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Carney, T, Wells, J, Bergin, M, Dada, S, Foley, M, McGuiness, P, Rapca, A, Rich, E and van Hout, MC

A Comparative Exploration of Community Pharmacists' Views on the Nature and Management of Over-the-Counter (OTC) and Prescription Codeine Misuse in Three Regulatory Regimes: Ireland, South Africa and the United Kingdom

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A comparative exploration of community pharmacists' views on the nature and management of Over-the-Counter (OTC) and Prescription codeine misuse in three regulatory regimes; Ireland, South Africa and the United Kingdom.

Abstract

Misuse of codeine containing preparations is a public health concern given the potential for associated harms and dependence. This study explores the perspectives of community pharmacists in three regulatory regimes on issues of customer misuse of over the counter (OTC) and prescribed codeine containing preparations. A qualitative design comprising six focus groups (n=45) was conducted in Ireland, United Kingdom, South Africa. Transcripts were analysed using the constant comparative method of content analysis. Pharmacists described popular codeine containing products; the need for improved medicine information and warning labels. Issues around legitimate availability of codeine and regulatory status; presence of therapeutic need; difficulties in customer–pharmacist communication; business environments and retail focus were raised. Participants also discussed how they identified customers potentially misusing codeine; customer pharmacy 'hopping' and difficulties in relationships between pharmacists and prescribers. Specialist training; reimbursement for customer consultation; screening and brief interventions; visible referral structures and assisted community pharmacy detoxification were discussed as ways to manage the issues. The study highlights the difficulties encountered by community pharmacists operating under various regulatory regimes when supplying codeine containing preparations in negotiating patient awareness and compliance and dealing with misuse and dependence.

Key Words

Codeine containing preparations; Misuse; Community pharmacy; Pharmacists; Regulation

What is known about this topic

- Over-the-counter (OTC) and prescription codeine containing products, as dispensed in pharmacies, have the potential for misuse and dependence.
- Different countries have different regulations with regards to the provision and display of codeine and level of pharmacist intervention at point of sale.
- Strategies which prevent and address codeine misuse include screening, information provision and referral.

What this paper adds

- Pharmacists in Ireland, South Africa, and the UK have multiple roles and face a number of challenges related to financial and time resources; perceptions of the pharmacist profession and advising on safe and appropriate use of medication, not only codeine.
- Pharmacists have their own ways to identify customers who may be misusing codeine, but customers' strategies such as 'pharmacy hopping' and some use of online pharmacies make this challenging.
- Support and referral interventions are provided by pharmacists, but these are not standard, and more information is needed on which services to refer customers to for codeine misuse.

Introduction

Misuse of codeine containing preparations, particularly combination analgesics is on the rise (McAvoy, Dobbin et al. 2011). Pure codeine is listed as a controlled drug to be monitored (Schedule II of the 1961 convention on Narcotic drugs (United Nations, 1972) as it has a high potential for abuse,. However, most codeine products are classified under Schedule III as they are compounded with one or more other ingredients and therefore are viewed as having less potential for misuse and abuse. Such products do not contain more than 100 milligrams of the drug per dosage unit with a concentration of not more than 2.5 per cent in undivided preparations (INCB 2011). The global shift toward patient self-care and treatment, alongside availability and advertisement of over the counter (OTC) codeine-containing products has contributed to a public perception that such products are safe, with an accompanying lack of awareness for the potential for misuse, dependence and public health harms (Tobin, Dobbin et al. 2013; Van Hout, Bergin et al. 2014).

While codeine is generally administered for its analgesic, antitussive and anti-diarrheal properties (Derry, Karlin et al. 2013), it has an identified abuse potential (Jones, Mogali et al. 2012) due to its opiate effect and the potential for tolerance developing when used regularly or excessively within a short time period (Nielsen, Cameron et al. 2010). Availability of OTC codeine containing products complicates consumer recognition of personal misuse and potential for dependence, with individuals who experience problematic use not always recognising that they require help (Pates, A.J. et al. 2002; Dobbin and Tobin 2008; Cooper 2013b).

Misuse of OTC purchased codeine includes use which never exceeds the maximum recommended dose but is prolonged, consumption of slightly higher than the recommended dose and consumption of higher than the recommended dose (Cooper 2011). A wide range of profiles of OTC codeine misuse and dependence are observed in the literature (Van Hout, Bergin et al. 2014), which seems unique and distinct from other forms of opiate dependence (Nielsen, Cameron et al. 2010; Nielsen, Cameron et al. 2011). Dependence on codeine can occur due to legitimate (therapeutic) and intoxicating (non-

therapeutic) forms of use and misuse (McDonough 2011; Van Hout, Bergin et al. 2014). Reinforcers for problematic consumption include use relating to intoxicating purposes and when benefits of misuse outweigh adverse consequences (Casati, Sedefov et al. 2012). The interplay between chronic non-cancer pain, self-medication of codeine and iatrogenic dependence has also been observed (Arora, Roxburgh et al. 2013; Roussin, Bouyssi et al. 2013; Hamer, Spark et al. 2014). Reported health consequences from long term and/or excessive misuse of combination codeine analgesics include headaches, nephrotoxicity, gastro-intestinal conditions, hypokalaemia, acute haemorrhagic and necrotizing pancreatitis (Dyer, Martin et al. 2004; Dutch 2008; Ernest, Chia et al. 2010; Evans, Chalmers-Watson et al. 2010; Frei, Nielsen et al. 2010; McDonough 2011; Pilgrim, Dobbin et al. 2013; Pilgrim and Drummer 2014).

Regulating Use of Codeine

Efforts to tackle the use of codeine misuse relate primarily to up-scheduling and guidelines for restricting supply, advertising and pharmacy practice (Cooper 2011; Cooper 2013c; Hamer, Spark et al. 2014). General standards advise on supply of non-prescription codeine when initial, single ingredient medicinal products (paracetamol, aspirin, ibuprofen) are ineffective and '*second line'* form of treatment for and restricted to use in accordance with marketing authorisations for short term use (no longer than three days). Common strategies utilized by the pharmacy industry to prevent misuse include increased visibility of health warnings on labels and patient information leaflets ('*Do not use for more than 3 days unless on medical advice*' (MHRA 2009), reduced package sizes and restricted display of codeine. Pharmacists' roles include record keeping and direct pharmacist intervention at point of sale (Cooper 2011; Cooper 2013c; Hamer, Spark et al. 2014). Whilst such regulatory measures may contribute to positive outcomes relating to public deterrence of codeine misuse (Agyapong, Singh et al. 2013), the empirical support for such interventions specific to codeine is not well developed.

Pharmacists' concerns regarding the misuse of OTC codeine products are well documented in the literature (MacFadyen, Eadie et al. 2001; Matheson, Bond et al. 2002; Pates, A.J. et al. 2002; Cooper

2011; Reed, Bond et al. 2011; Cooper 2013a; Cooper 2013c). Pharmacists' roles are not only to act as *'custodian of medicines',* but also encompass a range of services including health screening, referral and customer support which, in the case of OTC codeine, centres on customer information, therapeutic need through screening and decisions to supply the requested codeine product relating to suspected misuse (Le Roux 2013; Hamrosi, Raynor et al. 2014).

Regulation of OTC codeine products in the UK, Ireland and South Africa

This study was conducted in three countries with distinct regulatory regimes for the safe supply of codeine containing preparations - Ireland, South Africa and the United Kingdom (UK). In these countries codeine containing preparations are available over-the-counter to the public in combination products containing additional pain-killers (paracetamol, ibuprofen or aspirin). In the UK, the maximum codeine content that is available OTC is 12.8mg, with pack sizes restricted to 32 tablets per single transaction under supervision of the community pharmacist. In Ireland OTC pack sizes of codeine are limited to 24. Codeine Linctus is also available (15mg per 5 ml) OTC in Ireland and the UK if requested by customers. In Ireland, products are kept out of sight and with advertising not permitted.

South African regulations stipulate permissible sale of OTC codeine containing products (10mg or less of codeine phosphate and compounded with another drug) under supervision of the pharmacist, but with pack sizes containing up to 100 tablets. In contrast to Ireland and the UK, sale must be recorded in the Schedule II register. In all three countries, pharmacists are duty bound to refuse the sale if misuse is suspected.

Study design

A series of focus groups with community pharmacists were conducted in each country in order to provide in-depth information on thesimilarities and differences relating to community pharmacy practitioner roles in identification of customer misuse of prescribed and OTC codeine containing preparations, efforts to enhance patient awareness of risks and manage patient compliance, and

support those individuals experiencing problematic use and dependence. Ethical approval was sought and given by the research ethics committees of Waterford Institute of Technology in Ireland; King's College London in the UK and the Medical Research Council of South Africa. This study is part of a larger EU funded research project called CODEMISUSED.

Methods

A total of six focus groups were undertaken in Ireland (n=2), South Africa (n=2), and the UK (n=2). Participants were identified through discussions with the lead applicants of the academic institutions involved in the study and local community pharmacy chains partnering[1].

A question guide with specific probes was developed based on a scoping review of literature conducted as part of the larger CODEMISUSED study (Van Hout, Bergin et al. 2014) . The focus group guide covered experience of being a community pharmacist, regulation and monitoring of codeine containing preparations, public awareness, , , relationships with other medical health professionals, training needs, extent of public misuse and dependence intervention and customer support for misuse and dependence.

National community pharmacy chain partners in the project assisted in the recruitment of participants via an email invitation and/or telephone communication, as well as the organisation of focus group locations and co-facilitation. Convenience sampling was used to secure pharmacist participation in urban and rural areas. Inclusion criteria centred on being a registered community pharmacist and having experience with dispensing codeine.

All potential participants received an information leaflet about both the larger project and the specific study in which they were being invited to take part. This was accompanied by an informed consent form. Participants who wished to take part then signed this and returned it to the study team.

[1] www.codemisused.org

The deliberations of thefocus groups were guided by thefocus group guide outlined above. Deliberations were audio-recorded with the permission of participants and conducted by a lead researcher based in the country where the focus groups took place, with a co-facilitator present to assist and take notes if necessary. Focus groups were held in privaterooms on premises used by the pharmacies' administration, after working hours (See Table 1 for the demographic characteristics of the six focus groups).

Insert Table 1 here

Table 1 Focus Group Details

Country	Number (n) of Participants	Males (n)	Females (n)
Ireland	11	1	10
Ireland	4	1	3
United Kingdom	10	6	4
United Kingdom	8	4	4
South Africa	6	5	1
South Africa	6	3	3
Total Focus Groups 6	45	20	25

Audio recordings were transcribed verbatim and analysed using the constant comparative method of content analysis (Glaser and Strauss 1967; Lincoln and Guba 1985). Data analysis involved joint coding and analysis whilst continually reviewing the data for emergent categories. This method adhered to the following key stages: comparison of incidents applicable to each category; integration of categories; delimitation and writing of theory. Open, axial and selective coding (Glaser and Strauss 1967) was employed to identify main and sub-categories in order to enhance generality and explanatory power (Strauss 1987).

Results

Eight themes emerged from the analysis of data. We present each theme with illustrative quotes.

Pharmacy Practice Strengths, Challenges and Patient Self Care

In this theme, participants in all countries were supportive of their role as a community based health professional in the front line of treatment and an important resource to the community for the treatment of minor ailments and provision of medical and health related advice:

> I think 9 out of 10 times a pharmacist is the first line of therapy… you are the first treatment line so you are approached first. (South African Focus Group #2)

There was some discussion among South African participants as to whether public awareness around the role and community value of the pharmacist's profession was increasing.

> Regarding say 5 years ago, I think the people are getting more aware about pharmacy and the profession of pharmacy. Maybe, as pharmacists we need to train the public about what we are and what we do. I think there is a positive in that direction. We need to be one of the most professional people with the lowest professional recognition so…. (South Africa Focus Group #1)

However, some South African participants felt that pharmacists have become 'glorified shop keepers' and reported a lack of respect for their profession from customers.

> A lot of our patients, if you were to suggest something, they would rather take the next customer's advice rather than the pharmacist's advice or would say, no listen, I would rather phone my doctor instead of listening to you that know medicines much better than the doctor. (South Africa Focus Group #1)

The development of relationships between customers and pharmacists were viewed as important by all participants in each country, with trust and confidentiality being key ingredients:

> People have great trust in you. It's not just being a pharmacist but they think of you, sometimes, as more of a friend or somebody to talk to. or someone to talk to. Which is always a good thing. (Ireland Focus Group #1)

> We've got the faith of the patients, really they believe and you hear nearly every day, I've got more faith in you as a pharmacist than the doctor, all of us hear that and I mean the people really mean that. I mean we are there to give a good service. (South Africa Focus Group #2)

Business environmental challenges centred on generic substitution of medicines and funding models for payment. Retail pressures were viewed in both South Africa and the UK as contributing to decisions to supply OTC codeine products ('giving the patient what they want'). Commercial chains in South Africa were viewed as especially competitive. Irish participants also experienced financial pressures but were bound by the Pharmaceutical Society of Ireland 2010 guidelines for safe sale and supply of OTC codeine containing preparations

> There is really no profit, the price is fixed, the mark-up for our dispensing fees is fixed to a large extent but the costs are escalating like in any other business so we earn smaller and smaller margins and more and more pressure, it is very difficult to remain professional in the face of the financial constraints. (South African Focus Group 2)

> Poverty walks through the front door and ethics usually goes out the back door!! I should not really sell to the patient but you need to pay the rent at the month. (South African Focus Group #2)

Another challenge mentioned was the resource intensive nature of their work in terms of time spent advising customers. Participants in all countries perceived this as difficult due to the lack of time available to interact and consult with customers, despite some requiring more information and advice than others. A further challenge mentioned only by Irish pharmacists was that lack of access to private

medical care sometimes contributed to customer requests for longer duration scripts from their primary care physician.

> Hard work I was going to say. I suppose because you have to pay to see the doctor, people do come in and ask you a lot of questions over the counter and ask your advice (Ireland Focus Group #1)

Public Awareness of Codeine Containing Products

This theme illustrated participants' views on public preferences and awareness of side effects for prescribed and non-prescription codeine containing preparations. Popular OTC codeine containing preparations available included Solpadine®, Nurofen Plus®, Migraleve®, Feminex®, and Uniflu Plus® in Ireland, Adcodol®, Syndol® and Myprodol® in South Africa, and Co-Codamol® in the UK. South African participants described how customers were sometimes not aware of the names of products that contained codeine, but recognised the colour, appearance and packaging of desired products.

> They will say I want the green box. …I don't think the patients are aware of what is inside. (South African Focus Group #1)

Generally customers in all countries appearunaware of the side effects of codeine, both in the short term and the long term, and the associated harms relating to additives such as paracetamol and ibuprofen in combination analgesics. Marketing and advertising was thought by UK participants to fuel the perceptions that codeine was an effective and safe treatment for pain.

> A lot of customers don't know the side effect profile, so that they can be constipating [ed] or sometimes Solpadine, if it's used very regularly, can induce headaches. Sometimes I would inform people and they've never heard of that before or they're not familiar with it. (Ireland Focus Group #1)

Most of the participants reported that for customers who misused or were dependent on codeine, , denial of the risks around excessive and/or long term consumption of combination products existed. Irish participants also discussed that despite pharmacists' efforts to inform customers of these risks, certain customers still wanted to obtain the desired codeine product:

> I think it's the combination products. They don't realise and just don't really care as long as they get their codeine fix. (Ireland Focus Group #1)

In contrast, in South Africa, participants reported that there has been a shift in public awareness and toward the recommendation of codeine-free products among customers in recent times:

> We get a tendency where a lot of patients actually ask for something that is codeine free. (South African Focus Group #2)

Perceptions of Customer Misuse of Codeine

In this theme, the types of customers that potentially misuse codeine were described, with pharmacists viewing the spectrum of misusers as broad in all three countries

> It's more of their behaviour, you could get from poorly dressed to finely dressed, from poor to excessive rich. (South African Focus Group #1)

> It's a broad spectrum of patients, a young working mother or an elderly lady (United Kingdom Focus Group #1)

Participants discussed how they identified customers that they suspected of misusing codeine. This included recognition of customer behaviours exhibiting a denial of risks involved in use of codeine preparations, and the lack of eye contact and agitation on requesting certain branded products. Often participants in all countries simply had a sense of who would request a codeine containing preparations: Participants in all three countries also explained that in their experience, customers that misused OTC codeine containing products often requested specific products:.

> You could probably know they walk through the door and you know they're coming in to get a box of "fizzies"[Solpedeine] or whatever? (Ireland Focus Group #1)

Some Irish participants commented that not all customers intentionally misused codeine, but that they had developed habits for a number of reasons for example to deal with the after-effects of excessive alcohol use:

> I think it's something that could be caught really easily.. So how common is it that patients are like "Oh I need my two fizzies in the morning to get out of bed"? (Ireland Focus Group #1)

One of the perceived reasons for customers' continued misuse of codeine-based products centred on psychological anticipatory triggers relating to soluble codeine products, according to some Irish participants.

> Some people get the buzz from the soluble… out of watching it fizz" (Ireland Focus Group #1)

> Some people chew them. They chew soluble tablets, the big one, and it works that way. They put the two of them in their mouth? (Ireland Focus Group #1)

Customer recognition of tolerance, withdrawals and dependence was described by Irish and South African participants as occurring later in the cycle of misuse, and with dependence trajectories often complicated by the presence of untreated pain.

> Like it might take them even longer to consider there to be an addiction, it's usually much further along. Before they might…realise they've got a problem. (Ireland Focus Group #2).

> I don't think patients really know of the addiction of it. They just know 'I've got constant pain and this stuff works' and they just continue using this, I don't know, that's my opinion. I really think they don't really know they are addicted, ya. (South African Focus Group #1)

Sourcing of Codeine-Containing Preparations

This theme illustrated awareness around ways that customers source codeine containing preparations. In all three countries, participants were aware of customers travelling to different pharmacies to purchase ' codeine containing products ('*pharmacy hopping'*). This was viewed as an underlying problematic factor in dealing with inappropriate requests and misuse of codeine products, and despite best efforts of medicines control in each country:

> They still look you in the eye and say "If you don't want to give it to me, just tell me, I'll go to the next pharmacy". (South African Focus Group #1)

> They'll do things like cycle round, I've worked in the community where there is three branches and I can pop between the three and see the same person come in again and they turn round and walk out because they saw it was me and they knew they were going to hit that barrier if they requested it..(United Kingdom Focus Group #1)

Other tactics included using family and friends to purchase OTC codeine products and in-store theft of codeine products.

> And getting other people to get it for them as well. Their sibling and their parents … (Ireland Focus Group #2)

Irish participants reported low awareness of online pharmacies operating in and outside of the European Union. In contrast UK participants involved in the operation of online pharmacies reported concern about frequency of requests for codeine and the development of innovative IT mechanisms to restrict amounts purchased.

> One of the advantages of the internet is that it's harder to be anonymous, you know you can try with multiple e-mail addresses but you generally come back

> down to having just one credit card, so we worked hard at setting up systems that allow us to question people who appear to be trying to obtain more codeine than they should. (United Kingdom Focus Group #1).

South African participants were aware of online pharmacies and postal pharmacies, and reported concern about lack of customer screening and consultation in these routes for access. There was also concern around the couriering of codeine containing products:

> Here they are even talking about postal pharmacies – posting medicines direct. I don't think they've got an idea what they're doing to the patients sometimes. (South African Focus Group #1)

Some South African participants also mentioned that certain customers obtain codeine-containing preparations in pharmacies by stealing them, especially when pharmacists are busy assisting other customers.

> It comes from the most unbelievable source, they don't look like criminals, I have this typically normal housewife that comes in and I was just in time to see her packing the Syndols®, into her handbag (South African Focus Group #2)

Decisions to Dispense OTC Codeine Based on Regulations

This theme illustrates participant views on decisions to dispense non-prescription codeine. This is somewhat pre-decided by the regulations that exist in each country. Decisions to dispense these products centred partly on national regulations in the countries where the focus groups took place. In the UK the specific mnemonic WWHAM (*who is the patient, what are the symptoms, how long have the symptoms been present, action taken, other medication being taken*), was used by pharmacy staff to gather information and reduce the risk of misuse. In contrast to South African participants who are required to keep a Schedule Two record of codeine sales, informal record keeping and awareness of certain customers frequency of requests for codeine products was described by Irish participants.

> I'm talking about now the regulations are very strict with access I mean physically being denied, I mean in those days you had a counter and anyone could walk around, in your case you had to put a little door there. So it's been made more difficult (South African Focus Group #2)

> Everybody knows now that Solpadine® in this country, you're gonna get the "shake down" or whatever… .(Ireland Focus Group #2)

A challenge to providing the appropriate intervention as described by Irish pharmacies was that requests for codeine were frequent and therefore the appropriate response can be repetitive and time consuming. Some of the Irish participants mentioned that the required regulatory questions for customers buying OTC codeine products were over time well known to them, and with well rehearsed scripting on the part of the customer seeking the product. Concerns given the varied approach to non-prescription codeine sales were particularly evident for independent community pharmacies. Refusal to dispense conflicted with efforts to maintain a customer base and relations.

> It can be difficult though at this stage because people have gone through the questions so many times. They know that if you say "have you tried something else?" they know to say yes. And if you say "what are you using it for?" they immediately jump to "I was in a car crash/ I was on morphine" They immediately go for something really extreme because the more dramatic it is you know… Ireland Focus Group #2)

> And they've said before "I haven't been here in ages, can I not get it again?" and then came back in again and queried "Why? Why can I not have it?" So you have to go through the whole thing again. …(Ireland Focus Group #1)

The availability of OTC codeine-containing products was also discussed in terms of its legitimate use in effective pain management after first line pain management using paracetamol or ibuprofen. Debate arose around the merits of up-scheduling codeine products versus the requirement of available pain relief over-the-counter to the general public. Some were of the view that given the difficulties in customer communication during the dispensing transaction, up-scheduling would remove the potential for conflict, and prevent customers from accessing multiple pharmacies.

> Codeine has a definite use especially as far as cost effective medication in pain killers; codeine is a very good drug so one mustn't just up-schedule them to schedule 6 but then you have a void for effective pain medication. (South African Focus Group #2)

In contrast, others in all three countries were of the view that given the difficulties in customer communication during the dispensing transaction, up-scheduling would remove the potential for conflict, and the prevention of customers accessing multiple pharmacies.

> Then at least you've, sort of, a blame mechanism saying "I'm not allowed to sell anymore". Then it's not your fault, it's remover from you. (Ireland Focus Group #1)
>
> I suppose it would to an extent because you know, at least then they're potentially just on prescription, so there's going to be a record kept of everybody who gets them because you'd have a record of everything you've dispensed. So you won't have the problem that people can just go anywhere and get them. (Ireland Focus Group #2)

Methods pharmacists utilise in dealing with suspected codeine misuse

Besides the existing regulations around the sales of OTC codeine products, participants in each country spoke about their own methods of dealing with suspected codeine misuse. One of these was to either refuse the sale, or do a one-off sale of the product to deal with frequent requests for codeine.

> Ordinarily I would give it to them and say, "look if you're going to be needing it a lot, you might need to get the doctor to write a note or write something down". I

would say “I’ll give it to you this time but if you’re needing it again, you might want to speak with the doctor” …*(Ireland Focus Group 1)

Attempts to intervene centred on offering first line pain management prior to supplying the codeine product or offering a product with similar packaging.

They say “I’ve tried that” or “that’s no good for me” Sometimes it does, like if you offer them Panadol Extra®, that’s in a box that looks like Solpadine ® they might take it.*Laughter*Because they might think it might have codeine in it … (Ireland Focus Group #2)

Participants in all three countries discussed their efforts to switch customers experiencing problematic codeine use to alternative codeine free products such as paracetamol.

I’ve always tried to offer an alternative and try to explain that this has codeine in it and can lead to dependence (Interviewer: Ok). But it’s the patient’s right. Most of the time they don’t feel like listening to you. (South African Focus Group #1)

A challenge to their, efforts to act responsibly when they were deciding whether to dispense codeine or not were that less consistent approaches in other pharmacies were often the case. This was described by all participants in each country.

I think I know the problem of society who talks about the negatives come from those pharmacists who are busy, who don’t follow the rule. So when a patient comes in and says ‘oh I’d like some Stilpane®’ and you say no it’s on schedule 5 and you need a script. ‘But ‘I get this all the time at (other pharmacy) ‘.Some pharmacists are also undermining the profession. (South African Focus Group #1)

There’s a variation between stores obviously on how strict they are. I know from working in other shops and talking to other pharmacists, some shops are really strict and others are very blasé about the amount… (Ireland Focus Group #2)

Perceptions of Prescribing and Customer Prescriber Management/ Manipulation

In this theme, while some participants discussed relationships and alliances with prescribers in relation to managing codeine misuse and dependence, others discussed medical professionals as possibly contributing to the problem by overprescribing and repeat-prescribing of pain medication containing codeine and other stronger opioids. In the UK some participants described codeine prescribing as the norm and implied that patients were being prescribed codeine for prolonged periods. Concerns were raised around this, and a number of pharmacists described poor relationships between themselves and the prescriber. Irish participants reported that they only questioned customer dosage on scripts if misuse was suspected, dosage was unusually high or if forged scripts were presented.

> You wouldn't really question it. Not unless it was a really obscure dose or something. (Ireland Focus Group #1)
>
> I suppose if it's the dose or something, you'd do the same as any other item if the dose is wrong, you'd phone the prescriber and say "look, this isn't a normal dose" and ask for the reasoning behind it or adjustments to be made to it. (Ireland Focus Group #2)

Some South African participants described refusing to dispense prescribed codeine when concerned around dosage.

> Said to the patient, you don't want to phone the dr, you don't want to change it, I'm not giving it. Here's your script you can go to another pharmacy or go to the doctor and he will give you your medication, but this dose I don't give it out . (South African Focus Group #1)

. Other South African participants discussed concerns for length of time used:

> With codeine, they don't actually listen to us. They stay within the prescribed dose, but it's the period (length) of prescribing that is my problem. (South African Focus Group 1)

Displacement between prescribed and OTC codeine, often in the event of under managed pain was observed by Irish participants.

> You wouldn't give it to them. You wouldn't let them take it. You'd ask why they're looking for it or try to get to the bottom of why it is and there may be something, a greater need so you'd refer them back to the doctor. And you remind them of the maximum dose that can be taken as well, (Ireland Focus Group #1)

Displacement in customer preferences were observed between prescribed and non-prescription codeine containing preparations, with customers often asking for non-prescribed products containing codeine in addition to the products prescribed by their doctor..

> It's a combination of both. I would say 50/50. Prescribed are more effective of course. (South African Focus Group #1)
>
> I have experience of patients who will get say 30/500 co-codamol on prescription and they will know exactly how to get more ie. they will go for Nurofen plus and they know exactly the milligrams to take which is safe of the ibuprofen. In a way they are really very highly educated in the effects of codeine and also preparations that contain it. (United Kingdom Focus Group #1)

Some awareness of customer 'double doctoring' (frequenting multiple prescribers to obtain required medication) was described by Irish and South Africa participants, particularly between medical card and private doctors. Accessing multiple pharmacies for multiple scripts was also observed by Irish and South African participants for prescribed codeine. Doctors in this instance were often not aware of this:

> A very difficult scenario because they're one professional against another professional and the other one is as entitled to prescribe as anyone else. (Ireland Focus Group #1)

Efforts to inhibit accessing of multiple prescribing in South Africa centred on being in contact with local doctors and faxing prescriptions to them if necessary.

Community Pharmacy Intervention

This theme described views on potential for enhanced community pharmacy training, care and intervention with customers experiencing problems associated with misuse, as participants reported that it is often difficult to recognize customers who may have a substance use problem. Discussions centred on the potential for enhanced community pharmacy training, care and intervention. Specialist training in addiction and conflict resolution and communication skills was viewed as necessary:

> Once you have seen a patient that has been addicted you'll realize why it is important to learn the steps of constructive confrontation. (South African Focus Group 2)

Screening, brief intervention and referral were described as a useful system but complicated by lack of resources and reimbursement. A challenge to utilising this approach was also the lack of awareness of referral structures and appropriate addiction centres, along with perceived conflict of duty of care and patient confidentiality and trust:Both Irish and South African participants discussed that the only referral source that they were aware of was the customer's doctor.

> I think there's no clear structure in place. I wouldn't know if somebody came to me in the morning and said "I have a codeine addiction" so unaware would you be that himself or herself probable wouldn't know what… That's my personal opinion; I don't think there's any…(Ireland Focus Group #1)

> The biggest challenge for us is once we have identified them what next, there is no proper referral mechanism to who we can refer them too. (South African Focus Group #2)

Public stigma relating to addiction, delays and long waiting times for methadone substitution were observed to complicate referral pathways in Ireland.

> I'd always look at those people and go "they're accidental addicts" whereas I mightn't necessarily have that opinion of other people who are addicted to things. …you know, they're addicted but addiction isn't something that's in their social class as far as they're concerned…(Ireland Focus Group #2).

Only one Irish participant described the experience of medically supervised tapering and detoxification using codeine, while South African participants discussed that community pharmacy tapering and detoxification was an option provided the customer was willing to undergo this procedure, but was not always successful

> Once you have got their confidence you can try that but it is very seldom successful. More successful is to have a support arrangement with other pharmacies. I had an arrangement with a GP in the hospital that treated out patients because he knows that ……. Can't treat the patients with the drugs that are most useful….so if you book them with ……..that's usually the most effective because even with the drug wise council you can never become a counselor you become an intervener, all you can do is intervention and referral and you should have referral pathways and get to know where to refer them to (South African Focus Group #2).

Integrated total care pharmacy within existing care structures was discussed as a potential solution. Community pharmacy tapering and detoxification was discussed as an option provided the customer was willing to undergo this procedure. Timeliness and readiness to commence treatment within a support relationship with the pharmacist was observed by South African pharmacists as useful. Family involvement in treatment pathways were deemed important by South African pharmacists.

> There is a program that's starting up now that a multiple treatment regime they get doctors psychologists and pharmacists involved, you will have spoken to them, so that's starting off now but you need to have all those people relatively

close to each other for it to be effective but its early days yet for that so we will have to wait to see how that works out. ISouth African Focus Group #2)

Discussion

The findings of this study indicate that codeine misuse is a widespread problem in which the pharmacy and pharmacists are central in terms of the observation of the phenomena. In addition, pharmacists are also the first point of intervention in relation to the management of the problem, though their response is largely shaped by the particular regulatory regime under which they operate. In this regard, it should be noted that caught between the demands of a commercial customer based model of dispensing and prescribers who approach the issue solely in terms of pain management, the ability of the pharmacist to effectively intervene to manage the problem is somewhat circumscribed at present. Community pharmacy and prescriber dynamics centre on overprescribing and repeat prescribing of codeine medication, with concerns around dosage and length of treatment regime voiced irrespective of regulatory controls for sale OTC. Accessing of multiple prescribers and pharmacies was experienced and discussion centred on the need for enhanced surveillance and integrated prescriber-dispensing data. Strengths of community pharmacy practice however centre on the development of trust and relations within the customer base and surrounding community and offer an important community resource in addressing codeine misuse and dependence.

One striking result of this study is the ineffectiveness of information provision models that currently exist for customers/ users at the point of sale/ dispensing. The reported lack of interest in current sources of information (such as the information leaflet in some products) is likely to reflect the ubiquitous nature of the product and a general perception that it is safe. This not only underscores the continued need for improved patient information package inserts andwarning labels; restricted pack sizes and overall interagency pharmaco-vigilence (Cooper 2013b), but also suggests that other approaches to raising public awareness through education need to be explored to improve first line response in beginning to manage the problem of misuse. Initiatives to enhance public knowledge, improve compliance and patient informed decision-making, around safe use of OTC codeine are

therefore warranted (Boyd, Waring et al. 2013; Van Hout, Bergin et al. 2014). Awareness of health literacy and lay definitions around use of over the counter medicines would appear to be key to a successful approach (Bjornsdottir, Almarsdottir et al. 2009). This is alongside a tailored approach to provision of medicine information (written, verbal or combined) to particular groups of customers requesting codeine (Hamrosi, Raynor et al. 2013; Hamrosi, Raynor et al. 2014). In this context the community pharmacy is a trusted source of consumer advice and information around safe and appropriate use of medicines (Wazaify, Shields et al. 2005; French and James 2008) and would need to play a central role in information giving to users at point of dispensing.

The findings indicate that consultations between pharmacy staff and customers are influenced by communication and information exchange. This is in line with previous studies (Watson, Hart et al. 2008). However, difficulties in effectively identifying customers that have substance use problems, including codeine were mentioned since many misusers maintain normal day to day functioning and do not show overt signs of misuse. Previous literature also found that the identification of the myriad forms of misuse is challenging (Nielsen, Tobin et al. 2012; Hamer, Spark et al. 2014) which are visible to community pharmacist in the form of frequency of supply and habitual purchasing.

Pharmacists taking part in these focus groups demonstrated a desire to assist in the management of the problem of misuse and suggested ways that their role in this context could be enhanced. Formal screening, brief intervention and referral pathways were discussed at length as a viable option for dealing with customers who have substance use problems in general, including those that misuse codeine. The SBIRT (screening, brief intervention, referral to treatment) model has been recommended and utilised in health care settings for substance use with a number of populations.

The current literature indicates that providing pharmacy staff training in the delivery of targeted substance misuse screening and brief interventions show promise in addressing staff knowledge, attitudes, skills and competencies in counselling and patient consultations (McBride, Pates et al. 2003; Sheridan, Wheeler et al. 2008; Fitzgerald, Watson et al. 2009; Butler and Sheridan 2010; Dhital, Whittlesea et al. 2013). Given the difficulties involved in engaging with difficult customers,

recommendations have included increased practice based emphasis on pharmacist and technician training in the area of addiction and communication skills (Butler and Sheridan 2010; Cooper 2011; Cooper 2013b; Hamer, Spark et al. 2014). Specialist training, reimbursement for customer consultation, and expansion to include screening brief interventions, visible referral structures and assisted community pharmacy detoxification were discussed.

Harm minimisation models in community pharmacy have indicated some success in tackling misuse of codeine, and centre on targeted patient identification, treatment referrals and data monitoring (Fleming, McElnay et al. 2004; Wazaify, Hughes et al. 2006). In this context of particular interest arising from this study was the approach being taken in South Africa in relation to multiple treatment regime collaboration and better information sharing between pharmacists. However, one should not underestimate the logistical, professional and inter-sectoral barriers that may arise in establishing such collaborative structures.

Limitations

The legitimate therapeutic need and public right to essential medicines complicates the issue of codeine misuse (Van Hout and Norman, 2015) In this context this study explores the issue of codeine misuse and dependence across three regulatory regimes with a cross comparison of community pharmacist views, opinions and recommendations for improved surveillance and practice. As the study was only conducted in three countries with a small number of pharmacists, we do recognise that the findings cannot be generalised to the general pharmacy community in these three countries, and are cognisant of the limitations present in qualitative design. That said, the study offers key insights into the comparable experiences of community pharmacists in dealing with this public health issue.

Conclusion

This study illustrates the issues faced by community pharmacists in dealing with OTC codeine dispensing and misuse. It highlights that current tactics used to prevent and treat codeine misuse and dependence such as labelling, health information and regulations are insufficient and needed to be improved. . The study indicates that further research is warranted in this area, particularly as it relates

to the central role of the community pharmacy and pharmacists in the first line management and reduction of codeine misuse. Community pharmacy in its capacity to provide customer education around safe and compliant use of habit forming medicines such as codeine, risk surveillance and enhance self-care planning represents a vital mainstay in the public health system (Westerlund, Andersson et al. 2007; Ryan, Santesso et al. 2011; Ryan, Santesso et al. 2014). The continued availability of OTC codeine as a useful medicine is desireable (Van Hout and Norman, 2015). However, current tactics to ensure safe use (labelling, health information, pharmacist involvement in sale) for the vast majority remains desirable (Roumie and Griffin 2004; Cooper 2013b), based on this study's findings, appear to warrant improvement .

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Appendix A. Initial interview guide

1. Tell us what it is like to be a pharmacist in Ireland?
    a. Let's discuss the general policies around pharmacists in this context
    b. What are some of the challenges that pharmacists face?
    c. What are some of the strengths of the pharmacy industry in Ireland?

2. Let us discuss the products that you provide to customers as a pharmacist that contain codeine?
    a. Are these products usually over-the-counter products or prescribed/dispensed?
    b. What are the most common products that contain codeine that you sell?
    c. What, in your opinion, are the most harmful aspects of codeine use for customers that use codeine products?
    d. How do you keep records of customers that buy products containing codeine?
    e. Do you think codeine misuse is a problem for customers that visit the pharmacy that you work in, and why?
3. What is your relationship with medical professionals that prescribe codeine products?
    a. What would you do if you received a prescription containing codeine that was clearly problematic (i.e. much more than the expected amount)?
    b. How do you respond to repeat prescriptions?
    c. Describe some of the difficulties in working with medical professionals when codeine has been prescribed.
4. What would lead you to suspect that someone is misusing codeine products?
    a. Can you describe the patterns of behaviour that customers that may have a problem with codeine use display?
    b. Discuss the kind of consequences that as a pharmacist, you have seen codeine misusers face?
    c. Are there any alternatives to products containing codeine that you offer to customers?
    d. Have you ever refused to provide a customer with a product containing codeine? If so, tell us what happened and how you dealt with it.
    e. Does your pharmacy have a monitoring system for those suspected of codeine misuse?
5. Alternative Methods to obtain Codeine Products
    a. What do you understand by double-doctoring, and have you ever come across it either in the pharmacy where you work or other pharmacies?
    b. What are your views on web-based pharmacies?

c. Have you had any experiences of suspected codeine misusers using their family or friends to buy products for them? Tell us about these instances.

6. Management and Referral
    a. If you suspect that a customer has a problem with codeine use, what would the procedures be that you follow to try and help them?
    b. Do you know of places that you could refer customers to for treatment for codeine and/or other drug misuse?
7. Training
    a. What kind of training have you received (if any) for what to do if customers may need help with their codeine use?
    b. Would you like more training on codeine prescription, monitoring and referral?
    c. If so, what kind of training do you think would be helpful?
8. Finally, if you could change only one thing (either within the pharmacy or in the wider healthcare system more generally) to reduce the frequency of codeine misuse what would it be?'
    a. What changes might be possible for the future?
    b. What resources would be needed for these (human or other)?
    c. What would be the facilitators and barriers to implementation of these changes that you envisage?
    d. Do you think that the current legislation or regulation of codeine is helping to reduce codeine misuse?
    e. What could be put into place to protect patients more?