

Societal perspectives on over-the-counter (OTC) medicines

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Background. Over-the-counter (OTC) medicines are increasingly used for self-medication, but such products can be misused/abused.

Objectives. The aim of this study was to investigate the general public's opinion and perceptions of OTC medicines, including the misuse/abuse of such preparations.

Methods. Data were collected using a survey administered to 1000 members of the public in 10 study sites in Northern Ireland, using a structured interview technique. The questionnaire was divided into four sections addressing: (a) attitudes towards community pharmacy and patients' contact with pharmacies; (b) attitudes towards the use of OTC medicines; (c) views on OTC medicines in terms of safety, potency and effectiveness; and (d) knowledge and opinion of abuse/misuse of OTC medicines. Data were coded and entered into a custom designed SPSS® database for statistical analysis.

Results. The majority of participants (74.6%) visited a community pharmacy at least once per month. Almost one-third (32.2%) of participants reported buying OTC drugs at least once per month and the majority (86.4%) would always or often follow the directions on the product. The general public in Northern Ireland were highly aware of the abuse potential of some OTC drugs, with the majority naming painkillers as the products most liable for abuse. Almost one third of the participants reported having personally encountered cases of OTC abuse.

Conclusions. This survey revealed that the general public had a high level of awareness of the abuse potential of OTC medicines. These findings indicate that pharmacists could be more proactive in the management of inappropriate OTC drug use.

Keywords. Non-prescription medicines, over-the-counter drugs, public opinion, survey.

Introduction

In recent years there has been an increasing trend in self-medication with non-prescription drugs [sometimes referred to as over-the-counter (OTC) medicines] available in pharmacies and in retail outlets. In parallel, more products have been deregulated for purchase without a prescription.¹ The deregulation process has been championed by the pharmaceutical industry, the pharmacy profession and government health policy makers and is supported by the view that patients wish to have a greater role in their treatment choices.²

Self-medication also has advantages for healthcare systems as it facilitates better use of clinical skills of

pharmacists, increases access to medication and may contribute to reducing prescribed drug costs associated with publicly funded health programmes.³ However, increasing availability of non-prescription medicines may encourage patients to believe that there is a drug treatment for every ailment. Furthermore, the use of such products may delay/mask the diagnosis of serious illness,⁴ with increased risks of interactions and adverse reactions and of self-treatment being undertaken when medical aid should have been sought.^{5,6} There is also the potential for misuse and abuse of such products.⁷

The terms 'misuse' and 'abuse' are often used interchangeably, but they have precise meanings in this context. 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.⁷ There has been relatively little systematic research on the topic, partly due to the perception

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that misuse/abuse of OTC drugs is not as problematic as other types of drug abuse.⁸ Work in Australia^{9,10} and the UK on abuse and misuse focused mainly on the views of pharmacists^{7,11,12} and GPs^{13,14} and public opinion work on community pharmacy services have not investigated inappropriate use of OTC drugs.^{15,16} Therefore, this study sought to elicit the opinions of the public regarding OTC medicines generally and explore views around potential misuse and abuse.

Methods

This public opinion survey was administered using a structured interview technique. The target sample size was 1000. The questionnaire (available from the authors upon request) consisted of 34 questions (a mix of pre-formulated and free-text responses) and was piloted in a small sample of the general public ($n = 20$); these data were not included in the analysis.

All interviews were conducted in shopping centres in Belfast or in provincial towns (10 study sites in total) which were representative of different geographical areas within Northern Ireland. The study took place between April and July 2002 (ten weeks), with one week being spent in each shopping centre. This ensured that interviewers visited each shopping centre on different weekdays (including weekends) thereby encountering a wide cross-section of the community. Members of the public who appeared to be over 16 years of age were randomly approached and asked to participate. Participants were informed that the questionnaire was about 'non-prescription' medicines and the researchers wore badges that identified them as researchers from Queen's University Belfast. No reference was made to the School of Pharmacy during the interviews. The interviews (10–15 min duration) were conducted by two researchers (MW and ES) who had been trained with regard to interviewing skills and questionnaire administration.

The questionnaire was divided into four sections: (a) attitudes towards community pharmacy and patient contact with pharmacies; (b) attitudes towards the use of OTC medicines; (c) views on OTC medicines' use in terms of safety, potency and effectiveness; and (d) an exploration of knowledge and opinion on the inappropriate use of OTC medicines. In these latter questions, the terms 'abuse' and 'misuse' were carefully explained to respondents (as defined in the Introduction). Demographic data for each respondent were collected to assist with data interpretation and analysis. The National Statistics Socio-Economic Classification (NS-SEC) was used to classify participants' occupations.¹⁷

Responses were coded and entered into SPSS for Windows, version 11, for statistical analysis. Chi-square and Fisher exact tests were used to test for significant differences between groups ($P < 0.05$). In a few cases, participants failed to answer every question, resulting in

missing data. Missing data were not estimated or used in analyses.

Results

Demographics

Of the 1000 members of the public interviewed, 417 were male (41.7%) and 583 were female (58.3%). The gender of the sample was shown to mirror closely that of the general population of Northern Ireland (48.7% males and 51.2% females).¹⁸ Almost half of all participants took regular prescription medicines (48.4%). More than half of the interviewees (55.4%) were exempt from prescription charges. The postcode districts were normally distributed throughout the sample.

Patient contact with pharmacies

Almost three-quarters of participants (74.6%) reported visiting the community pharmacy at least once per month. Females and those >60 years visited community pharmacies on a more regular basis than males or other age groups ($P < 0.001$).

Almost 700 ($n = 679$; 68.5%) reported always or often using the same pharmacy, with the main reason being to obtain a prescription medicine (54.4%). Only 11.3% of interviewees visited a pharmacy primarily to purchase non-prescription medicines. There was no difference in terms of gender with regard to non-prescription medicines' purchase ($P > 0.05$).

Just over 60% (61.1%) reported that they would seek advice from a pharmacist rather than from a GP when the condition was not serious enough to visit the doctor. Just over one in every ten participants (11.3%) indicated that they would seek a pharmacist's advice if they had no time to wait for a GP appointment.

General attitudes towards the use of OTC medicines

Almost one-third (32.2%) of participants reported buying non-prescription medicines as shown in Figure 1. Females (36.1%) and people ≤ 60 years of age (35.5%) bought OTC medicines on a more regular basis than males (26.5%, $\chi^2 = 10.457$, $df = 2$, $P < 0.05$) and people older than 60 years of age (20.5%, $\chi^2 = 19.724$, $df = 2$, $P < 0.001$).

Most non-prescription medicine purchases were made from pharmacies (82.1%). Those who paid for their prescriptions bought OTC medicines on a more regular basis than those who were exempt ($\chi^2 = 6.59$, $df = 1$, $P < 0.05$).

The factor which most frequently influenced the choice of OTC medicines, was a recommendation by the pharmacist (27.3%). Figure 2 summarizes these findings. Table 1 indicates that more than 75% of the study sample (76.4%) reported that they would always stock painkillers at home, followed by vitamins and/or minerals (43.4%).

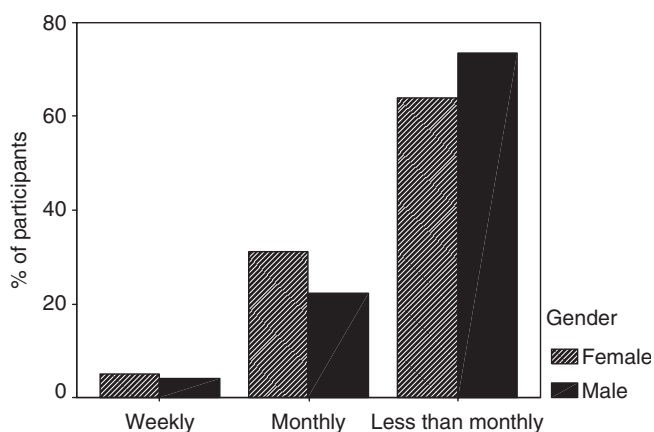


FIGURE 1 Frequency of purchase of OTC medicines by participants

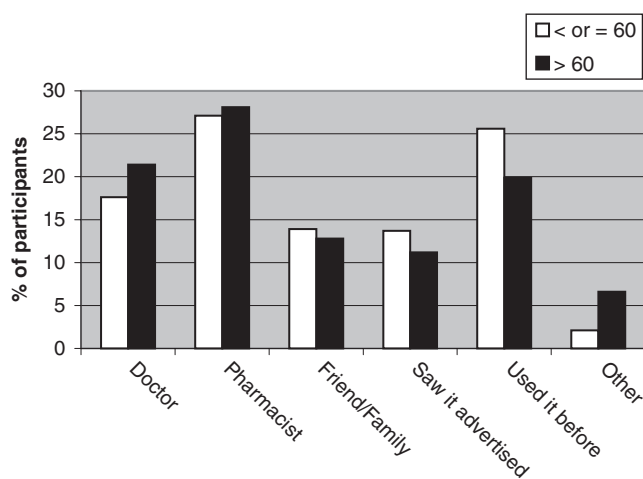


FIGURE 2 Factors which influenced the public's choice of OTC medicines (subdivided by age: <60 years old or >60 years old)

Views on the safety, potency and effectiveness of OTC drugs

From this sample, 74.5% reported that they always followed the directions on the OTC drug package, while 11.9% said they often followed the directions. Just under 7% of participants (6.6%) said they would sometimes follow these directions while 1.8% and 1.6% would rarely or never follow the directions respectively. Females and those >60 years old were more likely to follow the directions on the packet ($\chi^2 = 10.38$, $df = 2$, $P < 0.05$, and $\chi^2 = 7.23$, $df = 2$, $P < 0.05$, respectively).

When asked what action they would take if an OTC medicine did not work within the recommended period of time, 40.8% reported that they would stop and go to their GP. Almost a quarter (24.3%) said they would stop using the product and return to the pharmacy while 22.1% said they would decrease the dose or stop the

medication. Less than 9% indicated that they would increase the dose while only 2.3% and 2.2% respectively would use the product more often or for a longer time than recommended. Males were more likely to increase the dose or use the product more often than recommended, while females were more likely to decrease the dose or stop using the OTC product if it did not work within the recommended period of time ($\chi^2 = 18.07$, $df = 5$, $P < 0.05$).

Respondents' views on ten statements about OTC drugs in terms of safety, potency, effectiveness and liability for abuse or dependence are summarized in Table 2. Gender had little effect on responses to these statements apart from two cases; males were more likely than females to agree that 'non-prescription medicines can sometimes mask serious health problems' ($\chi^2 = 11.26$, $df = 4$, $P < 0.05$) and that 'some non-prescription medicines interfere with the natural healing process of the body' ($\chi^2 = 18.10$, $df = 4$, $P = 0.001$).

Younger people (53.7%) favoured further deregulation of prescription only medicines (POM) to OTC status compared to those over 60 (37.0%, $\chi^2 = 20.94$, $df = 4$, $P < 0.001$). Older people (>60) were reluctant to use OTC medicines at the first sign of illness with 22.8% of them strongly disagreeing with this statement compared to 9.8% of the younger age group. Those older than 60 were more likely to go to their GP than use OTC drugs compared to their younger counterparts.

Knowledge and opinion on misuse and abuse of OTC medicines

Following an explanation of the difference between the terms abuse and misuse, 84.8% ($n = 848$) of participants thought that non-prescription medicines could be abused. Almost 700 participants ($n = 637$) named at least one OTC product or category, 121 named two and 16 named 3 OTC products or categories (Table 3). The most frequent OTC medicine categories thought to be liable for abuse were painkillers ($n = 501$), sleep aids ($n = 83$) and cough mixtures ($n = 81$). Almost one in every three participants (33.1%; $n = 242$) identified specific products by name rather than category (e.g. co-codamol rather than painkillers).

Interviewees were asked if they had encountered (based on personal experience, knowledge or observation) any cases of abuse or misuse of OTC medicines. Almost one third ($n = 298$) reported having personally encountered cases of OTC abuse (see Figure 3). Younger people had encountered significantly more cases (33.6% of those younger than 60, $n = 261$) of OTC abuse/misuse than older people (16.5% of those older than 60, $n = 37$, $\chi^2 = 26.47$, $df = 1$, $P < 0.001$). There was a significant difference between reports made by males and females, with more females being aware of cases of laxative abuse to lose weight, while males described examples of mixing OTC medicines with alcohol ($\chi^2 = 31.6$, $df = 7$, $P < 0.001$).

TABLE 1 *Frequency of stocking common OTC medicines at home by participants*

OTC product	Sample size ^a	Always %	Sometimes %	Seldom %	Never %
Painkillers	983	76.4	14.8	3.0	5.8
Vitamins and/or minerals	983	43.4	22.8	5.2	28.6
Indigestion/heart burn	983	33.6	16.0	9.0	41.4
Medicated skin care products	981	22.3	21.3	5.7	50.7
Cough remedies	983	21.4	36.3	14.7	27.6
Sore throat products	983	21.3	33.9	14.2	30.6
Hay fever products	983	16.2	8.9	5.6	69.3
Herbal remedies	981	12.9	20.7	7.5	58.9
Laxatives	983	11.4	9.9	9.0	69.7
Medicated eye care products	983	11.1	11.4	8.0	69.5
Medicated foot care products	983	10.3	15.1	10.4	64.2
Sleep aids	983	9.1	7.1	4.8	79.0
Antidiarrhoeals	982	8.2	11.5	11.1	69.2
Medicated ear care products	983	6.6	11.3	7.2	74.9
Haemorrhoids products	983	3.9	6.0	6.1	84.0

^a Sample size is 983 because 17 people reported that they stored no OTC drugs at home.

TABLE 2 *Views of the public on the safety, potency and effectiveness of OTC drugs (n = 1000)*

Statement	Strongly agree %	Agree %	Unsure %	Disagree %	Strongly disagree %
More POM drugs should be deregulated to OTC status	6.5	43.5	15.5	24.7	9.8
I reach for OTC medicines at the first sign of illness	1.8	25.9	5.9	53.7	12.7
I use OTC medicines only if the illness is quite severe	4.1	53.1	9.2	25.7	7.9
Non-prescription medicines are totally safe to use	2.9	44.5	22.7	25.6	4.3
Non-prescription medicines can have dangerous side-effects	5.9	59.7	20.0	14.1	0.3
The effect of incorrect use of non-prescription medicines can be as serious as that of prescription medicines	9.8	69.8	13.6	6.5	0.3
Non-prescription medicines can sometimes mask serious health problems	4.0	57.7	28.9	9.1	0.3
Some non-prescription medicines interfere with the natural healing process of the body	4.1	50.5	31.9	13.3	0.2
With continual use, some non-prescription medicines lose their effectiveness	9.2	74.0	12.0	4.7	0.1
Some non-prescription medicines may cause dependency or addiction if taken for a long period of time	14.7	65.2	10.8	9.0	0.3

Those who thought there could be a problem of OTC medicines' abuse ($n = 848$) were asked for their views on solutions. More than half ($n = 501$) either did not know how, or reported that something should be done but did

not offer any suggestions. One in every eight respondents (12.5%, $n = 106$) said that nothing could be done or that it was difficult to control since people could move from pharmacy to pharmacy to obtain them. Eight per cent

($n = 68$) suggested reclassification of OTC medicines liable to abuse to POM status, while 7% ($n = 59$) suggested labelling of suspected products, together with education and raising public awareness. Some thought that the community pharmacist should have a greater role ($n = 33$) and should refuse any suspicious sale of these products. Nine people suggested that OTC sales should be recorded in pharmacies, with all OTC purchase information being stored on a 'smart card'.

Discussion

Overall, this study revealed that three-quarter of participants in this survey were regular users of community pharmacy services for self-medication purposes and almost one-third reported having personally encountered OTC drug abuse.

The percentage of participants who reported that they visited a pharmacy at least once per month represented a slight increase in frequency of pharmacy visits from that previously reported,^{15,16} thus emphasizing the accessibility and importance of community pharmacy within the UK's National Health Service.¹⁹ There was also a rise in the number of people buying OTC

medicines regularly (32.2%) from that previously reported^{15,16,20} which may reflect the public's growing confidence in self-care.^{6,21}

More than a quarter of those receiving regular prescriptions reported buying OTC medicines at least monthly. This may have implications in respect of safety. Interactions between prescribed medication and OTC products are well documented.²² A large nationally representative survey in the US revealed high levels of concurrent prescription and non-prescription drug use in respondents, leading to concerns about unintended interactions;²³ this confirmed similar findings reported by Finnish researchers who utilized data from a population-based interview survey on health care.²⁴ Doctors and pharmacists must be aware of polypharmacy and any non-prescribed remedies that the patient may be taking.²⁵

The main factor found to influence the public's choice of OTC medicines was pharmacist recommendation. This is reassuring especially with increasing availability of potent medications without prescription and the increased potential for interactions.^{16,27}

Almost 20% of respondents reported that their GP was likely to recommend an OTC product which represented an almost two-fold increase over a similar survey in 1992. This may reflect a more favourable attitude on the part of GPs to patient self-care.^{13,20} Sihvo *et al.*²⁸ reported that Finnish GPs were moderately positive towards the availability of selected drugs on an over-the-counter basis, but were less supportive of products that had been recently deregulated. Research commissioned by the Proprietary Association of Great Britain (PAGB) in 1997 has revealed GP support for self-medication is growing, with 83% of the GPs stating that they would feel comfortable about referring patients to pharmacists.²⁹

Just over 80.0% of participants reported always or often reading the instructions on the OTC drug package before they used the product, which is less than that reported previously during the Everyday Healthcare Study (96.0%).³⁰ This decrease could be due to an

TABLE 3 OTC products reported by the public as liable for abuse^a

OTC drug	<i>n</i>	OTC drug	<i>n</i>	OTC drug	<i>N</i>
Paracetamol	106	Benylin®	13	Pro-plus®	4
Paracodol®	37	Anadin®	8	Nytol®	3
Co-codamol	30	Kaolin & Morphine	7	Panadol®	2
Aspirin	27	Ibuprofen	6	Calpol®	1
Codeine	15	Vicks®-inhaler	6	Nurofen plus®	1
Solpadeine®	13	Night nurse®	5	Sudafed®	1

^a The numbers in the table add up to 285 because some participants mentioned more than one product.

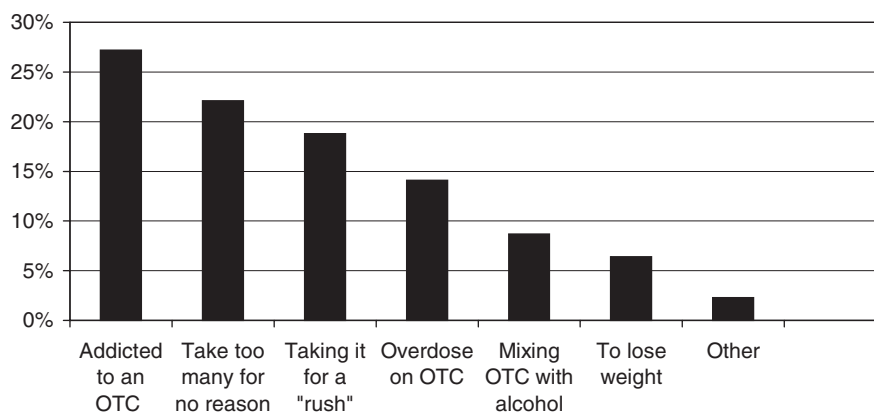


FIGURE 3 Cases of inappropriate OTC drug use reported by interviewees ($n = 298$)

increase in people's confidence over time in relation to self-treatment. It could also be due to people's belief that only safe medicines are permitted to be sold without prescription and that OTC medicines do not usually have serious side-effects.⁶

Although detailed information may be found in a package insert of the OTC product, the package label is usually the primary source of this information.¹ In the present study, only 3.4% of the participants said they would rarely or never read the information on the OTC drug package. This proportion is small; however, when including those who reported reading the instructions 'sometimes', one in every ten people (10%) would be at risk of misusing OTC medicines.

In a previous study, reading the enclosed instructions was confined to using a product that had not been used before, if a side-effect was experienced or if the medication was for a child.⁶ The main reason for not reading it was having read it on a previous occasion. Some criticism has been reported regarding the poor design of leaflets e.g. small font size, non-specific information, long lists of side-effects and confusing dosing instructions for children.⁴ In 1999, The Food and Drug Administration (FDA) issued a regulation regarding new standardized easy-to-understand labels for OTC products that all such products in the USA will be required to adopt by 2005.³¹

Moreover, a number of respondents were at risk of misusing OTC medicines. Males were found to be at higher risk of misuse than females as they were more likely than females to increase the dose or use the OTC product more often than recommended.

This research revealed that almost 85.0% were aware of the abuse potential of OTC medicines, with painkillers, sleeping aids, cough mixtures and laxatives being the main categories reported. This supports the findings from a community pharmacy survey in Northern Ireland in which pharmacists identified opioid-containing products, antihistamines and laxatives as being prone to abuse.⁷ However, there were some differences as pharmacists had identified kaolin and morphine as being associated with abuse and misuse,⁷ while the public specifically identified paracetamol. This may be due to differences in the personal experience and perspective of pharmacists and the general public. Although the terms misuse and abuse were explained to respondents, some confusion may have occurred in the meaning of the two terms. We acknowledge that this is a drawback of this study. However, health care professionals have also demonstrated confusion between the two terms.⁷ Furthermore, some of the cases cited by the respondents (see below) in this present study indicated that they clearly understood and had encountered cases of OTC abuse and these reflected what had been previously reported in the literature.

Almost one-third of participants reported encountering cases of inappropriate OTC drug use that they had classified as abuse. Some participants reported

cases of mixing OTC products with alcohol. Wills (1997) described the use of soluble aspirin tablets along with fizzy cola drinks or beer in order to produce a 'high',³² despite the lack of pharmacological evidence. The use of laxatives to lose weight especially by young women with eating disorders has been often cited.³³ One participant in this study reported witnessing separation of codeine from OTC analgesics using coffee filters in an attempt to avoid toxicity of other ingredients of the product of abuse. This method has been reported previously documented.^{26,27} Such cases clearly represent abuse.

Record-keeping could be a method of restricting access to some OTC drugs. In this case, individuals would have to register with a certain community pharmacy and all purchases of restricted OTC drugs would be recorded. Using this method, pharmacists could control the quantities of OTC drugs that people could purchase and prevent 'hopping' from one pharmacy to another. This could be supported by technology in the form of smart cards in which all patients' data related to OTC purchase could be stored confidentially and only pharmacists would have access to such information.³⁶ However, Rogers and Rees³⁷ have found that a minority of the community pharmacists in the UK use patient medication record (PMR) systems to store information relating to OTC sales. This approach may require further investigation.

The challenge in controlling the problem of OTC misuse and abuse is to achieve the necessary high level of consumer safety for the few at risk, while not restricting access to OTC products for those who continue to use them safely. It is recommended that by monitoring usage of certain OTC products, in addition to data recording and education, safe and effective use of such medicines can be promoted.

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Declaration

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