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# **A Snapshot Investigation Into the Availability and Access to Codeine-Containing Medications Amongst the Irish Population**

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## **ABSTRACT**

Codeine phosphate is a mild to moderate analgesic and has a weak cough suppressant activity that is available to purchase as an over the counter (OTC) painkiller in Ireland as a compound product. In recent years, countries such as Australia have introduced laws that prohibit the sale of the drug without a valid prescription. The primary aims of the study were to determine knowledge among the public of codeine-containing medications and their usage levels. The survey also investigated whether current regulations and recommendations are being followed in Ireland. The survey was distributed to 543 Irish adults using an online platform in February 2020. Only 47.2% (n=256) of those surveyed were able to correctly identify a codeine-containing medicine from a list provided.

Analysis of the results obtained from the study revealed that only 8.6% of the surveyed population were unaware of the potentially addictive nature of the drug. Consumers were more likely to be questioned and sold an over the counter (OTC) codeine-containing medicine under the supervision of a member of pharmacy staff rather than the pharmacist (73%) which is not compliant with Irish Law. This may pose a potential danger to patient safety. An examination of the population's opinion on whether the drug should remain an OTC medicine or introduce changes in regulation that would make the drug a prescription-only item showed that 47% of those asked believed that the medicine should remain OTC, while 53% would be of the opposing opinion.

## **INTRODUCTION**

Codeine phosphate is a mild to moderate analgesic and has a weak cough suppressant activity that is often sold in conjunction with other over-the-counter analgesics. The Pharmaceutical Society of Ireland (PSI) currently recognises codeine as a schedule 5 controlled drug; as such it may be purchased in a pharmacy without a prescription under the supervision of a pharmacist (PSI, 2019). Compound codeine products can currently be purchased over the counter (OTC) in 12 of the 27 EU states and also within the United Kingdom. A compound codeine product contains the drug codeine, as codeine phosphate, as an active pharmaceutical agent but may also contain one or more other active ingredients such as paracetamol or ibuprofen.

Unlike pain medications such as paracetamol which block the release of prostaglandins to reduce pain and inflammation (Graham, 2005), 5-10% of codeine phosphate is converted to morphine when consumed. The morphine binds to mu-opioid receptors in the brain preventing the recognition of pain signals (Bhandari, 2011) giving the 'high' or sedative qualities sometimes associated with codeine consumption however, equally this is the reason the drug is subject to being abused.

Codeine has been demonstrated to be a highly abused substance in countries such as the United States contributing to the so-called 'opioid crisis' (Kahan, 2011). Abuse of the drug has resulted in some countries such as Australia taking legal measures to ensure that the drug cannot be misused due to ease

of access (TGA, 2020). From February 2018, medicines that contain codeine can no longer be purchased over the counter in pharmacies in Australia and a prescription is necessary.

The purpose of the current research was to gain an insight of the knowledge individuals have on codeine-containing medicines, where individuals source the medication and the procedure involved in sourcing a codeine product. It is hoped that this research will begin further research into codeine medicines in Ireland and the associated regulations.

## **MATERIALS & METHODS:**

### **Survey Design**

People of varying ages and who reside in the Republic of Ireland for at least 10 months of the year were surveyed using a survey entitled “A snapshot investigation into the availability and access to codeine-containing medications amongst the Irish Population.” An anonymous survey comprising 19 questions was created using Google Forms where applicable, it was optional to choose multiple answers or skip the entire question. Questions were included to gather relevant information such as participant demographics, usage and acquisition of codeine-containing medications and knowledge of codeine products. Opinions on the supply of codeine were also welcomed.

### **Distribution of the survey**

The main method used to distribute the survey was online via social media platforms, namely Facebook, WhatsApp and Instagram. It was also circulated via email among the UCC student body using the service surveys@uemail.ucc.ie. WhatsApp and Facebook were mainly used to reach the older population (>51 years). This was important to reduce bias and the likelihood of an invalid response. The survey was open for responses from the 18<sup>th</sup> February 2020 until the 9<sup>th</sup> March 2020..

### **Inclusion and exclusion criteria**

For a response to be included in the data, the respondent had to be able to identify any codeine-containing product in Question 16 of the survey. If the respondent selected a non-codeine-containing medication, they were excluded from the data analysis. If a respondent identified a non-codeine-containing product as a codeine-containing product it was determined that they may not have a comprehensive understanding of the drug.

### **Data analysis**

Data analysis was conducted us Microsoft EXCEL which allowed the responses to be organized based on age, gender and uses of codeine. Chi square testing was used to test the statistical significance of any novel findings, using the formula:

$$X^2 = \sum_{i=1}^k \frac{(O_i - E_i)^2}{E_i}$$

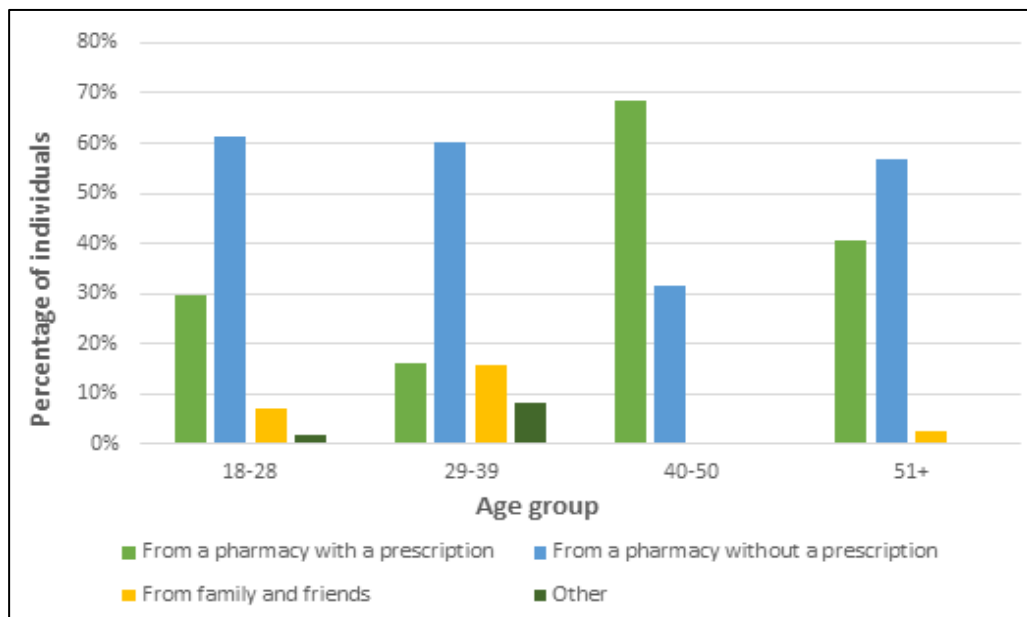
$O_i$  = observed frequency counts in each category

$E_i$  = expected frequency counts in each category

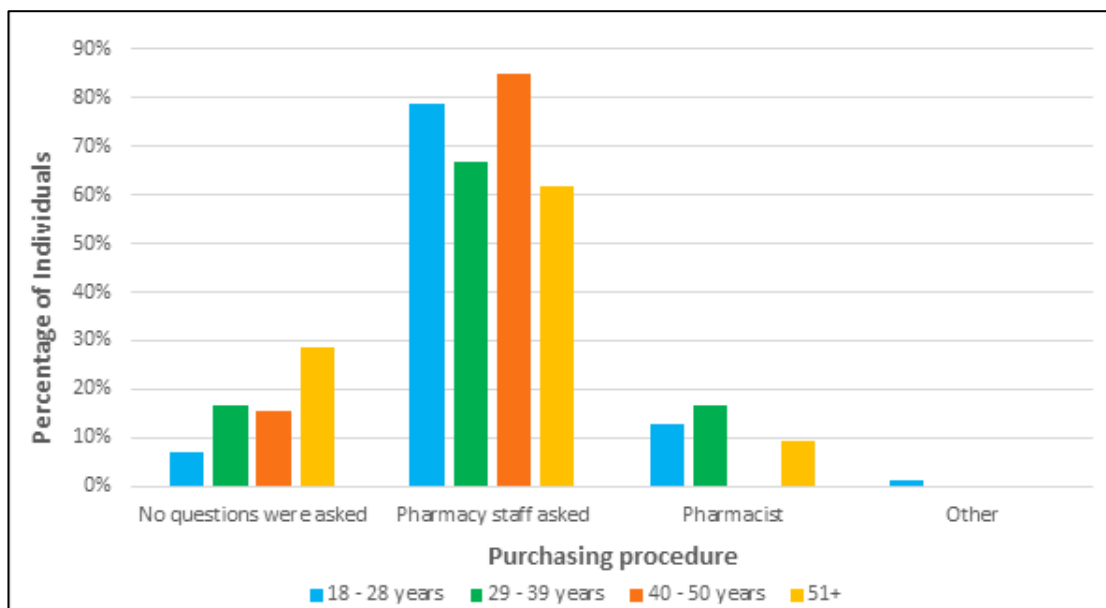
k = number of categories

## RESULTS

The survey yielded a total of 543 responses. These responses yielded 256 responses from individuals who could correctly identify codeine-containing products from a provided list, 63% of whom were aged 18-28y; 10% were aged 29-39y; 9% were aged 40-50y; 18% were 50y or older. There were two inclusion criteria which had to be met for the individual's response to be considered for data analysis - 1) the respondent had to be able to identify at least one codeine containing drug from the list provided, and 2) the respondent did not incorrectly identify a non-codeine-containing product as a codeine-containing product. These criteria were put in place to ensure that respondents had a suitable knowledge of codeine containing products, which may influence their responses. The responses of these individuals formed the basis of the results below. Figure 1 shows the means of procurement of codeine by age and Figure 2 outlines the approach used by age of those who entered a pharmacy without a prescription.

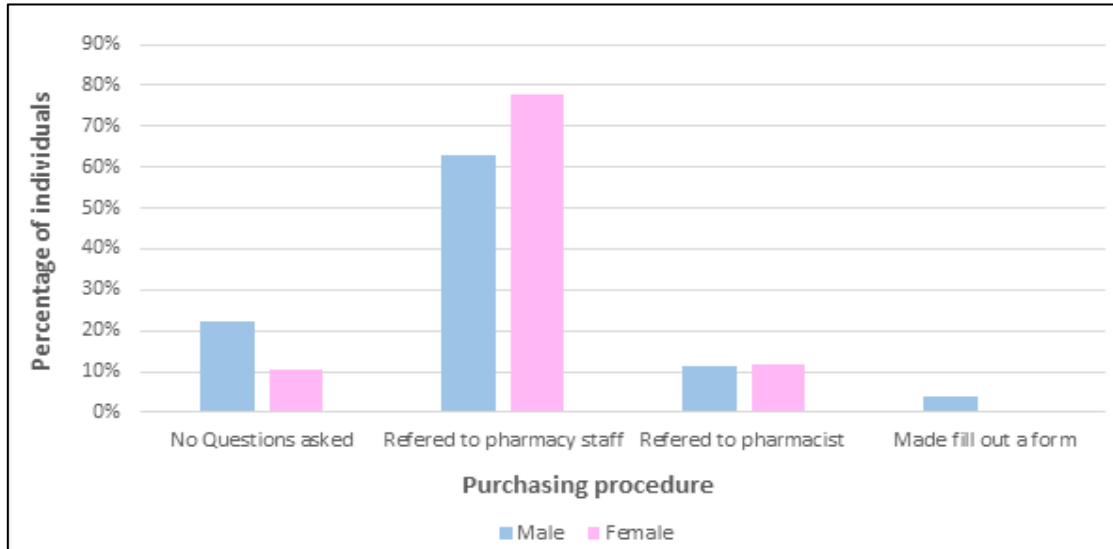


**Figure 1: Influence of age on the means of procurement of codeine containing medications.**



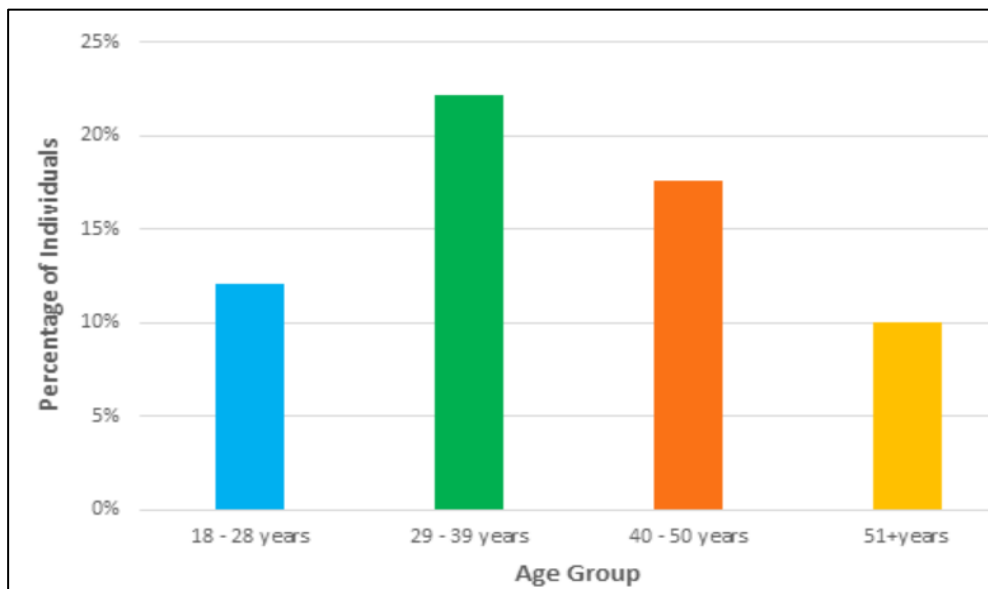
**Figure 2: Analysis of the influence of age on the purchasing protocol for individuals whose primary means of sourcing codeine is from a pharmacy without a prescription.**

Chi square statistical analysis of the apparent finding that men are twice as likely not to be asked questions prior to purchasing Codeine-containing medications compared with women [Figure 3], found that at a 0.1 confidence interval that the result was not significant: with a p-value of 0.1522. This suggests that the finding may be an artifact of the disparity between the number of male and female participants.

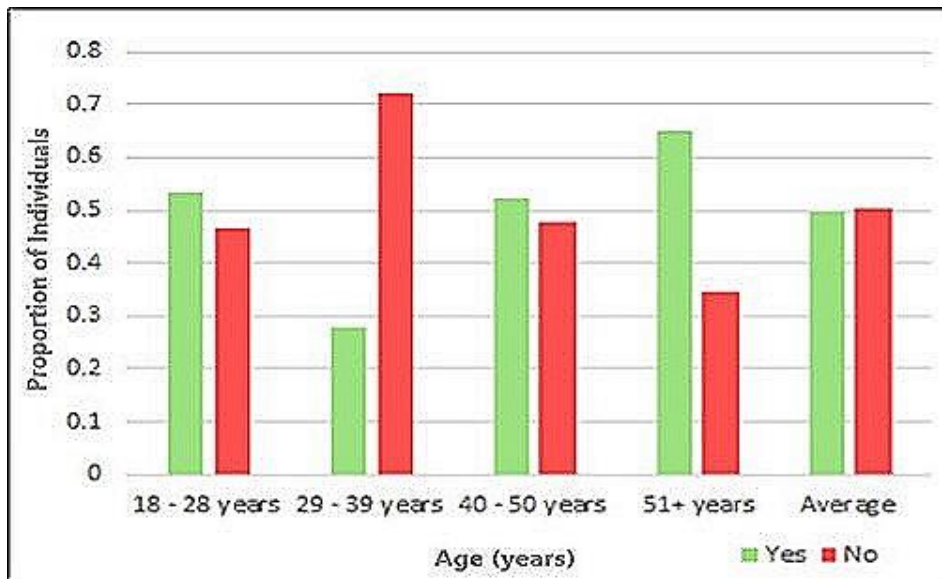


**Figure 3: Analysis of the influence of gender on the purchasing protocol of codeine containing products.**

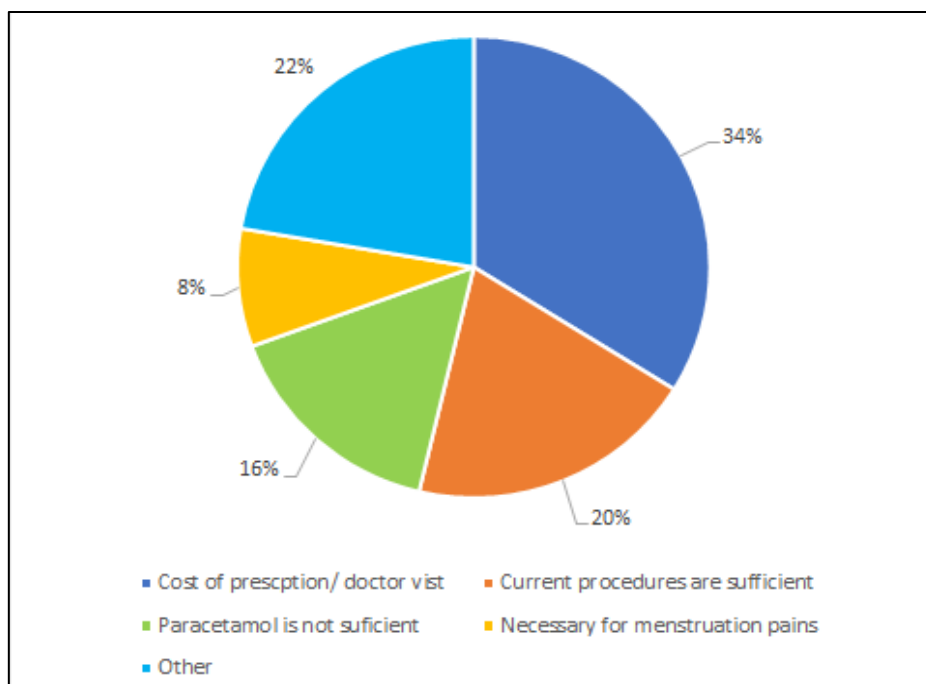
Figure 4 shows the results of investigating the propensity to lie in order to acquire codeine, sorted by age-group. Figure 5 shows the survey population’s opinion on whether codeine acquisition should need a prescription, by age-group.



**Figure 4: Analysis of the influence of age on an individuals’ willingness to lie to a healthcare professional in order to obtain codeine.** Each bar represents the percentage of individuals in that age cohort who admitted to lying to obtain a codeine counting product.



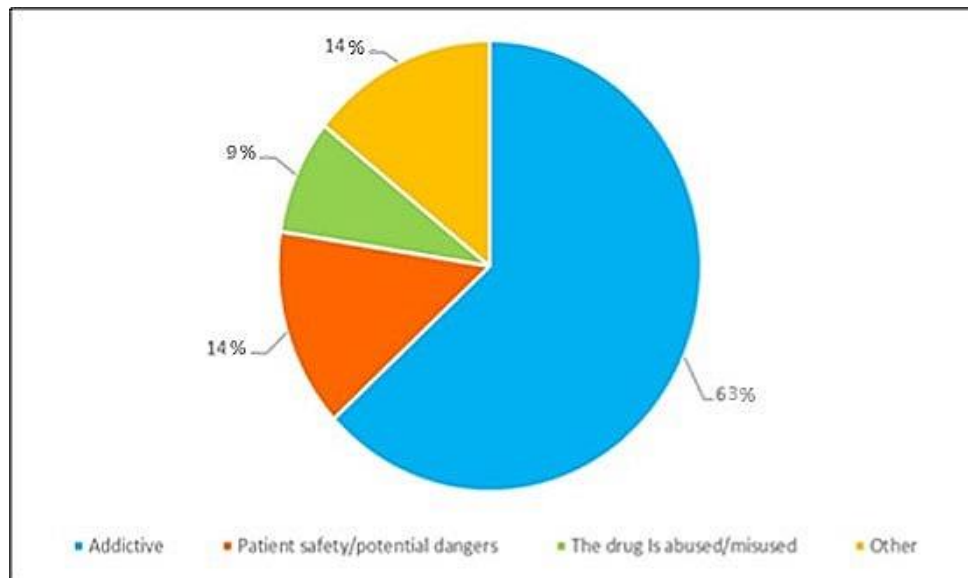
**Figure 5: Analysis of 256 Irish individuals' opinions as to whether or not codeine should be prescription only, by age group.**



**Figure 6: Justification of 121 Irish survey respondents who believe codeine should remain an over-the-counter drug.**

Figure 6 is concerned with the respondent's (n=121) reasons for retaining codeine containing medications as over the counter products. The most common reason for this was the cost associated with visiting a doctor to obtain a prescription (34%), followed by the belief current regulation of codeine was sufficient (20%). Other reasons given were: individuals should know to use codeine containing medications responsibly, requiring a prescription to obtain codeine containing medications would cause an added strain on the healthcare system and some individuals believed it should be freely available after answering a series of questions in relation to the purchase of the medication.

Figure 7 demonstrates the respondent's (n=135) reasons for codeine containing medications being available on prescription only. Under the category "Other" reasons supplied were that the drug is abused and misused and that supervision of the drug is required.



**Figure 7: Justifications of 135 Irish respondents who believe that codeine should be available by prescription only.**

## DISCUSSION

Codeine phosphate is a mild to moderate analgesic available to purchase over the counter (OTC) in Ireland and is often used to treat more serious types of pain that cannot be suppressed using other OTC medications such as paracetamol or ibuprofen. Codeine has been the most consumed opiate in the world in terms of countries in which it is consumed (International Narcotics Board, 2012).

Under Irish law, codeine is classified as schedule 5 under the Controlled Drug Regulations meaning that it is available to patients OTC in pharmacies under the supervision of a pharmacist who should make the patient aware of the side effects, especially of the sedating nature of the drug and emphasize the addictive potential of the drug (PSI, 2012).

Analysis of the results obtained from the study revealed that 91.4% were aware of the potentially addictive nature of the drug. This finding suggests that this common side-effect is well-known within the population who can correctly identify a codeine-containing medicine. Based on these data, the addictive nature of the drug appears to be well known.

The inability of individuals to correctly identify codeine-containing medicines was used as an exclusion parameter for the rest of the questions, for accuracy. Current legislation in Ireland (Pharmacy Act, 2007; Regulation of Retail Pharmacy Businesses Regulations, 2008) for the supply of codeine states that any form of advertising of codeine is strictly prohibited and it cannot be placed in the self-selection area of a pharmacy. The inability to self-select a codeine-containing product may explain why 52.8% of individuals incorrectly identified codeine-containing medicines.

Results illustrated in Figure 2 show that in all age brackets, consumers were more likely to be questioned and sold an OTC codeine-containing medicine under the supervision of a member of pharmacy staff rather than the pharmacist (73%). Over 80% of all patients aged between 40-50 were asked questions by pharmacy staff rather than the pharmacist which is not compliant with Irish Law (Regulation of

Retail Pharmacy Businesses Regulations, 2008). More concerning, 28.5% of consumers aged 51+ were not asked any of the necessary questions by any member of staff in the purchasing process. These regulatory questions include who the medication is for, the type of pain experienced, the duration of symptoms and if they are on any other medication; the purpose of asking these questions is to assess whether the individual is suitable for codeine treatment.

Of all the population, it is this age branch who are more likely to be suffering from an underlying health condition or taking other prescription medications which may interact with the drug and produce side-effects. For example, antidiarrhoeal drugs such as loperamide & kaolin when taken with codeine can result in severe constipation. Carrington Reid *et al.* (2015) found that chronic pain in later life is a worldwide problem and there are many causative agents of chronic pain such as cancer, musculoskeletal disorders such as arthritis or peripheral neuropathies.

In additional investigations into the impact of age on purchasing procedure it showed there was a clear positive correlation between age and individuals not being asked questions was seen ( $R = 0.92$ ). This may be due to the assumption that older adults (51+) are less likely to abuse substances such as codeine; however, the fact that individuals, particularly of this age group, are less likely to be asked questions regarding the purpose of purchase is worrying. Whilst there is limited research into the effect codeine is having in Ireland, a comprehensive 13-year study in Australia identified the prevalence of accidental codeine overdoses. The data highlighted that the majority of accidental deaths were in individuals over the age of 50 (30%) (Cairns *et al.*, 2019).

This study found that younger respondents were found to be more likely to obtain codeine from family and friends, with 29–39-year-olds being more than twice as likely to obtain codeine from friends than any other group (17%). The 18–28-year-olds were also seen to obtain codeine from friends and family; however, this was less common (7%). It is postulated that the increased number of younger people sharing codeine medications may be associated with the lower prescription rate of codeine in individuals <39yrs (23%), compared with individuals of 39yrs or older, who were more likely to receive the drug on prescription (55%). A systematic review by (Beyene *et al.*, 2014) on the subject of sharing prescription medications demonstrated a similar result. Regardless of the reasoning, the sharing of potentially addictive drugs is suboptimal. It is also unlikely when supplying these medications that family members/friends who supply the medication would advise of potential side-effects or the addictive nature of codeine; and as such, may be unwittingly fuelling addiction as suggested by Kennedy-Hendrick *et al.* (2016).

In an investigation of the relationship between gender and the purchasing process, illustrated in Figure 3, males were twice as likely to receive a codeine-containing medicine without any form of a consultation process. Chi-square statistics tested determined that at a 10% confidence interval, the result was statistically insignificant suggesting that this finding may be the result of differences in sample size between men and women. However, as the  $p$ -value was 0.15, further study using a larger sample population with a more even gender distribution could be used to investigate again for inequalities when it comes to the impact of gender on the procurement of controlled substances.

Of the 15% of survey respondents willing to lie to obtain codeine (Figure 4), most of the individuals justified their lying by stating it was easier to receive the medication this way (68%) whilst most others said they were aware of the side effects and did not require advice (31%). The rate of lying was particularly high in 29-39-year-old age group (22%), and it is noteworthy that Cairns *et al.* (2019) recognised that 30-39 year-olds made up the second greatest proportion of unintentional codeine overdose (28.8%).

Subsequently, the sub-population of individuals who did not use their codeine for its intended medical purpose (herein referred to as codeine misuse) was examined. Of the 59 respondents who obtained codeine from a pharmacy with a prescription, all used the product for its intended medicinal purpose, with 53 of these individuals using the codeine medication for pain relief and the remainder using it for



cough relief. Similar findings were seen among individuals who obtained codeine from family and friends.

However, when the 118 individuals who obtained codeine from a pharmacy without a prescription was examined, 98 individuals consumed codeine for pain relief whilst 13 used the drug for cough suppression. The remaining 9 individuals who obtained codeine from a pharmacy without a prescription abused the drug for recreational use, euphoria, or relaxation purposes. These figures suggest that individuals who obtain codeine for non-medicinal purposes are most likely to obtain the drug from a pharmacy without a prescription. Of the 9 individuals who admitted to abusing codeine, four were 18–28-year-old full-time third level students who used the drug for recreational purposes. Two individuals were aged 40-50, and one aged 61+. Two of these participants both aged 29-39 admitted to being reliant on codeine and agreed that codeine was widely available and easy to obtain. Perhaps the most alarming piece of data obtained from the subset of codeine misusers, is that all the individuals described their purchasing procedure as being asked questions by pharmacy staff rather than being referred to a pharmacist. This finding highlights the need for stronger enforcement of regulation around codeine.

The examination of the populations' opinion on whether the drug should remain an OTC medicine or introduce changes in regulation which would make the drug a prescription-only item the population is closely split and those whose opinion is that it should remain OTC are differentiated by age-group in Figure 5. The main validation for the belief that codeine should remain an OTC product (Figure 6) included the cost associated with obtaining and renewing prescriptions (41%), followed by the idea that current procedures and guidelines are adequate (24%) and that other pain-relieving OTC drugs are not as effective (19%). Those who believe that regulations surrounding the drug need to be adjusted gave the following reasons: the addictive nature of the drug (62%), maintaining patient safety (14%), and to prevent abuse of the drug (8%)

All age categories, except one, suggested that the drug should only be available on prescription. Notably, 72% of respondents aged 29-39y believe the drug should be available to purchase without a prescription. Reasons for this were found to largely be associated with the added cost and wait time that would be associated with obtaining the drug. It was also established that this age group is also the most likely to obtain codeine from a family member or friend (8%) and represents the age group most likely to lie to obtain codeine (22%). The suggestion by respondents that the cost of the drug would increase with a change in regulations is a valid one. These additional charges would come from GP consultation fees and the added pharmacy dispensing fee. The average GP visit fee in Ireland is €55-60 (Weston, 2019) and the average pharmacy dispensing fee can vary greatly dependent upon the items being dispensed. This increase in cost would primarily affect private healthcare patients who are not enrolled in any drug-related schemes such as the medical card (GMS) or drugs payment scheme (DPS). It was also found that there is concern amongst the public that making codeine available on prescription only would encourage those that are dependent on the medication to turn to illegal substance abuse due to the additional costs associated with obtaining the drug (Shying., 2018).

A recent study published in 2019 showed that since the introduction of stricter measures on the sale of the drug, which was enforced by the PSI through inspection, that there was a 33% decrease in the number of codeine related overdoses in Ireland (Kennedy *et al.*, 2019).

To conclude, the data obtained from this survey suggest that common side-effects of codeine are widely known amongst the population. Clearly the surveyed population are mostly concerned with the addictive nature of the drug and the impact it can have on the well-being of others as demonstrated in figure 7. Considering the addictive nature of the drug, the low percentage (47%) of the population who can differentiate between codeine-containing and non-codeine containing medications was concerning. As most of the population surveyed purchased codeine over the counter, there is a need for additional education of the population on the safe use and the dangers of codeine-containing products. Our findings suggest a need for mandatory training to be introduced for all pharmacy staff on the protocol regarding the sale of the drug, if only to act as a reminder of the legislation.

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