exploring individual perspectives;
- reliable quantitative data in some countries;
- fully evaluated or implemented interventions;
- data relating to Internet supplies; and
- consensus over definitional terms.

These concerns are now considered in turn, before a number of specific suggestions for further research and policy involvement are proposed.

The various definitions described previously have a number of implications for research and understanding in this area. First, whilst they can positively reflect a range of different types of societal medicine use, they may also lead to confusion, particularly if, like some studies did, there are not accurate and consistent attempts to distinguish between them. This may be further complicated by the origins of these terms, with some such as “dependency” and “abuse” being associated with a clinical or diagnostic perspective (American Psychiatric Association, 2000), “addiction” carrying a societal broader interpretation and “misuse” being associated with pharmacy studies particularly. This reflects enduring debates about and changes to terminology in the wider addiction literature, including the WHO’s adoption of “dependence” over “addiction” (World Health Organisation, 1964) nearly half a century ago, to recent debates about these terms in the DSM-IV and proposed DSM-V (Dean & Rud, 1984; O’Brien et al., 2006). Underscoring this definitional variation are also fundamental issues about stigma, identify and also agency. The use of the term “dependency” and not “addiction” has been argued to have occurred due to issues of stigma of the latter (Dean & Rud, 1984; Erickson & Wilcox, 2006; Reay, 2009) as well as the issue of an “addict” or “spoilt” identity (Goffman, 1990; McIntosh & Mckeganey, 2000). In terms of agency, it is interesting to reflect on the distinction between misuse and abuse in some of the extant literature, since this appears to recognise a difference between intentionally experimenting with a medicine (to elicit a different effect) and abusing it, and unintentionally deviating from standard use (taking at different dose or indication) and therefore misusing it. Whether these can be adequately mapped onto additional concerns about the loss of control in addiction, as argued by Reith (2004), for example, are additional issues. One further omission is the absence of any reference to pseudo-addiction in the OTC literature identified in this review. Pseudo-addiction has been defined as the under-treatment of pain (Bell & Salmon, 2009), which may lead to symptoms that are similar to dependency and which reveal a potentially even more complex area.

Methodologically, quantitative approaches have dominated, illustrated by the use of cross-sectional descriptive survey designs, often using self-completion postal surveys of pharmacist participants in UK studies. Response rates appear to have varied significantly using this approach, and whilst Matheson et al. (2002) reported very good response rates across two surveys using a prepaid envelope and two reminder letters, and Hughes et al. (1999b) received responses from just under half of pharmacists sampled using two mailings. These studies reflect a trend to using pharmacists proxies and hence obtaining data that reported on pharmacists’ perceptions of the problem and the profile of those they considered to be affected, which as Orriols et al. (2009) noted is “much too subjective to obtain reliable qualitative and quantitative data”. Although not explicitly noted by the researchers, this may reflect a belief that those who are abusing or misusing OTC medicines may be a hard-to-reach or *covert* (Reay, 2009) group and hence using pharmacist proxies is perhaps perceived as being more appropriate. However, several study designs have involved sampling those suspected of abusing/misusing OTC medicines, either via pharmacies (Phelan & Akram, 2002; Orriols et al., 2009), at targeted venues such as gyms (Kanayama, et al., 2001) or by post (Sproule et al., 1999). Although these represent less subjective accounts of the problem, they have resulted in poor response rates except in the study by Orriols et al. (2009), who argued that allowing purchasers to complete a questionnaire away from the pharmacy and return it via post, as compared to completing it in the pharmacy, meant those who were abusing or misusing could complete the forms anonymously. However, Orriols et al. (2009) were disappointed by the poor level of pharmacy participation, which may be related to the need for the pharmacies involved to undertake the

administration of the questionnaires, as was identified in other studies (Wazaify et al., 2006).

Of particular note is that qualitative methods have been neglected and only one identified study used focus groups (Björnsdóttir et al., 2009) and one which reported the use of semi-structured interviews (Mattoo et al., 1997) presented detailed statistical data and the absence of qualitative data suggested this was a structured survey design. Nielsen et al. (2010) used qualitative interviews and reported a range of different types of abuse of codeine, as well as barriers to treatment, illustrating the unique data that this method can generate. Adopting such methods may reveal further insights that could help understanding of the contested definitional issues raised above, as well as providing more than the proxy summaries of those perceived to be affected, as offered by some pharmacist-participant studies.

The use of secondary data sources, such as those in various US reports (Substance Abuse and Mental Health Services Administration, 2004, 2008, 2010) and using details of patients attending drug treatment centres in South Africa (Myers et al., 2003), for example, offers potentially more robust statistical information on the extent of the problem. However, such data are not unproblematic and in the case of some US data, for example, prescription and OTC medicines were often reported together.

Linked to the source of this last type of secondary data is any evaluation or indeed thorough detail of treatment options for those affected by OTC medicine abuse. Empirical studies have identified a range of often pragmatic solutions, but evidence-based interventions and attendant evaluations are a clear omission in this field.

Finally, the emergence of new forms of medicine supply, such as via the Internet, in what Fox et al. (2005) termed the “second moment” of “e-pharmacy” has not been studied, despite being recognised as a potential threat (McBride et al., 2003). Such developments may not only stretch the metonymic accuracy of the term OTC, but also require a redefinition of what such supplies involve, as such supplies transcend national boundaries and attendant regulation in many cases (Bessell et al., 2003) and may challenge the international patterns identified.

In relation to policy, this review confirms that there is a problem in a number of countries but concerns about what is being investigated – whether this is misuse, abuse, dependency, addiction or pseudo-addiction – coupled with a lack of systematic data on the scale of the problem make appropriate and proportionate policy-based interventions difficult to consider. There exists a tension between making OTC medicines available to individuals to increase their access to medicines and enabling them to self-manage conditions and accepting that there is some degree of risk of such products being misused or abused, with potentially serious consequences for some. Raising awareness of potential problems of OTC medicines, as the recent response in the United Kingdom has illustrated in terms of making purchasers aware of the possibility of addiction, would appear a prudent response. But whilst this may arguably warn those using products for the first time, for those with an existing problem, more support may be needed in the clinical pathway.

## **Conclusion**

This review of the literature relating to OTC medicine abuse has revealed that there is a recognised problem internationally involving a range of medicine and potential harms. Methodological concerns have emerged in relation to the use of proxy, self-report and non-OTC specific data and the relative lack of qualitative research involving individual

experiences of OTC medicine abuse. These represent urgent areas where research is needed; to explore the extent of the problem and to provide insights into those affected, coupled with providing clarification of the type of problem being investigated. Such research is needed to inform policy, regulation and the preparedness of a range of health care professionals to avoid harm to those who purchase OTC medicines that may be liable to abuse.

### *Declaration of interest*

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