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Foley, M, Carney, T, Harris, R, Fitzpatrick, E, Rapca-Veillet, A and Van Hout, MC (2017) Medicines containing codeine: perspectives of medical professionals in the Republic of Ireland. Irish Journal of Medical Science, 186 (3). pp. 555-563. ISSN 0021-1265

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Title Page: Medicines containing codeine: Perspectives of medical professionals in the Republic of Ireland

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Funding: The research leading to these results has received funding from the European Community's Seventh Framework Programme FP7/2007-2013 under grant agreement no 611736.

Acknowledgments: We wish to acknowledge the CODEMISUSED research team and their participation in the collection of data used in this research

ABSTRACT

Aims: The aim of the study was to examine prescribing professional's perceptions on prescribed and OTC medicines, containing codeine in the Republic of Ireland. A secondary aim was to examine perceptions on codeine dependence, screening and treatment.

Methods: A cross sectional study of a nationally representative group of prescribing professionals was conducted using a questionnaire containing a number of open and closed ended items. Data were analysed using SPSS version 21 and content analysis techniques.

Results: 398 medical professionals participated in the study giving a response rate of 18%. 77% of respondents agreed to routinely review patient prescribed codeine. 59% of respondents routinely asked patients about their use of OTC medicines and 50% documented use of OTC codeine in their patients' medical notes. 93% indicated concern about the potential to purchase codeine from multiple sources. 88% implied that patients did not fully understand the risks of taking OTC medicine containing codeine. Only 21% of respondents were confident in identifying codeine dependence without being informed by the patient and 11.4% agreed to having suitable screening methods in practice. 76% indicated that they would like more instruction on prescribing addictive medicines.

Conclusion: Policy should examine the need for greater public health awareness on codeine use and should examine the role of OTC and internet sales in the development of dependence. Further consideration should be given to training and support for those who prescribe addictive medicines in practice.

Introduction

The potential misuse and dependence on medicines containing codeine has become a global public health concern (1). Misuse is defined as using the medication outside of normal guidelines, for example to induce psychoactive effects or alter effects of other consumed drugs, or where the dosage has been increased or used longer than advised without medical supervision (1). Dependence is classified as a psychiatric disorder under the ICD-10. Codeine a weak opiate is commonly used in the treatment of mild to moderate pain in adults and usually combined with paracetamol, aspirin or ibuprofen to improve analgesic efficacy. The maximum recommended dosage of codeine is 240mg daily (2). However, prescribed lower codeine combination strengths are unlikely to reach the maximum dose (240mg) due to the ratio of other constituents (paracetamol, ibuprofen or aspirin) contained in combined formulations. The literature suggests that prolonged use, excessive use and misuse of combination products containing codeine have resulted in significant health problems, including gastrointestinal haemorrhage, nephro-toxicity, hypokalaemia and acute haemorrhagic necrotising pancreatitis attributed to the combined drug component (3-6). Psychiatric disorders, falls in older people, and medication overuse headache have also been reported with continued codeine use (7-10).

One factor adding to the codeine debate relates to its availability as an 'over the counter' (OTC) drug for sale in pharmacies and on the Internet. In 2010, tighter restrictions on the sale of OTC medicines containing codeine were placed on pharmacies in the Republic of Ireland. The restrictions focused on safe supply of codeine containing medicines and restricted the quantity of drug for sale in a single transaction, it removed its availability for self-selection and incurred a ban on direct advisement (11). In addition, online pharmacies must comply with EU regulations and must carry a logo to inform consumers of their legitimacy as a safe supplier. While measures have been taken to reduce the risks associated with codeine consumption, displacement between prescribed and OTC availability and the ability to obtain codeine from multiple sources remains a problem (12). Consumers are reported to have misconceptions surrounding the safety of OTC medicines and a tendency to exchange them freely with friends or relatives (13). Use of codeine amongst recreational and problematic drug users is also evident with descriptions of consumption of high doses by extracting codeine from typical codeine combination formulations through a process known as 'cold water extraction' (14, 15).

There is limited data on current prevalence rates of codeine use, misuse and dependence in Ireland (16) and limited information on perspectives of practitioners who prescribe codeine or treat those who become dependent on the drug. Equally, there is limited information on screening methods used in detection of codeine misuse or treatment options for patients who encounter problems. Some evidence suggests that general practitioners (GPs) remain unaware of patients' OTC medicine use (17), and have limited resources available to them when issues of misuse arise.

The aim of the study was to examine medical professional's perspectives on prescribed and OTC codeine, codeine dependence, screening and treatment options in Ireland. This study was conducted as part of a European Union (EU) research project (www.codemisused.org) that investigated prescribed, OTC and web retail codeine use, misuse and dependence in Ireland, United Kingdom and South Africa. Data for other countries is reported separately.

Methods

A cross-sectional postal survey of a representative sample of GPs in Ireland in 2014 was conducted. Contact details for GPs were obtained from the Irish Medical Directory. This directory lists all current practicing GPs in Ireland (2,552 at the time of survey) stratified by region. A sample size calculation indicated that to achieve an 80% power to detect a 50% difference in response distribution and a significance level of 0.05, 335 responses would be required. Using the expected response rate of between 25 to 30%, it was estimated that 1000 participants should be contacted in order for the study to be adequately powered. A random sample calculator was used to generate a random numbers list and the corresponding details were extracted from the directory and prepared for mailing by two members of the research team. 40 Pain Specialists, representing the total population available in this field, were also mailed as described. To ensure representation from nurse prescribers, 200 Nurse Prescribers were randomly selected to the study and address labelling and postage was facilitated via the Irish Nursing Board.

A questionnaire informed by the existing literature was developed to explore items related to prescribed and OTC codeine, dependence, screening and treatment. This questionnaire was developed following a comprehensive review of the literature and consultation between the research team and medical professionals

(18). Answers were predominantly on a 5 point Likert scale, with several options for free text insertion. Eight questions were used to determine the demographics of the sample. Minor revisions to the questionnaire were made following a pilot survey carried out with 8 GPs practising in Ireland. The questionnaire was posted to participants with a covering letter requesting participation, information sheet, and a consent form. A stamped addressed return envelope was included. A postcard reminder followed two weeks later. Each participant was also given the opportunity to complete the questionnaire online (Bristol online surveys) and a link to facilitate this was provided in the covering letter. 220 questionnaires were returned complete, six were completed online and a further two from direct contact with GPs at an Irish medical conference, 19 -declined to participate and one was returned address unknown. Due to the low response rate a further 1000 GPs were recruited in order to reach the target number of participants. This mailing was conducted as previously described. This yielded a further 170 responses and a further two GPs completed the survey online. In total 398 questionnaires were completed.

Data were coded and entered into IBM SPSS software version 20. For the purposes of data analysis, responses to Likert scales (strongly agree, agree, strongly disagree and disagree) were collapsed into binary variables (agree and disagree). Neutral responses were also reported. Exploratory factor analysis was used to explore the interrelationship between statements and the possibility of refining items into a number of subscales for hypothesis testing. Statements specific to 'Over the Counter Codeine' showed similar commonalities in the form of levels of concern for OTC codeine use. 17 items in the scale were subjected to principle component analysis and scree plots were examined. Those with eigenvalues above 1 were chosen as being of interest and examined further. Nine of the 17 items were found to be highly correlated and were subsequently collapsed to produce a single dimension "level of concern" by combining the nine statements (see figure 1). Variables were recoded and given values (strongly agree=2, agree=1, neutral =0, disagree=-1 and strongly disagree=-2) Negative item scores were reversed as appropriate and items combined to produce a scale of +18 to -18. Scores approaching +18 were highly indicative of concern regarding OTC codeine and vice versa. One way analysis of variance (ANOVA) was performed to evaluate the effect of gender, age, years of practice, profession and specialist training on perceived levels of concern.

Data from the open-ended questions were entered into a separate Excel®. This data consisted of verbatim quotes. This data were examined and thematic categories were created based on the dominant subjects identified in the text. Three researchers independently coded the data and discussion took place to check for level of agreement with each of the identified categories. Where discrepancies were noted these were resolved through group discussion until consensus was reached. Data were then presented as a percentage of the total number of responses in each of the identified thematic categories. Ethical approval was granted by the Waterford Institute of Technology Research Ethics Committee.

Results

398 medical prescribers participated in the study giving an overall response rate of 18%. Table 1 show the demographic details of those who responded to the questionnaire. 83% were working as general practitioners (GPs), 13.6% were independent nurse prescribers. 26.9% had formal training in substance misuse. Table 2 below shows the results for questions examining medical professionals' experiences of prescribed codeine. 76% agreed to routinely review patient prescribed codeine. 35% believed that patients resented them for asking about their use of medicine containing codeine while a similar number disagreed with this statement (39%). 40% believed that requests for codeine were increasing while 29% disagreed. There was a high level of agreement amongst participants that they would only prescribe codeine following unsuccessful treatment with non-opioid analgesics (65%). 74% indicated their preference as 'agree' (either strongly agree, agree) and would avoid the prescribing of codeine with other drugs producing a depressant effect on the body.

Results regarding statement items related to OTC codeine are shown in Table 3. 59% of respondents routinely asked patients about their use of OTC medicines and 50% agreed that they documented the use of OTC codeine in their patients' medical notes. Concern about the availability of OTC medicines containing codeine was indicated by 59% of all those responding. However concern about the potential to purchase codeine from multiple sources was higher at 93%. Similar levels of agreement (34%) and disagreement (40%) were shown for the statement item, 'Patients are given sufficient information on use of over the counter medicines containing codeine'. 62% of respondents failed to indicate agreement or disagreement with the statement 'codeine is easily extracted from compounded formulations'. 88% of respondents implied that patients did not fully understand the risks of taking OTC medicine containing codeine and 84% indicated agreement that patients' believed OTC codeine to be safe.

Results of statement items related to dependence, screening and treatment are depicted in Table 4. 21% of those responding to the questionnaire were confident in identifying codeine dependence in their patients without the patient informing them of an issue. Only 11.4% agreed to have suitable screening methods to detect

codeine dependence. 76% of all respondents indicated that they would like more instruction on prescribing addictive medicines in practice.

Perceived levels of concern surrounding OTC codeine use were examined by collapsing the scores of 9 statements. Scores of +18 were highly indicative of concern while scores approaching -18 were highly indicative of a lack of concern regarding OTC codeine. The mean score was 8.05 (SD 4.11), implying a moderate level of concern amongst professionals related to patients' codeine use. A one-way ANOVA revealed a non-statistically significant difference ($p < 0.05$) on perceived levels of concern, for gender, age, years of practice, profession and specialist training in substance misuse (see Table 5).

Figure 2 shows the thematic responses as a total percentage of responses from the three main open ended questions. Suspicion of codeine dependence was aroused by patients' requests for prescriptions and requesting codeine specifically by name or brand name. Other triggers included patients complaining of unresolved pain and aberrant behaviours such as aggression when refused codeine. Treatment by professionals was most likely to include the slow and gradual withdrawal of codeine, restricting prescriptions and using education and counselling techniques. Referrals to specialist care were indicated where the person could not be managed in primary care and were a complex case. Additional comments made by the respondents in the open text section expressed concern regarding public understanding of safe and compliant medicine use and the availability to purchase codeine from multiple sources.

Discussion

Concern with regard to use of codeine medication is evident in the current study. Questioning and documenting the use of OTC codeine containing medicines in patients' medical notes appears to be lacking and may be related to the continuity of GP care in Ireland with options for patients to move freely through practices (19). Documentation and questioning regarding medicine use in routine consultations are considered of vital importance for prescribing professionals as it initiates discussion, helps to counteract any patient misconceptions and provides opportunities for intervention (20). Concern about the availability of codeine, ability to purchase online and through multiple sources is apparent and cannot be ignored. Irish research has found that problematic users of codeine obtained their supply by accessing multiple pharmacies, prescribers and purchasing codeine based products abroad (21). Availability and access to medicine is of particular concern if the public do not engage with information regarding the associated risks (21). Purchasing medicine online is not only a concern for codeine containing medicines but for all medicines and in particular where there is a risk that the medicine may not be legitimate (22). Methods to combat illegal sales of medicines across Europe are principally through regulated regulatory logos on websites (23). While this approach helps legitimate consumers to make informed decisions it does not prevent sales in the illicit market (24).

Participants' responses generally indicated disagreement that patients were provided with sufficient information on use of medicine containing codeine. Patients were thought to be unaware of risk of dependence and safe use of codeine-containing medicines. This was similar to findings reported by practitioners in the UK (25). The indication by prescribing professionals regarding patients' lack of knowledge surrounding their use of codeine medicines is worrying and requires greater exploration. Future efforts must identify the current level of knowledge and understanding of the public when purchasing codeine products -particularly for self-medication purposes or where they receive a regular supply on prescription (26). Codeine containing medicines are required to contain a patient information leaflet (PIL) and carry a warning of addiction on the outside of the packaging. However, such measures do not provide any guarantee that patients fully understand the associated risks. A qualitative study examining the views of patients on the usefulness of patient information leaflets (PIL) and information on medicines from their professionals found that they only offered partial information. Patients were found to read PILs selectively and were most interested in the side effects; however, the language was often considered to be too scientific and required greater simplification (27). There is a level of questioning by pharmacy staff to check for the appropriate sale of OTC codeine in pharmacies in Ireland. However, it is feasible that patients do not engage with the information provided, find it complex, choose to ignore it, and have become normalised to questioning during the transaction (21, 28). How this questioning should precede at the point of sale should be examined in closer detail. A qualitative study of pharmacists working in Ireland found that refusing codeine usually resulted in the product being bought elsewhere (29).

The question remains on how best to educate patients and improve literacy on medication use. While GPs and pharmacists have their role in patient education, it is unlikely that they can perform this function alone. A recent review suggest various levels of health literacy exists across countries and significant improvement is needed at government level (30). E and M-health technologies may help to improve patients' understanding of medicines and thus improve medication compliance (31). However, evidence of use of such technologies in this manner - remains conflicted (32, 33).

This study also highlights that - options for screening and identification of patients suspected of codeine dependence appear lacking. Routine screening is found to be very effective in early identification of

issues related to substance use (34). Awareness on best practice in managing codeine dependence was only indicated by a quarter of the respondents, with professionals' suggesting that they were most likely to use the process of gradual withdrawal of medication. Future efforts should establish best practice in management and treatment of codeine dependence in primary care, community and outpatient settings.

This is one of the first studies comprehensively examining prescribing professional's perceptions of medicines containing codeine in Ireland. There are limitations to this study as it is cross sectional and therefore can only be applied to a specific time period. Although the principals of random sampling were used in recruitment some bias may exist and it is possible that those experiencing greater problems with codeine in practice were more likely to participate in the study. The response rate was also lower than expected. Therefore, some caution should be exercised in generalising these findings.

The findings of this study show that medical professionals working in Ireland have significant levels of concern surrounding the sourcing of codeine from multiple outlets and have reservations regarding public understanding on use of medicines containing codeine. Policy should examine the need for greater public health awareness on codeine use and should further examine diversionary patterns in development of dependence issues. Further consideration should be given to training and support, including screening tools for those who prescribe potentially addictive medicines.

Funding: The research leading to these results has received funding from the European Community's Seventh Framework Programme FP7/2007-2013 under grant agreement no 611736.

Conflict of Interest: None

Ethical approval: Ethical Approval was granted by Waterford Institute of Technology Research Ethics Committee. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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Table 1 – Showing Demographics of participants by frequency and percentage and 95% CI

n=398			
	Frequency (n)	% Respondents	95%CI
Gender			
Male	197	49.5	44.5-54.3
Female	201	50.5	45.7-55.5
Profession			
General Practitioner	330	82.9	79.2-86.4
Independent/Supplementary prescriber	54	13.6	10.3-17.1
Other	14	3.5	1.3-4.0
County			
Munster	116	30	24.8-34.4
Leinster excluding Dublin	93	24	19.5-27.6
Dublin	99	25.1	21.0-29.6
Ulster	32	8.1	5.3-10.9
Connacht	55	14	10.9-17.5
Location			
Urban	150	37.9	33.3-42.2
Rural	87	22.0	18.2-26.3
Mix of both	159	40.2	35.4-44.9
Specialist training in substance misuse			
Yes	107	26.9	22.6-31.2
No	291	73.1	68.8-77.4
Age			
Mean (years)	50		
Range	28–74		
Years of practice			
Mean (years)	22.78		
Range	1-55		
Number of consultations per week			
Range	106 (Md100)		
	0 -370		

Table 2 – Showing level of agreement (strongly agree and agree) and disagreement (strongly disagree and disagree) and associated confidence intervals for each of the statements related to prescribed codeine medicines

Statement	Agree		Neutral		Disagree	
	n(%)	95% CI	n(%)	95%CI	n(%)	95%CI
I routinely review patients who are prescribed medicines containing codeine	280(77)	72.5-81	37(9)	6.5-12.3	56(14)	10.8-17.6
I believe that patients resent me asking about their use of medicines containing codeine	138 (35)	30-39.9	105(27)	22.2-31.3	153(39)	33.3-43.9
I feel awkward about asking patients about their codeine use because they will think I am accusing them of having a problem	49(12)	9.1-15.7	60 (15)	11.9-18.2	286(72)	68.1-76.7
Patients are aware of adverse health consequence associated with high doses of combination codeine preparations	105(27)	22.2-30.1	79(20)	16.4-24.0	212(54)	49.0-58.3
It is unlikely that prescribed medicines containing codeine are used as recreational drugs	42(11)	7.9-13.7	43(11)	8.1-14.2	308(78)	74.6-82.2
Patients' requests for prescribed medicines containing codeine is increasing	151(40)	34.6-44.3	121(32)	24.5-33.6	112(29)	24.5-33.6
I would avoid prescribing medicines containing codeine with other drug groups that also produce a depressant effect on the central nervous system	290(74)	69.2-77.9	69(18)	14.2-21.6	34(9)	6.1-11.2
I would generally prescribe medicines containing codeine following unsuccessful treatment with non-opioid analgesics	252(65)	59.8-69.8	78(20)	16.1-23.8	61(16)	12.3-19.4
I would generally prescribe codeine linctus following unsuccessful treatment of cough with non-codeine containing cough suppressants	126(32)	27.8-37	68(18)	14.1-21.6	195(50)	45.8-55.3
Doses of less than 30mg of codeine phosphate (compounded or uncompounded) are not very effective for treating mild to moderate pain	64(16)	12.8-19.7	68(17)	13.3-21.2	265(67)	61.5-71.5

Statement	Agree		Neutral		Disagree	
	n(%)	95%CI	n%	95%CI	n%	95%CI
I routinely ask patients about their use of over the counter medicines	234(59)	54.1-64.0	69(17)	13.6-21.2	93(24)	19-29
I document the use of over the counter medicine in a patient's medical notes	198(50)	44.2-55.1	85(22)	17.9-26	113(29)	24.2-33.3
I am concerned about the availability of over the counter medicines containing codeine in pharmacies	236(59)	54.4-64.2	79(20)	16.1-23.7	82(21)	16.9-24.7
The availability of medicines containing codeine on the internet is a growing concern for the medical profession	279(71)	65.7-74.8	100(25.3)	21.2-29.3	17(4.3)	2.5-6.3
The potential to buy medicines containing codeine from multiple sources adds significantly to the potential for misuse	368(93)	90.2-95.2	20(5)	3.0-7.3	9(2.3)	1.0-3.5
Patients are given sufficient information on use of over the counter medicines containing codeine	135(34)	29.5-38.5	103(26)	21.9-30.5	159(40)	35-44.6
Medicines containing codeine should be regulated to a prescription only medicine (POM)	247(62)	56.9-67	75(19)	15.4-23.2	75(19)	15.1-22.7
Over the counter medicines containing codeine give patients better choice for pain relief	196(50)	44.7-54	93(24)	19.4-27.8	107(27)	23-31.3
Over the counter mixtures containing codeine gives patients better choice for treating cough	112(28)	23.1-32.7	97(24.4)	20.6-28.6	189(48)	42.7-53.0
Over the counter medicines containing codeine are more effective than non-opioid analgesics such as paracetamol and ibuprofen in treating mild to moderate pain	97(25)	20.4-28.5	75(19)	15.1-23.7	225(57)	51.6-23.7
The potential for misuse of over the counter medicines containing codeine is minimal	21(5)	3.3-7.9	24(6)	3.8-8.7	347(89)	85.5-92.1
Over the counter medicines containing codeine have greater potential for inappropriate use compared to prescribed medicines containing codeine	244(62)	56.8-67	64(16)	12.4-20.1	86(22)	17.5-25.6
Codeine is easily extracted from compounded formulations (e.g. Cocodamol) increasing its abuse potential	108(28)	23.6-32.1	241(62)	57.4-66.2	41(11)	7.4- 13.8
It is likely that over the counter codeine medicines could be used as recreational drugs	326(83)	79.1-86.5	45(12)	8.7-14.5	21(5.5)	3.3-7.7

Codeine misuse is as serious a problem to society as misuse of stronger opioids	209(53)	47.8-58.2	76(19)	15.4-23.0	110(28)	23.5-33.2
Patients do not fully understand the risk of dependence in taking over the counter medicines containing codeine	348(88)	84.4-90.7	24(6)	3.8-8.6	25(6)	4.3-8.6
Patients believe that over the counter medicines containing codeine are safe	322(84)	79.8-87.4	48(12)	9.1-15.6	17(4)	2.3-6.3

Table 3 – Showing the level of agreement (strongly agree and agree) and disagreement (strongly disagree and disagree) and 95% CI intervals for statement items related to OTC codeine medicines

Table 4 – Showing level of agreement and disagreement and CI for statements related to dependence, screening and treatment for codeine use and misuse

Statement	Mean (SD)	Level of Significance	Agree		Neutral		Disagree	
			n (%)	95%CI	n(%)	95% CI	n(%)	95% CI
Patients who take their codeine medication as prescribed are not at risk of developing a codeine dependence			55(14)	10.6-17.4	34(9)	6.0-11.3	308(78)	73.6-81.6
Patients do not fully understand the risk of dependence when taking prescribed medicines containing codeine			326(83)	78.5-86.3	44(11)	8.1-14.9	25(6)	3.8-8.6
I find it difficult to identify problematic use of medicines containing codeine (including OTCs) without the patient first telling me			190(48)	43.5-53.2	99(25)	21.2-29.8	104(27)	24.4-31.3
I am confident that I can identify codeine dependence in my patients			81(21)	16.7-24.6	140(35)	30.6-40.3	174(44)	39.5-48.9
Females are at higher risk of developing a codeine dependence than their male counterparts			185(47)	42.1-51.9	164(41)	36.3-45.8	48(12)	9.1-15.4
Codeine dependence can be managed effectively in general practice			167(43)	38.1-47.7	82(21)	16.7-24.5	145(37)	32.1-41.7
I have suitable screening methods that I use to identify inappropriate use of medicines containing codeine			45(11)	8.6-14.7	105(27)	22.1-31.0	244(62)	244(62)
Support services are readily available in my area to help those with a codeine dependence problem			77(19)	15.4-23.4	58(15)	11.1-18.1	262(66)	61.0-70.8
I am fully aware of best practice in managing codeine misuse and dependence			103(76)	22-30.3	186(47)	41.9-52	107(27)	22.5-31.6
I would like more instruction on prescribing potentially addictive medications			300(76)	71.9-79.7	59(15)	11.6-18.5	36(9)	6.6-11.9

Gender		
Male	7.9(4.0)	F=0.260, DF 1, p=0.610
Female	8.4(4.3)	
AGE (years)		
Less than 30	9.5 (1.1)	F=1.159, DF 4, P=0.329
31-40	7.3 (7.3)	
41-50	8.2(3.7)	
51-60	8.2(3.9)	
61 or greater	8.5(4.4)	
Profession		
General Practitioner	8.2(4.1)	F=1.5, DF 2, P=0.199
Nurse/independent prescriber	7.0(4.2)	
Other	7.0(3.9)	
Years of practice		
0-5	7.3(4.1)	F=1.307, DF 3, P=0.272
6-10	7.3(4.9)	
11-20	8.4(3.7)	
21 or greater	8.1(4.1)	
Specialist training in substance misuse		
Yes	8.0 (3.9)	F=0.001, DF 1, P=972
No	8.05(4.1)	

Table 5 – Showing mean scores for scale item ‘level of concern’ regarding codeine use and level of significance by variable.

Figure 1 – Showing statement items used in generation of scale measuring concern about OTC codeine

Statement items
I am concerned about the availability of over the counter medicines containing codeine in pharmacies
The availability of medicines containing codeine on the internet is a growing concern for the medical profession
The potential to buy medicines containing codeine from multiple sources adds significantly to the potential for misuse
Medicines containing codeine should be regulated to a prescription only medicine (POM)
The potential for misuse of over the counter medicines containing codeine is minimal
It is likely that over the counter codeine medicines could be used as recreational drugs
Codeine misuse is as serious a problem to society as misuse of stronger opioids
Patients do not fully understand the risk of dependence in taking over the counter medicines containing codeine
Patient believe that over the counter codeine medicines are safe

Figure 2 – Frequency of responses displayed as a percentage for each thematic category

