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## **Misuse of Over the Counter (OTC) Medicines in Community Pharmacies in Scotland**

### **Abstract**

The general public are taking more responsibility for their health, using community pharmacy as a source to access medication.

There is a reported increase and change in the misuse of OTC medication from community pharmacies in Scotland (Wright et al, 2015).

This article was designed to examine the self-reported use of medication from a small sample of community pharmacies in Scotland. The questionnaire gathered patient demographics and details of medicines used.

The study concentrated on 2 treatment areas, opioid analgesics and sedative antihistamines licensed as a sleep aid. Both previously identified as the most prevalent OTC medications that were perceived to be misused (Matheson et al, 2007)

Data was collected over a short time period in 2015 from 15 community pharmacies. The data demonstrates the widespread misuse of OTC. The most prevalent group identified as females, 41-60 years old and employed. It was most commonly reported that the recommended treatment duration is exceeded rather than the maximum recommended daily dose.

The recommendations from the article are that there needs to be greater awareness for pharmacists, pharmacy staff and general public on the potential dangers of misusing OTC medications and the importance of adhering to the recommended dosing and duration guidelines.

## Background

Globally the general public are taking an increasingly greater responsibility for their health; as a result the use of OTC medicines for self-medication is growing (Sherazi et al, 2012). A significant problem with assessing the scale of OTC medicine use and its misuse is the limited research into the problem. Foley et al (2015) looked at the availability of over the counter codeine compounds across Europe, but this failed to quantify the scale of the problem, but gave an insight into the number of preparations available for the public to buy. It has been a recognised issue over the last few decades, however, the research focus remains on illegal drug abuse (Wazaify et al, 2004).

There are two classes of OTC medicines in the UK: 'GSL' medicines which can be sold to the general public from non-pharmacy stores and 'P' medicines which can only be purchased from a registered pharmacy requiring the supervision of a pharmacist (Reed et al, 2011). As no prescription is needed to purchase these products they can be obtained relatively easily. All products discussed in this project are 'P' medicines due to the potential for them to be abused /misused.

The ability of individuals to purchase over-the-counter (OTC) medicines promotes self-management whilst allowing pharmacist's input to be acknowledged. Pharmacists have a duty to provide advice and recommendation of suitable treatments from a perspective of safety of the medication. The safety includes assessment of other conditions, advising on the quantity, duration and dosing of the treatment. This both relieves GP's workload and allows rapport to be formed, benefitting the pharmacist-patient relationship. It is well known amongst the healthcare community that OTC medicines may be misused, with patients often underestimating the harm potential, and possible complacency amongst individuals who view these products as "safe" as they can be purchased.

To clarify the terms used in this report: abuse refers to the deliberate / intended use of a product for reasons other than those indicated, e.g. to experience euphoric or sedative effects, whilst misuse

refers to the medical use of a product with doses or durations of use in excess of those recommended, which may be unintended (Sherazi et al 2012 and Reed et al, 2011).

Both may occur in patients purchasing medication from community pharmacies, however, how this issue is addressed by the pharmacy may differ and the issue may be caused through lack of patient awareness and education. Wright et al (2015) reported that a number of pharmacies developed strategies to reduce possible misuse, many introduced sales policies ranging from pharmacist involvement, refusing sales, GP referral, monitoring of sales, keeping products out of vision, removing from sale or offering alternatives.

Reasons for unintentional misuse may include patient's reluctance to visit their GP to address the problem or GP discontinuation of medication the patient feels is still necessary. Patients may experience side effects from the medication they are overusing, such as in chronic daily headaches potentiated by co-codamol. (NICE, 2012) This may instigate continued use in order to treat the issue causing an extended cycle of misuse.

In this article it is not possible to differentiate whether the misuse is intentional or unintentional and although the excessive consumption or duration or treatments will be addressed, the term "misuse" will be used throughout as the intent is unascertained.

The extent of OTC drug misuse in the UK has not been fully quantified and the total number of people affected remains unknown. Research however has looked at what pharmacists perceive the problem to be, this has generally only been how often it occurs in their community pharmacy (Matheson (2002), Wright (2015)). Wright et al (2015) reported that 80.8% of community pharmacists suspected OTC misuse. These papers reported shift in the pharmacists views of the medications that are being misused, moving away from the sedating antihistamines (decreasing from 51.9% (2000) to 26.4% (2104)) and increasing use of codeine based analgesics (Co-codamol

(Paracetamol and Codeine) increasing from 11.2% (2000) to 48.5% (2014) and Nurofen Plus (Ibuprofen and Codeine proprietary branded product) increasing from 17.9% (2000) to 30.4% (2014))

A separate postal study conducted in west central Scotland contacted n=110 pharmacies, reported that around one third (31%) have encountered frequent misuse, and 58% encounter occasional misuse. The same survey estimated the mean number of patients suspected of OTC misuse to be 5.63 per week per pharmacy (MacFadyen et al 2001). Community pharmacy has been shown to be a straightforward way to access many medicines. Misusers explained sales could be made in various pharmacies located in close proximity and pharmacy staff seldom challenged purchases (Cooper, 2013).

Fingleton (2014) recently reported that of 972 members of the general public surveyed, 2% were currently or previously addicted to OTC medicine. It may be assumed that people may not recognise they are misusing a product and the actual number may be much higher.

A larger cross-sectional study conducted in Scotland (Wright, 2015) had similar results with reports from 57% (n=1246) of pharmacists believing there was a problem in their local area. When compared to the findings from the previous studies completed in 1995 (Matheson, 1999), 2000 (Matheson, 2002) and 2006 (Matheson, 2007) respectively, the percentage of pharmacists that perceive that there is OTC misuse has increased 68.4%, 69.0% and 70.8% to the newly reported figure of 80.8%. Further evidence of the prevalence of the problem was collected by an anonymous questionnaire sent to n=180 community pharmacists across one health authority in South Wales, with a higher response rate of 89%. A comparable result of 66% of respondents felt similarly about the issue. (Pates et al, 2002). These studies show that pharmacists across the UK are concerned about the purchase and subsequent inappropriate use of a range of OTC medication. However, the available studies only give the pharmacist's perception of the scale of misuse; they do not attempt to directly quantify its extent or the patients view.

A few articles on case studies relating to the misuse of OTC medications (Van Hout (2015), Marr and Hill (2015)) have been published, demonstrating some of the issues associated with the misuse such as health concerns (gastric ulcers and bleeds from prolonged /excessive ibuprofen / codeine use), relationship strain and suppression of other health needs e.g. mental health. (Hard (2014) and Conroy & Hill (2014)).

This study will produce some demographic information on patients accessing OTC medications and will attempt to provide some quantification of the extent of the issue and also whether this is due to excessive consumption or prolonged consumption.

### **Aim**

The study was developed to identify trends and prevalence of OTC misuse from community pharmacies in 3 geographical areas of Scotland in terms of patient demographics, misuse of medications, sources of recommendation and action taken if the product was unavailable.

The study was conducted as part of a final year pharmacy student project undertaken by 3 students in 3 geographical areas.

All data collected was anonymous. Local ethics groups for both University of Strathclyde and NHS Lanarkshire were contacted and there was agreement that ethical approval was not required for the study.

## **Method**

An easy-to-use short self completion form for data collection in regards to codeine containing analgesics and sleep aid medication was developed (Appendix A). The anonymous multiple choice forms gathered basic demographics in addition to questions regarding product choice and dosing regimens. A restricted number of questions ensured the form was easily comprehended and completed in a short period of time. The form was tested for suitability on a small number of patients attending an additional pharmacy to ensure clarity and suitability of use. These results are not included in the data presented.

The data collection was completed over a period of two week in January / February 2014 was undertaken throughout 15 community pharmacies in Lanarkshire and North East Scotland reflecting the geographical areas of the students.

All patients purchasing either codeine containing analgesics or sleep aids (sedative antihistamines) available from the community pharmacy without prescription were invited to self complete a form relating to the medication. Patients were offered assistance from the pharmacy staff to complete the form if required. All pharmacy staff were briefed on the project and the questionnaires by the data collectors, who also spent half a day per week in the community pharmacies to support with data collection.

The completed forms were collected from each of the pharmacies and aggregated per site /group (5 pharmacies) and analysed.

## **Results**

### **Pharmacies**

15 pharmacies (10 in NHS Lanarkshire and 5 in North East Scotland) agreed to participate and these were divided between the 3 researchers. The data collection sites were selected from an opt-in response to a letter issued to all community pharmacy contractors in the NHS Lanarkshire area. 120 pharmacies in NHS Lanarkshire were approached with 10 sites self nominating (8%). However the sample in North East Scotland, 5 pharmacies were approached due to the increased rurality of the location.

### **General patient demographics**

A total of 474 completed forms were received throughout the collection period from all the sites.

The breakdown of replies is contained in Table 1.

As the forms were self completion, it is not possible to reconcile the number of patients that refused or were unwilling to complete a questionnaire therefore results may be a conservative estimate.

The demographics of the responses are show in Table 2. The gender breakdown of the patients completing the forms was 58% female, whilst the most common age group was 41 – 60 (40.72%), followed by 25 – 40 years (33.76%). Economically, 53.16% were employed (n=252) with 6.54% reporting to being in education.

Of the information reported, over  $\frac{3}{4}$  (76.37%) were for patients purchasing opioid containing medication. This was dissected further to the medication obtained, i.e. paracetamol/codeine or ibuprofen/codeine.

### **Misuse of medication**

Using the definitions outlined previously, 187 of the completed forms (39.45%) were indicative of misuse of the medication either due to the quantity of medication consumed or the duration of



consumption. (Table 3) From the data reported, the prevalence of females purchasing OTC medications in these categories and misusing in relation to the definitions used is 55.1% of the forms (n=103). The most common age groups reported are 41 – 60 years (34.76%) and 25 – 40 years (34.22%). In one area (Site A), the most commonly associated age group with misuse was for the 61+ years, although this site had the lowest number of forms returned meeting the criteria for misuse. As with the overall data the largest reporting group are employed (39.57%) but there was a greater variability between the data collection sites. (Site A covered a more rural area which was more affluent than the other areas)

The shaded areas in Table 4 highlight when the maximum recommended daily quantity has been reported as being exceeded. Fewer people reported to misusing excessive numbers of individual doses on a daily basis in comparison to the duration of treatment. Only 4 patients reported to using paracetamol/codeine (2.14% of the misuse group) in excess of the recommended levels but 13 of the ibuprofen/codeine and diphenhydramine (both 6.95% of misuse, n=13) reporting to excessive consumption.

In Table 5, the shaded areas highlight when the recommended duration of self treatment was exceeded. It can be seen that all the medications included have been reported as being used for an excessive time period and in addition all were also reported by some as being used continuously. Specifically for the codeine containing medication, paracetamol/codeine is being used by over 60% of the group determined as misusing medication for longer than recommended, with 20.86% using this medication continuously. This is reduced for ibuprofen/codeine, with 14.5% of the medication misuse group reported to the use of this preparation, and nearly 5% taking it continuously.

Diphenhydramine can be used for longer before it is classified as misuse, but 14% of the patients meet the criteria exceeding the maximum recommended duration with 11% reporting to continuous use. Promethazine appears to be less misused with only 3% of patients meeting the definition, however it equates to 100% using continuously.

Table 6 contains the data relating to 2 questions who recommended the medication? and what the patient would do if they could not get the medication requested. Friends (32%), were reported as the main reported source of recommendation although pharmacy recommendation (26%) and discontinued prescribed medication (24%) were widely reported. If patients were unable to get the medication requested most responded they would take an alternative (37.34%), although 29.32% said they would visit another pharmacy to try to obtain the same product and 27.85% would go to the GP. 13.71% said they would “do without” the medication whilst only very few (3.24%) reported they would purchase on the internet.

## **Discussion**

Wright et al, (2015) reported that the prevalence of pharmacists who perceive OTC medication misuse from their pharmacies has increased to 80% from levels of 70% in previous studies. This article states that codeine containing analgesics are now perceived to be more likely misused than other medication groups and the misuse of sleep aid medication has reduced.

This study goes towards providing further detail around the levels of reported misuse of limited groups of medication. The results demonstrate, there is a significant level of patients reporting to misusing medication either in terms of the quantity consumed daily or the duration of use. The reported data shows this prevalence to be nearly 40% of the completed forms (39.45%).

From the results, all of the recruited pharmacies experienced patients that were misusing medications using the defined criteria despite being in varied locations and socio-demographic areas.

The demographics from the responses illustrate that it is not an issue restricted to a small cohort of patients but it is open to all age g, socio-economic and gender groups. However, it is still possible to identify from this study some of the more common patient characteristics. I.e. most commonly the

patients were female, aged 41 – 60 and employed. It should be noted however this was common to both the number of forms returned and responses meeting the misuse criteria.

The results show that misuse reported more commonly is exceeding recommended treatment duration rather than consuming of excessive medication daily. This varied between the medications included in the study e.g. Misuse of quantity consumed is greater for ibuprofen-codeine than paracetamol-codeine, which is converse to the reported duration of treatment with more patients reporting to take paracetamol-codeine continuously (20.86%). The excess consumption of either paracetamol-codeine or ibuprofen-codeine can be severe and carry a life threatening risks. E.g. hepatotoxic nature of excessive paracetamol and the gastro-intestinal and renal side effects of excessive ibuprofen.

### **Recommendations**

The study demonstrated that the misuse of OTC medication is widespread and crossed the socio-economic spectrum. From the widespread nature of the issue, there should be calls for a wider survey and data collection to allow further investigation with clear and achievable outcomes and recommendations such as public awareness of the issue and increased awareness of the problem for pharmacists and pharmacy staff.

Additionally, there is an identified need for increased training and support for healthcare professionals including; information on how to communicate with patients potentially misusing OTC medicines and updated information regarding misused products.

This potentially demonstrates the need to develop training on methods used to address the issue of OTC misuse with patients and consultation skills to develop a more successful interaction and improved patient care. The Royal Pharmaceutical Society in Scotland have commenced offering Local Practice Forum meetings to raise the issue of training and awareness and this type of activity should be encouraged and widened to ensure there is an offering of this to all pharmacists.

In the future a possible development could be the introduction of a referral system between pharmacies and local services allowing signposting for patients seeking help. Additionally, again for the future, the use of shared care records between pharmacies and GP surgeries for patients would allow information to be kept up to date and early interventions made.

### **Limitations**

The study was a convenience sample and was self reported by the patients. It relied on the pharmacists/ staff distributing the questionnaire, inherently building in a number of limitations e.g. was it inclusive to all patients? Were the responses from participants honest? Did patients misusing medicine opt not to complete the questionnaire? Many of these factors may lead to underreporting on the issue of OTC medication misuse.

The numbers of pharmacies involved was small with fewer than 10% for the Lanarkshire pharmacies taking part. The pharmacies in Lanarkshire self selected to take part, the group in the North East were approached through the previous experience of the student in the area. If this was to be repeated it would be preferable to have a larger number of pharmacies participating and a singular approach to recruitment used.

Data collection was a 2 week period in winter 2014. This is a short time frame for data collection and the sample maybe affected by the need for medications to treat seasonal illnesses e.g. colds and flu.

Prejudiced offering of surveys from staff may affect the data collected as staff are possibly more willing to approach patients they know better or that are more willing to complete the questionnaire.

The medication examined was limited to codeine containing analgesics and sleep aids, this is restrictive and a wider review including all opioid analgesics, other opioid containing medications and antihistamines (sedative) would be able to provide a comprehensive review and examination of the issue of OTC medication misuse.



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