‘Respectable Addiction’ -

A qualitative study of over the counter medicine abuse in the UK

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Executive Summary

Background and aims

The sale of over the counter (OTC) medicines from pharmacies represents an opportunity for people to self-medicate and manage their own symptoms. However, some OTC medicines have the potential for being used incorrectly or abused, and there have been increasing concerns about risks associated with some medicines. The primary aim of this study was to describe and understand current issues relating to OTC medicine addiction by investigating the experiences of individuals affected by OTC medicine addiction in the United Kingdom (UK), pharmacists and medicines counter assistants (MCAs), and key UK stakeholders. Additional aims involved exploring the role of the internet, pharmacy involvement, and different types of medicine use.

Method

Qualitative, semi-structured interviews were undertaken with three purposively sampled groups. Firstly, 16 key stakeholders from organizations and employment related to OTC medicine addiction were interviewed including representatives from pharmacy organisations and businesses, industry representation, medical addiction interest groups, addiction and eating disorder charities, clinical perspectives from public, private and voluntary treatment services, and academia; secondly, 10 pharmacists and 7 MCAs were interviewed, representing different locations (England, Scotland and Wales) and pharmacy ownership types (multiple, independent, rural, city); thirdly, 25 individuals were recruited via two UK on-line medicine addiction support groups (Overcount and Codeine Free). Semi-structured qualitative interviews were undertaken by telephone and in-person and audio recorded, save for one participant who requested email/text-based communication. Interviews were conducted during 2009 and 2010 and all were audio recorded and transcribed verbatim. Analysis involved a process of constant comparison, with initial open and descriptive coding, and subsequent axial coding, with refinement of emergent themes. University of Sheffield ethics approval was obtained.

Key findings

Individuals who had experienced OTC medicine addiction – *Three types of 'respectable addict'*

Individuals referred to themselves as 'addicts' or 'addicted' and all described the use of an opiate – usually codeine - containing medicine, but with occasional examples of pseudoephedrine and diphenhydramine containing products being reported. All but two participants had begun using OTC medicines for genuine medical reasons to treat symptoms that included headaches, migraine, period, joint or post-operative pain. For some this had occurred after medical treatment had ended but for others, varying relationships between past and on-going use of prescription medicines and OTC medicines were identified, including examples of topping-up, gap filling and variable consumption (fig. 1). Some had attempted to self-treat symptoms completely and only two participants had intended to exploit a medicine side effect for non-therapeutic reasons from the outset.

Three distinct types of OTC medicine addiction were identified based upon the quantity of medicine taken: type I involved those who never exceeded the maximum dose; type II involved those who sometimes took slightly higher than recommended doses; and type III included those who took significantly higher doses than recommended (fig. 2).

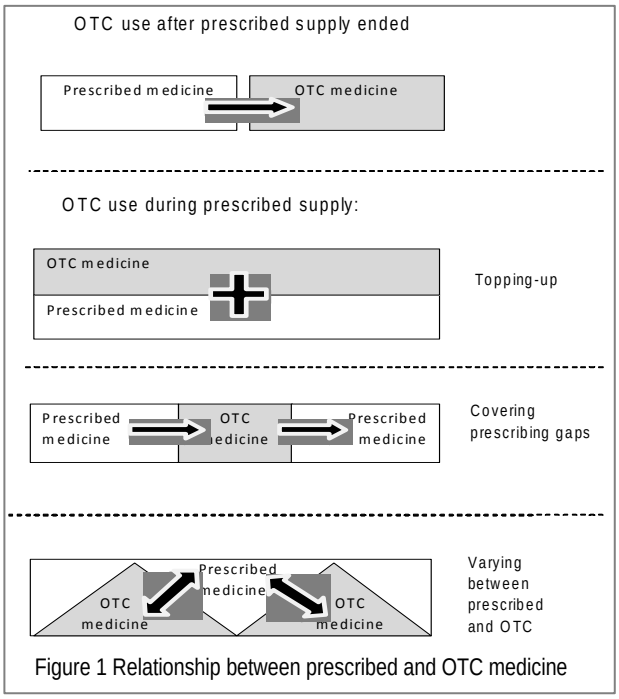

Figure 1 Relationship between prescribed and OTC medicine

The three types appeared discrete and there was no evidence of transitioning between them. All three types described withdrawal symptoms and using the product for different reasons than clinically indicated, often describing 'a buzz' or 'calm' from codeine. Recurrent patterns of drug-seeking behaviour were described, including purchasing and use rituals such as brand specificity, deception and secretiveness, anxiety when supplies diminished, and intentionally varying the pharmacies they used. Two participants had used the internet to obtain supplies, and described obtaining multiple packets with relatively lax control and registration procedures. Most individuals raised safety concerns about internet-supplied medicines.

All individuals had attempted to stop but some were still taking an OTC medicine; self-treatment, advice from on-line help forums, involvement of doctors and drug and alcohol treatment services and narcotics anonymous were variously described (fig. 2). None sought pharmacy advice, and some explicitly rejected medical help or support from help forums due to concerns about their addiction being recorded, concerns about lack of GP understanding, or a desire to hide their addiction. Views of the role of pharmacists/ MCAs were mixed, but mainly centred on the ease of obtaining supplies and the ineffectiveness of standard questions.

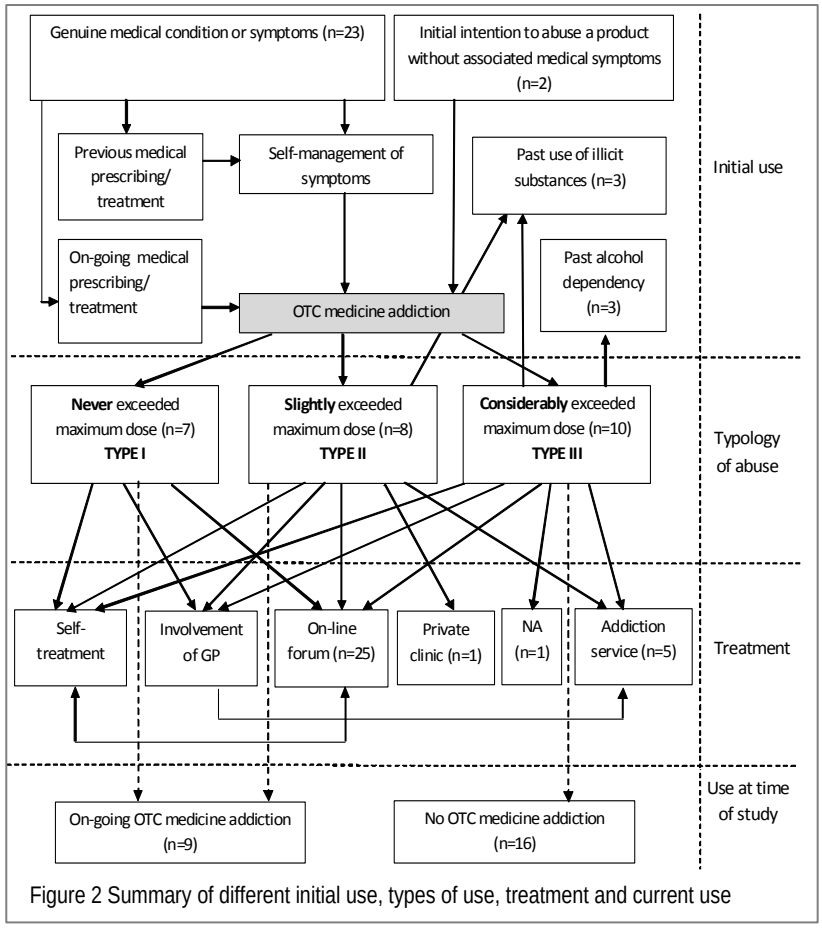

Figure 2 Summary of different initial use, types of use, treatment and current use

Complex and potentially conflicting identity claims were expressed (fig. 3), including explicit recognition of an 'addict' identity which was contrasted with those who were addicted to illicit drugs or alcohol, which has negative connotations. A respectable identity claim was clearly identified in descriptions of individual's professional roles and self-perceived intelligence and frequent desire not to have addiction recorded; secrecy was often described along with shame for some.

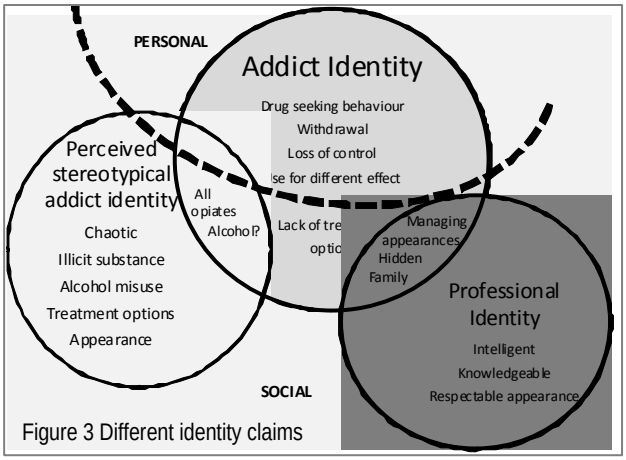

Figure 3 Different identity claims

Individuals were aware of risks associated with OTC medicines and distinguished these from more potentially harmful or problematic substances, such as illicit drugs, medicines sold via the internet and some prescription medicines. In relation to policy and regulation, the majority were in favour of continued availability of OTC medicines that may cause addiction, and generally viewed addiction warnings on medicine packs and leaflets as being ineffective for those already addicted but of some benefit to warn new users. Individuals blamed themselves more than pharmacists, regulation, manufacturers or doctors for their OTC medicine addiction.

Stakeholders – *'Raising awareness, improving treatment'*

The wide range of stakeholder groups provided different insights and backgrounds but many common themes. Emergent themes included issues around products involved, the scale of the problem, treatment, internet supply, views on pharmacists, and policies. The medicine referred to most frequently, and for some the only medicine associated with OTC medicine abuse, was codeine. Like those with direct experience, and also pharmacists and MCAs, the majority of stakeholders were in favour of continued availability overall but emphasized the need to raise awareness and understanding amongst the public and health care professionals, and to improve treatment options. These were linked to concerns about the inadequacy of formal, evidence-based treatment options. Stakeholders held mixed views about pharmacists and their role, and viewed the internet availability of medicines as a currently small but significant future issue. There was evidence of co-operation between regulators, manufacturers and those representing support groups.

Assistants – *'Uncertainty and Monitoring'*

For those working in pharmacies, OTC medicine problems were often referred to in terms of the phrase abuse rather than addiction and were focused on the type of medicine and the frequency of purchases overall. The *frequency* of purchases by customers appeared to define who MCAs considered to be abusing an OTC medicine, reflecting a monitoring and surveillance approach. A range of products were implicated and referring customers to pharmacists was a key activity in this area, which avoided confrontation. Pharmacists identified a wider range of medicines as being abused, but appeared to be uncertain about signposting options and were often not aware of how and where to refer them. Many identified the lack of information about customer's medical and current medication history and use of other pharmacies to be a key barrier to doing more. Pharmacists could be grouped into those who were negative about pharmacy involvement in supporting OTC medicine abuse or addiction, and those who, despite current problems, felt pharmacists could do more. Both pharmacists and MCAs recognised that OTC abuse was facilitated by having many different pharmacies that did not communicate with each other.

Recommendations	Impact (or responsibility) upon:						
	Health Care Professionals			Public	Those already addicted	Researchers	Policy makers
	General Practitioners	Pharmacists /MCAs	Specialist drug service staff				
Raise awareness of OTC medicine addiction/abuse	Need to recognise that addiction can occur with differing doses of medicines; to understand implications of opiate prescribing decisions (on-going and when stopping). Understand hidden nature of OTC medicine addiction.	Need to understand different types of addiction not just based on frequency and dose. To recognise hidden nature of OTC medicine addiction. Provide in-pharmacy information.	Need to recognise the different types of addiction, and particularly those who may be using relatively low doses.	Public need to be made aware of addiction potential of OTC medicines.	May help develop insight into personal addiction.	Study the impact of warning advice on packets and leaflets.	Continue to require codeine addiction warnings. Consider for other medicines (sedative antihistamines, pseudoephedrine) Consider other means of communicating risks.
Improve interventions and treatment and awareness of them	Understand treatment options. Appropriate referrals made. Consider pain management reviews.	Consider use of brief interventions. Know where to signpost.	To consider specific treatment needs of OTC addiction clients.		Successful cessation of OTC addiction.	Evaluate clinical effectiveness of compound opiate analgesics. Evaluate interventions in referring and treating.	
Identify the scale of OTC medicine addiction and study clinical harms						Robust quantitative UK & international studies needed. Study extent of harm caused by compound opiate medicine.	Make regulation proportionate to scale of the problem. Report OTC medicines in NDTMS data analysis.
Monitoring internet sites that sell medicines				Safe and appropriate supply of medicines	Safe and appropriate supply of medicines		Continue process of monitoring internet sites that sell medicines
Explore options to record OTC medicine sales		Ability to monitor frequency of sales accurately		Personal information recorded	Personal information recorded	Evaluate impact of monitoring on medicine use, & impact of recording	Consider feasibility of adding OTC sales to summary care record
Continued stakeholder collaboration							Ensure different viewpoints represented and mutual goals agreed

Limitations

This study provides a UK perspective on OTC medicine addiction and reflects the medicines, pharmacies, services and policies available in this country. However, many of the medicines available reflect those in other countries in Europe and Australia, for example. The sampling of participants with direct experience of OTC medicine addiction was purposive but represented a self-selecting group and therefore reflects only those who responded to invitations to participate. Furthermore, sampling occurred through two internet support groups and this reflected individuals who had internet access and who had already used such sites in some way. Finally, one of the internet groups focused on codeine and in the other, this medicine dominated too. The study design precluded recruiting participants with experience related to laxatives.

Conclusions

OTC medicine addiction in the UK centres on codeine and its non-therapeutic effects often stemming from genuine medical reasons for treatment initially, often with either initial or on-going opiate prescription supply, and with three levels of consumption. Stakeholder perceptions and direct experience suggest a secretive 'respectable' addict who may be receiving varied and sub-optimal treatment and support, obtaining medicines from pharmacies that are often blamelessly unable to prevent addiction, and limited internet purchases which raise additional safety concerns for different participants. Continued availability of OTC codeine and other medicines was widely supported, to ensure the public had the ability to choose medicines based on information about possible risks. Five key tensions emerge from the study: protecting individuals from the potential harms of medicines whilst ensuring convenient access; viewing OTC medicines as less harmful than a prescription medicine, but still capable of causing addiction; reconciling very different types of OTC medicine addiction based on significantly different levels of consumption; providing addiction services to a 'hidden' and secretive group of individuals who perceive themselves to be respectable and professional. Specifc recommendations include raising awareness of OTC addiction, improving treatment and support options, monitoring internet and pharmacy sales, accurately determining the scale of the problem and ensure continued collaboration between key stakeholders.

Abstract

The sale of over the counter (OTC) medicines from pharmacies represents an opportunity for individuals to self-medicate and manage their own symptoms. However, some OTC medicines have the potential for being used incorrectly or abused, and there have been increasing concerns about health risks associated with some medicines. The primary aim of this study was to describe and understand current issues relating to OTC medicine addiction by investigating the experiences of individuals affected by OTC medicine addiction in the United Kingdom (UK), pharmacists and medicines counter assistants (MCAs), and key UK stakeholders. Additional aims involved exploring the role of the internet, pharmacy involvement, and different types of medicine use.

Qualitative, semi-structured interviews were undertaken with three purposively sampled groups: twenty five UK individuals who are or were addicted to OTC medicine (recruited via support websites); sixteen key stakeholders (representing pharmacy organisations and businesses, industry representation, medical addiction interest groups, addiction and eating disorder charities, clinical perspectives from public, private and voluntary treatment services, and academia); ten UK pharmacists and seven MCAs. Qualitative semi-structured interviews were undertaken in 2009-10 by telephone and in-person and audio recorded and transcribed verbatim in all but one case.

Three types of what participants termed 'addiction' were identified, usually involving codeine but occasionally pseudoephedrine and sedative antihistamines: never exceeding the recommended maximum dose, using slightly higher than recommended dose, and considerably higher doses than recommended were identified. The non-therapeutic 'buzz' of codeine and sedative effects appeared important but genuine initial reasons were apparent for medicine use, except for two cases of intentional initial abuse. Both past and on-going links to prescribed medicines were identified. The term 'respectable addict' was developed to describe participants who were often secretive and blamed themselves and often offered intelligence and professional identity claims, which were contrasted with stereotypical substance misusers. On-line support, self-help, GP involvement, specialist drug services and narcotics anonymous were variously reported and often criticised. Support website use varied but offered confirmation of addiction. Pharmacy staff were often viewed neutrally, using ineffective questioning. Most participants expressed safety concerns about internet medicines, although two individuals reported relatively unrestricted internet supplies.

Pharmacists' and MCAs' experiences involved a monitoring role based on frequency of purchases for MCAs. Pharmacists were frustrated by a lack of customer information and the inability to monitor supplies from other pharmacies. Ignorance of signposting options was apparent and although some were sceptical of pharmacist's ability to assist, others felt pharmacists could and should do more. Key stakeholders considered codeine the paradigm concern and raised concerns about the lack of awareness and treatment options for OTC medicine addiction; the internet was considered a currently small but increasing problem, in supply and information availability terms.

The majority of participants across all three groups were in favour of the continued availability of OTC codeine and other medicine, ensuring the public had the ability to choose, as long as addiction risks were made clear. An apparent tension exists between offering medicines that can potentially cause harm, whilst ensuring medicines are available for those who wish to use them. Raising awareness of OTC medicine addiction is recommended, together with improved treatment and support options.

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ACRONYMS

APPDMG	All Party Parliamentary Drugs Misuse Group
CHM	Commission on Human Medicines
DAAT	Drug and Alcohol Action Team
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders
GP	General Practitioner
ICD-10	International Classification of Disease
MCA	Medicines Counter Assistant
MHRA	Medical and Healthcare products Regulatory Authority
NA	Narcotics Anonymous
NDTMS	National Drug Treatment Monitoring System (NDTMS)
NHS	National Health Service
NTA	National Treatment Agency (for substance misuse)
OTC	Over the counter
PAGB	Proprietary Association of Great Britain
RPSGB	Royal Pharmaceutical Society of Great Britain (now a professional body, with General Pharmaceutical Council providing regulatory role since 2010)
UK	United Kingdom
WHO	World Health Organisation

1 INTRODUCTION

The availability of medicines to purchase over the counter (OTC) offers benefits in terms of convenient access to, and choice of, medicines as well as involving individuals as active participants in their own health and the treatment of illness (C. M. Bond & Bradley 1996; Nettleton 2006). In many countries, this has been facilitated by a tradition of OTC medicines being available through pharmacies (the origins of the metonymic 'counter' in OTC) but increasingly via outlets such as supermarkets, convenience stores, garages and most recently the internet (Fox, K. Ward & O'Rourke 2005b). In addition, a trend towards increased de-regulation of medicines from prescription to OTC supply has occurred in several countries, extending the range of medicines available to customers. There has been a tendency for the public to perceive such OTC medicines to be low-risk compared to prescription medicines (Bissell, Ward, & Noyce, 2001; Hughes & Whittlesea, 2002; Raynor et al., 2007) but it has been recognised that OTC medicines have the potential for harm as well as benefit. This may result in what has been referred to as the misuse or abuse of OTC medicines by individuals, and these are recognised as being a cause of substance-related disorders (American Psychiatric Association 2000). Of particular concern is the potential health risks associated with misuse or abuse of OTC medicines containing combinations of codeine and either ibuprofen or paracetamol, primarily due to gastric or hepatic damage respectively (Dobbin & Tobin, 2008; Ford & Good, 2007). The World Health Organisation International Classification of Diseases (ICD-10) also specifically recognises both the abuse potential of *'non-dependence producing substances'* such as laxatives and analgesics (F55) and dependence syndromes associated with opiates (F11.2) (World Health Organisation 1992).

Illustrating increased awareness of this issue have been two recent UK responses. The first was the findings of the All Party Parliamentary Drugs Misuse Group's Inquiry into Physical Dependency and Addiction to Prescription and Over-the-counter Medication (Reay 2009). This identified a range of concerns and recommended additional training for health care professionals (although pharmacists were not mentioned specifically), the need to raise awareness of these problems, better support for self-help groups and more co-ordinated and specific medical treatment. The report concluded that *"the problem does exist and does affect enough people for action to be required to address and combat it."* (Reay, 2009, p.36). This was followed by the introduction by the UK Medicine and Healthcare Products Regulatory Authority (MHRA) (2009) in September 2009 of several measures relating to the sale of codeine-containing medicines. These included restricting the indication of these medicines to analgesia only, adding addiction warning statements to packets and leaflets, and limiting use to three days only.

This report will describe, firstly, the literature in this area in more detail before going on to set out a description of the methodology of the study undertaken. Detailed results will be presented from three groups of participants, and a brief discussion and recommendations will be provided. The report uses the term 'addiction' not only in the title but also throughout intentionally, to reflect the descriptions provided in this study by those with direct experience of OTC medicine problems. This is consistent with the qualitative nature of this study and is considered in more detail later in the report in relation to definitional confusion in the literature relating to dependence, misuse, abuse and addiction (O'Brien et al. 2006).

2 LITERATURE REVIEW

2.1 Introduction

The aim in this chapter is to review the international literature relating to OTC medicine addiction and abuse and, in particular, to explore the extent of the problem, the types of medicines associated with OTC misuse, the type of individual who may be misusing such products, and strategies to deal with the issue of OTC misuse. It will be shown that the scale of OTC medicine misuse/abuse varies considerably based upon different study designs and data. There were no clear patterns as to those who were affected, and little data relating to their experiences. Products liable to abuse varied according to country and availability but four key groups were identified: codeine-based analgesics (and especially compound products), cough products, sedative antihistamines and decongestants. Some fatalities had been associated with OTC medicine abuse, together with complications from paracetamol and ibuprofen containing codeine products. Strategies to deal with OTC problems included practical pharmacy-based interventions such as removing products from display, raising awareness amongst public and health-care professionals, using existing drug and alcohol treatment centres and support from on-line forums. There was often no clear distinction between the terms misuse and abuse, and dependency/addiction was rarely mentioned. Overall, the literature could be characterised by omissions, in the relative lack of qualitative studies and accounts drawing upon the experiences of those affected by OTC misuse/abuse, specific treatment options and associated evaluations and research exploring increasing internet availability.

2.2 Review strategy

A thematic literature review approach was adopted, since there were a range of questions identified which a systematic review would have been inappropriate for, and also because there has been no identified published review undertaken.

Initial searches were conducted using ISI Web of Science, CINAHL, EMBASE and Medline together with specific searches of journals such as the *Pharmaceutical Journal* using combinations of the following terms: 'over the counter', 'OTC', 'medicine', 'drug', 'misuse', 'abuse', 'addiction', 'dependency' and 'non-prescription.' The reference lists of included publications were also checked and further searching undertaken as a result. Additional grey literature was explored by strategies such as extensively contacting researchers in the field, to identify current research and non-peer reviewed research publications. Additional non-peer reviewed journal literature such as official organisation documents were also identified by searching OpenSIGLE, key organisations such as the Royal Pharmaceutical Society of Great Britain, the Medicines and Health Care products Regulatory Authority and the Proprietary Association of Great Britain together with more general searches of common search engines such as Google. Searches were undertaken for publications from January 1990 to February 2011 and inclusion criteria included publications published in English, empirical, review or opinion pieces. Exclusion criteria included non-

English language publications, medicines for use in children and reference only to prescribed or illicitly obtained medicines.

2.3 Literature review findings

A total of forty two publications were identified, including twenty three empirical studies, eleven case reports, ten reviews articles, one book chapter, one doctoral thesis, one parliamentary enquiry, and three publications from organizations. The empirical studies represented ten countries, with the UK (England, Wales, Scotland and Northern Ireland) being the most studied, followed by the US (Table 1). The earliest identified study was conducted in 1996. A range of themes emerged from this literature and these related to definitional and terminological variation, the scale of the problem, the range of medicine implicated, associated harm, characteristics of those affected, interventions and support, and the role of pharmacists. These themes are now considered in turn.

2.3.1 Definitions and terminology

Some of the identified literature referred only to the term *'misuse'* and appeared to use this generically, to describe all forms of problematic OTC medicine use in pharmacies (see Pates et al. 2002; Matheson 2002; MacFadyen 2001; Ajuoga et al. 2008; Myers et al. 2003). As Akram (2000) noted however, this is unfortunate because it did not distinguish between misuse and abuse as separate problems, although some attempts to do this were identified in the literature:

> "*Misuse is defined as using an OTC product for a legitimate medical reason but in higher doses or for a longer period than recommended, e.g. taking more of a painkiller than recommended to treat headache. Abuse is the non-medical use of OTC drugs, e.g. to experience a 'high' or lose weight."*
> (Wazaify & Shields 2005 p.170)

According to Fleming et al (2004), misuse applied to potentially all medicines, whereas abuse related to specific medicines, such as laxatives, antihistamines and codeine-based products. There was no mention in the literature of the transition between misuse and abuse, as has been recognised in the medical prescribing situation of involuntary addiction (Reay 2009). Further distinctions were identified within these broad categories and, for example, with misuse, it was argued to be possible to view this as resulting from using a medicine at a higher than recommended dose, or using it to treat symptoms for which the medicine is not indicated (Abbott & Fraser 1998); with OTC medicine abuse, a distinction has also been made between sole OTC medicine abuse and substitution, where an individual is dependent upon another medicine, often an illicit drug, and uses an OTC product when the other is unavailable (Temple 2003; Abbott & Fraser 1998)

Several studies did draw upon the wider literature relating to clinical classification such as *DSM-IV* (American Psychiatric Association 2000) or *ICD*-10 (World Health Organisation 1992) in specifically contrasting the terms abuse and dependence or '*pharmacodependence'* (Orriols et al. 2009) and misuse and dependence (J. R. Hughes et al. 2004). The term 'addiction' was identified in some literature (J. R. Hughes et al. 2004; Reay 2009) but was infrequently used and, as (Reay 2009) noted, this may have occurred due to the perceived stigmatising effect that

the term and that of 'addict' might have on those affected (WHO 2007). One mixed methods study (Neilson, Cameron and Pahoki 2010), used the DSM-IV definition of dependence (but not abuse) as an inclusion criteria for their qualitative interviews with codeine-dependent individuals and described some users having 'therapeutic dependence' to doses at or less than the maximum, often over a prolonged period.

An additional and significant definitional point concerned the terms used to describe not just the condition but the actual individual themselves, who were affected by OTC medicine problems. Within the empirical literature, this related partly to the study design and sample and included the use of the word *'patient'* in studies where the participants were those attending hospitals to seek treatment (Myers et al. 2003; Mattoo et al. 1997) and the term *'client'* in a study which studied a pharmacy-based intervention (Fleming et al. 2004).Two studies referred to those affected by OTC medicine abuse/misuse as *'customers'* (McBride et al. 2003; Albsoul-Younes et al. 2010) reflecting the commercial nature of OTC medicine sales, although Albsoul-Younes et al also used the term '*abusers'* uniquely. One final definition offered for those abusing or misusing OTC medicines was that of a *'recreational user.'* This was used by the Scottish Specialists in Pharmaceutical Public Health and Trust Chief Pharmacists (Scottish Specialist in Pharmaceutical Public Health 2004) to describe a heterogeneous group of individuals who may be abusing anabolic steroids, 'soft drugs' such as cannabis or LSD, or OTC medicines. The authors contrasted this with other forms of substance misuse:

> *"Not all drug users are necessarily addicted to drugs or are chaotic users, and many manage their drug use as part of their normal daily routine. Such misuse is termed recreational use"* (Scottish Specialist in Pharmaceutical Public Health 2004 p.24)

Several studies used the word 'dependant' in relation to some use of codeine (Orriols et al. 2009; Tinsley & Watkins 1998).

2.3.2 Scale of OTC medicine addiction

Attempts to describe the extent of OTC medicine addiction have been made using a variety of data sources. These have included reporting of perceived misuse/abuse at a pharmacy level, perceptions of members of the public, self-reported misuse/abuse from US adolescents and gym users, data from drug treatment centres, poisons centres, and members of an on-line support group.

Dating relating to the UK has been obtained from various sources. One of the most frequently referred to in the literature (see Akram, 2000; Ford & Good, 2007; Reay, 2009) involves data reported from the UK-based on-line support group, *Overcount,* indicating the number of individuals who have registered with the site. This figure had been quoted as ranging from 'more than 4000' (Ford & Good 2007) to 16,000 (Reay 2009) but specific details of the data were not provided in either source and no further information about it were identified in this review. Several UK studies had explored the experiences and perceptions of pharmacists in relation to OTC medicine misuse and abuse and estimates of the extent of the problem were presented as a result. The earliest identified study involved a postal survey of pharmacists in a county in England (Paxton & Chapple 1996) which reported that 69% of pharmacists considered there to be some form of OTC medicine misuse in their pharmacies. Matheson (2002) reported on two postal surveys of pharmacists in Scotland undertaken in 1995 and 2000, which reported pharmacists' belief that OTC

product misuse was occurring in their area as 67.8% and 68.5% respectively. Also involving Scottish pharmacists and a postal survey, MacFadyen (2001) reported that 31% of pharmacists perceived there to be frequent misuse and 58% perceived occasional misuse. This study also estimated mean of 5.63 patients per week per suspected of misusing medicines for each pharmacy in an 'average week', with the maximum being 40 in one pharmacy. In Wales, Pates et al (2002) also used a postal survey design and reported that 66% of respondents believed there to be a problem in their area. In Northern Ireland, Hughes et al (1999) found that pharmacist estimates of abuse in the previous three months ranged from 0 to 700, with a median of 10, and a mode of 6. Wazaify (2006) reported that six pharmacists identified 196 clients suspected of OTC abuse/misuse over 6 months Geographically, urban pharmacies were associated with more suspected abuse than rural ones in two Scottish studies (Matheson et al. 2002; MacFadyen et al. 2001) and Mattoo et al (1997) reported that of those attending a clinic in India for addiction to codeine cough syrups, 80% were urban residents. Others studies identified no difference (G. F. Hughes, McElnay, et al. 1999)

Data relating to the USA has been reported from a range of sources, ranging from specifically collected national level data, to surveys of specific groups, such as gym users, nicotine gum users and highschool students. The annual National Survey on Drug Use and Health (NSDUH) has provided data relating to specific issues such as, for example, abuse of OTC cough medicines amongst adolescents (Substance Abuse and Mental Health Services Administration 2008), which revealed that in 2006 around 3.1 million people aged 12-25 stated they had used an OTC cough and cold medicine to *'get high'* for a non-medical reason. This appeared to involve dextromethorphan, a cough suppressant, in 140 different products. Emergency department admissions were used in the Drug Abuse Warning Network (DAWN) to provide national-level data relating to the involvement of dextromethorphan in admissions (Substance Abuse and Mental Health Services Administration 2010). This revealed that, for 2004, 0.7% (n=12,584) of all emergency department admissions involved dextromethorphan and that the rate of visits was significantly higher amongst those aged 12-20, than other age groups. The third national-level data collected in the USA involved that collected in the treatment episode data set (TEDS) for treatment admissions by the Drug and Alcohol Services Information System (DASIS) (Substance Abuse and Mental Health Services Administration 2004). Data from 2002 revealed that, as primary sources of abuse, only 4% of the 1.9 million admissions related to prescription or OTC medicines, which were described as including cough products, aspirin, sleep aids, diphenhydramine and other antihistamines). Of these, OTC medicines accounted for only 1% (n=600) of admissions, and the authors noted that:

> *"OTC medications are relatively rare as primary substances of abuse. They are more commonly noted as secondary or tertiary substances of abuse upon admission."* (Substance Abuse and Mental Health Services Administration 2004)

A further study was identified that used drug treatment admissions (Gonzales, Brecht, Mooney, & Rawson 2010) and this reported on more recent data from the state of California only. Prescription and OTC medicines in this study accounted for 6,841 (3.2%) of admissions, with adolescents (12-18 years old) accounting for 1.5% of overall admissions. As in the above national level study, the Californian study found OTC medicines to be relatively low, representing only1.9% (n=139) of the total prescribed and OTC medicine admissions. These were found to be

statistically more likely to be reported by adolescents, who were more likely to cite 'self' for referral to treatment than older clients, who cited 'others' more often. The authors identified methodological concerns about the recording of such data, noting that OTC and prescription medicine recording by treatment staff was inconsistent, and may be due not only to the relatively recent inclusion of such data but also two further factors:

> *"First, new prescription and OTC medications come on the market frequently. Second, there is wide variability in prescription and OTC drugs in relation to brand names, generic names, chemical names, and street names, which can change over time."* (Gonzales et al. 2010)

Steinman (2006) focused on the adolescent population and surveyed 39, 345 high school students in one county, and reported 4.7% as having occasionally misused OTC medicines, with 2.1% reporting use in the past month; the study did not explore the types of product involved. Hughes et al (2004) identified 20% of those using NRT gum for more than 90 days as being addicted, and Ajuoga et al (2008) identified 37.2% of HIV positive patients as misusing OTC products. Kanayama et al (2001) used data from a survey of gym users and national data on fitness club membership to estimate a national incidence of 1.5 million individuals using adrenal hormones and 2.8 million using ephedrine. Two studies drew upon admission data and involved

The situation in Jordan was studied by Albsoul-Younes et al (2010) who adopted similar methods to UK studies, and found that 94.1% of pharmacists suspected some abuse or misuse of OTC products, and a mean estimate of 'abusers' in the last three months per pharmacy to be 18.6 for regular, and 15.4 for new customers.. From a total of 710 patients attending treatment clinics in Cape Town, South Africa in a 6 month period, Myers et al (2003) identified 17 cases involving OTC codeine abuse.

Wazaify & Shields (2005) surveyed members of the public in Northern Ireland and described almost one third of participants as having personally encountered OTC abuse (either on personal experience, knowledge or observation). An on-line survey of 909 individuals who used codeine identified 138 (17.3%) as being 'likely to be codeine dependent' using a severity of dependence scale (Nielsen et al. 2010). Two studies sampled pharmacy customers: in France, Orriols et al (2009) questioned 53 pharmacy customers using surveys about their codeine use in the previous month and identified 15% as misusing, 7.5% as abusing and 7.5% as being dependent. Major & Vincze (2010) randomly surveyed pharmacy customers in Hungary and reported that almost one third had personally experienced OTC abuse. With a specific focus on analgesic use, Agaba et al (2004) randomly sampled an area in Nigeria, and reported analgesic abuse in 22.6% of respondents. They collected data on patients' self-reported weekly use and overall duration and defined abuse as being a cumulative lifetime use exceeding 5000 'pills.'

OTC medicine sales data was identified in two reviews. Almarsdóttir & Grimsson (2000) used secondary data and reported on a significant rise in codeine sales between 1993 and 1998 in Iceland, and attributed this not to the hypothesised influence of legislative changes but to increased Western consumption of medicines generally or more specific OTC codeine abuse reporting by treatment centres. Reed et al. (2011) reported on national UK sales data relating to codeine-containing OTC medicines from a trade association. Data indicated that 21.4 million packs of

codeine-containing OTC medicines were sold during 2008. This represented an increase from 19.5 million packets in 2006 but trends were not identifiable due to the limited data available.

2.3.3 Who is addicted to OTC medicines?

Data relating to those who may be abusing/misusing OTC medicines was obtained from several different sources. Several studies relied upon the perceptions of pharmacists, whilst others relied on sampling the public, pharmacy customers or those suspected of actual abuse. Several studies analysed case reports from addiction centres. Amongst the first type, Akram (2000) summarised several early UK studies as involving *'middle-aged females'* whereas Albsoul-Younes et al (2010) reported that pharmacists perceived the majority of abusers to be male (60.6%), and aged between 26 and 50 years old. Similarly, Sweileh et al (2004) reported pharmacists as perceiving males to be more likely to abuse or misuse OTC products than females in all categories except laxatives, and that customers in the age range 20-40 years old were most likely to be suspected. Other studies provided more equivocal pharmacist perceptions, and Pates et al (2002) noted that 54% of pharmacists considered all types of people to be suspected of OTC misuse, although female customers were more likely to be suspected of abusing or misusing laxatives. Of the remainder, there was variation in the ages suspected and Ajuoga et al (2008) found no association between OTC product misuse amongst HIV positive patients and age, gender, ethnicity or education status.

Some studies, however, did include designs that permitted the collection of demographic data. (Myers et al. 2003), for example, examined details of patients attending a drug treatment centre in Cape Town, South Africa. It should be noted that in this study, although some data pertained to an OTC specific medicine (codeine), the main findings did not present OTC medicines and those on prescription separately. This was also the case for data collected in the US by the Drug Abuse Warning Network (DAWN) (Substance Abuse and Mental Health Services Administration 2010). Steinman (2006) reported that female students misused OTC medicines more than males, and misuse was also higher amongst older white students and Native American youths. Agaba et al. (2004) reported those abusing analgesics to be slightly older (mean of 43.2 years old) than those who did not abuse (mean of 39). Nielsen et al (2010) compared codeine dependent and codeine users and, although not reporting any statistical data, found the former to be younger, with lower educational level, less likely to be in full-time employment but more likely to have used illicit substances and had family history of alcohol or drug problems.

2.3.4 Products Involved

A range of products have been identified as being involved in OTC medicine abuse and misuse, either through empirical studies or review papers. There appeared to be a historical, geographical and methodological variation in the products involved. Historically, the availability of products appeared to have changed over time and in Scotland, for example, codeine linctus (15mg/5ml) use was reported to have declined in one study due to restrictions in its

supply and Nurofen Plus (a combination of 12.8mg codeine and 200mg ibuprofen) was the fourth most commonly cited in 2000 but was not cited in 1995 as it was not available earlier (Matheson et al. 2002). Geographically, there was variation in terms of the country in which the study was undertaken due to different product availability and regulation. In Jordan, antibiotics and benzodiazepines were commonly cited by pharmacists as being abused, as regulations restricting their supply were not always enforced (Albsoul-Younes et al. 2010) .The same study also identified, amongst non-prescription medicines, sympathomimetic decongestants, cough products, analgesics, antihistamines and laxatives. These reflected a similar categorisation made by Matheson (2002) and (MacFadyen et al. 2001) who identified Nytol (a brand of diphenhydramine, an antihistamine) as the most suspected product of misuse in Scotland, and, like G. F. Hughes et al (1999), these were broadly similar to the methodological design of studies such as Orriols et al (2009) who grouped their survey of pharmacy customers into whether they purchased codeine (an analgesic), dextromethorphan (a cough suppressant), pseudoephedrine (a decongestant), and an antihistamine. Studies that used pharmacists appeared to generate more detailed and varied descriptions of medicines that may be abused or misused (G. F. Hughes, McElnay, et al. 1999; Matheson et al. 2002) compared to patient/customer/public accounts (Wazaify et al. 2005; Ajuoga et al. 2008; Major & Vincze 2010) reflecting pharmacists' knowledge of products and brands. One example was that whilst pharmacists specifically referred to codeine containing analgesics – 112 different OTC products in one study (G. F. Hughes, McElnay, et al. 1999) - patients/customers/public referred to the broader category of 'painkillers' (Major & Vincze 2010; Wazaify et al. 2005). Some studies focused on specific products, such as sedative antihistamines (Phelan & Akram 2002), nicotine replacement therapies (J. R. Hughes et al. 2004), codeine-containing cough syrups (Mattoo et al. 1997), codeine and promethazine cough syrups (Peters et al. 2007), analgesics (Agaba et al 2004) and laxatives (Bryant-Waugh et al. 2005).

2.3.5 Associated Harm

A range of problems and harms associated with OTC medicine abuse or misuse were identified and these comprised three broad categories. Firstly, there were direct physiological harms related to the pharmacological or psychological effects of the drug of abuse or misuse. Secondly, there were indirect physiological harms, of which the most frequently identified were adverse effects of another active ingredient in a compound formulation. Both these direct and indirect harms were included in concerns about overdoses and presentation at emergency services. Thirdly, there were those based on other consequences, such as progression to abuse of other substances and effects on personal and social life. Direct physiological harms included those reported by Murao et al (2008) involving convulsions and acidosis as a results of abuse of an antitussive medicine marketed in Japan, and containing codeine and an antihistamine; Banerji and Anderson (2001) reported on admissions to a poison control centre in the US due to abuse of Coricidin cough and cold tablets (dextromethorphan and chlorphenamine) and noted tachycardia, hypertension and lethargy amongst other symptoms. Lessenger & Feinberg (2008) produced a comprehensive list of physical findings of nonmedical use of abused OTC products, noting agitation with nicotine gum, caffeine and ephedra, priapism with ephedrine and pseudoephedrine, psychiatric effects with dextromethorphan, euphoric

psychosis with Coricidin and chlorphenamine and gastrointestinal disturbances with laxatives. Also within this category of direct physiological harms is the concern raised about chronic rebound headache associated with repeated use of analgesics.

In relation to indirect harms, two analgesic combination products - paracetamol and codeine (co-codamol) and ibuprofen and codeine – were considered problematic, with ibuprofen-containing medicine being particularly highlighted (G. M. Robinson et al. 2010; Ernest et al. 2010; Dutch 2008; Lambert & Close 2005; Dyer et al. 2004; Chetty et al. 2003; Dobbin & Tobin 2008; Frei et al. 2010; Ford & Good 2007)(Dobbin and Tobin 2008, Ford and Good 2007). Dutch (2008) and Ford and Good (2007) reported on two hospital and three primary care presentations respectively, of patients who had used a combination analgesic containing ibuprofen and codeine. Ford and Good (2007) noted side effects relating to ibuprofen and Dutch (2008) reported both patients having perforated gastric ulcers. Hypokalaemia secondary to renal acidosis was identified as a result of abuse of this combination product (Lambert & Close 2005; Chetty et al. 2003; Dyer et al. 2004; Ernest et al. 2010). Dobbin and Tobbin (2008) reported on 77 cases reported through personal networks of one of the authors where harm and dependence to ibuprofen and codeine OTC products had occurred. They identified similar clinical presentations as noted above and one death.

In relation to other consequences, several studies have referred to the association of OTC medicine abuse and use of illicit substances (Levine 2007; Reay 2009) or obtaining codeine supplies from 'street' supplies (Sproule et al. 1999). Tinsley & Watkins (1998) reported on seven patients with dependence (according to DSM-IV criteria for amphetamine-like abuse) to ephedrine or pseudoephedrine and reported adverse social consequences in relation to losing jobs, family-marital stresses, relapse into alcohol misuse, motor vehicle violations and accidents.

2.3.6 Interventions and support

A range of strategies were identified that were aimed at minimising the harm associated with OTC medicine abuse or misuse. They ranged from pharmacy-based strategies reported by pharmacists in their actual work, to suggested interventions such as increasing awareness of the problem, providing additional training, to allowing pharmacists to provide treatment withdrawal programmes. Many empirical studies that surveyed pharmacists sought their practical strategies and a number of common approaches emerged (Pates et al. 2002; Matheson et al. 2002; Albsoul-Younes et al. 2010).These included removing products from sight, claiming products were not in stock or not stocked anymore, alerting or counselling customers to the abuse potential of products, outright refusals to supply, suggesting the customer contact their doctor and supplying only limited amounts. A Delphi survey of experts also identified similar strategies (McBride et al. 2003)as well as broader strategies based on raising public awareness, establishing an official body to monitor internet sales, limiting advertising and making warnings on packets more visible. Fleming et al (2004) developed a harm reduction model based upon conference discussion and consultation with healthcare professionals. A manual and two treatment algorithms were produced: one for misuse, and linked to the involvement/awareness of a customer's doctor, the other for appropriate signposting relating to opioid, laxative and antihistamine abuse. A pilot using two pharmacists given additional training on motivational interviewing and health

promotion techniques, together with guidance on record keeping led to no formal enrolment in the pilot project but fourteen clients were advised about the OTC medicine use based on pharmacist concerns. Lack of pharmacist confidence, lack of GP engagement and competing work demands were identified as barriers to the project's success. Wazaify (2006) used the same model in six pharmacies, and reported 196 identified cases of suspected abuse or misuse involving opioids, antihistamines and laxatives, of which 70 were approached by pharmacists. Some clients agreed to stop, some used an alternative and some were referred to their doctor for maintenance on prescription. No clients were recruited to enable collection of quality of life data. Raising awareness amongst the public was recognised as being necessary (McBride et al. 2003; Reay 2009) but also amongst health care professionals such as doctors (Reay 2009; Williams & Kokotailo 2006; Lessenger & Feinberg 2008). A harm reduction strategy was proposed by (Temple 1996)whereby pharmacists would set a contract with individuals experiencing OTC medicine abuse to have regular supplies of medicines, reducing over time and involving detailed record keeping and adequate communication between pharmacies and involving drug team co-ordinators.

The APPDMG (Reay 2009) concluded that increased recognition and support was needed for the voluntary groups that provided support for those with an OTC problem. Two specific websites – Overcount and CodeineFree – were identified and considered to provide a valuable service that was not formally recognised (Reay 2009).

2.3.7 Discussion

This review of the literature has revealed a number of themes and emerging data to inform the problem of OTC medicine abuse/misuse and several associated concerns. These involve methodological and research concerns about the use of proxies and difficulty in identifying and involving individuals who were or who are abusing/misusing OTC medicines. However, what is perhaps most apparent is the extent of the *omissions* in the extant literature, particularly as they relate to the:

- Relative lack of qualitative individual perspectives,
- Lack of reliable quantitative data in some countries,
- Lack of any fully evaluated or implemented interventions,
- Lack of data relating to internet supplies
- Lack of consensus over definitional terms.

These concerns are now considered in turn, before a number of specific suggestions for further research and policy involvement are proposed.

The various definitions described previously have a number of implications for research and understanding in this area. Firstly, whilst they can positively reflect a range of different types of societal medicine use, they may also lead to confusion, particularly if, like some studies did, there are not accurate and consistent attempts to distinguish between them. This may be further complicated by the origins of these terms, with some such as dependency, abuse and addiction being firmly located in the clinical setting and attendant criteria and definitions, whilst others being more contextually defined in terms of individual use (such as the misuse of medicines). A further omission to note at

this point is the absence of any reference to pseudo-addiction in this literature. Pseudo-addiction has been defined as the under-treatment of pain, which may lead to symptoms that are similar to dependency and which reveal a potentially even more complex area. Underscoring much of this definitional confusion are more fundamental issues about stigma, identify and also agency. The WHO (2007) has argued that dependency and not addiction should be used, to avoid the stigma of the former (Reay 2009; Dean & Rud 1984; Erickson & Wilcox 2006) as well as the issue of an 'addict' or 'spoilt' identity (Goffman E., 1990; McIntosh and McKeganey 2000). In terms of agency, it is interesting to reflect on the distinction between misuse and abuse in some of the extant literature, since this appears to recognise a difference between intentionally experimenting with a medicine (to elicit a different effect) and abusing it, and unintentionally deviating from standard use (taking at different dose or indication) and therefore misusing it.

Methodologically, here has been an obvious trend in using quantitative approaches, and, in the UK for example, the use of cross-sectional descriptive survey designs, often using self-completion postal surveys of pharmacist participants. Response rates appear to have varied significantly using this approach, and whilst Matheson (2002) reported very good response rates across two surveys using a pre-paid envelope and two reminder letters, Hughes (1999) received responses from just under half of pharmacists sampled using two mailings. These studies reflect a trend to using pharmacists and hence obtaining data that reported on pharmacists' perceptions of the problem and the profile of those they considered to be affected, which as Orriols, Gaillard, Lapeyre-Mestre, & Roussin (2009) note is '*much too subjective to obtain reliable qualitative and quantitative data*'. Although not explicitly noted by the researchers, this may reflect a belief that those who are abusing or misusing OTC medicines may be a hard to reach or *'covert'* (Reay 2009) group and hence using pharmacist proxies is perhaps perceived as being more appropriate. However, several studies designs have involved sampling those suspected of abusing/misusing OTC medicines, either via pharmacies (Orriols et al. 2009; Phelan & Akram 2002), at targeted venues such as gyms Kanayama et al (2001) or by post (Sproule et al. 1999). Although these represent less subjective accounts of the problem, they have resulted in poor response rates except in the study by Orriols, Gaillard, Lapeyre-Mestre, & Roussin (2009) who argued that allowing purchasers to complete a questionnaire away from the pharmacy and return it via post, as compared to completing it in the pharmacy, meant those who were abusing or misusing could complete the forms anonymously. However, (Orriols et al. 2009)were disappointed by the poor level of pharmacy participation, which may be related to the need for the pharmacies involved to undertake the administration of the questionnaires, as was identified in other studies (Wazaify et al. 2006).

Of particular note is that qualitative methods have been neglected and only one identified study used focus groups (Bjornsdottir, Almarsdottir & Traulsen 2009) and one which reported the use of semi-structured interviews (Mattoo et al. 1997) presented detailed statistical data and the absence of qualitative data suggested this was a structured survey design. Nielsen et al (2010) did use qualitative interviews and reported a range of different types of abuse of codeine, as well as barriers to treatment, illustrating the unique data that this method can generate. Adopting such methods may reveal further insights that could help understanding of the contested definitional issues raised above, as well as providing more than the proxy summaries of those perceived to be affected, as offered by some pharmacist-participant studies.

The use of secondary data sources, such as those in various US reports ((Substance Abuse and Mental Health Services Administration 2004; Substance Abuse and Mental Health Services Administration 2008; Substance Abuse and Mental Health Services Administration 2010) and using details of patients attending drug treatment centres in South Africa , for example, offer potentially more robust statistical information on the extent of the problem. However, such data is not ideal and in the case of some US data, for example, prescription and OTC medicines were reported together in some publications.

Linked to the source of this last type of secondary data is any evaluation or indeed thorough detail of treatment options for those affected by OTC medicine addiction. Empirical studies have identified a range of often pragmatic solutions, but evidence-based interventions and attendant evaluations are a clear omission in this field.

Finally, the emergence of new forms of medicine supply, such as via the internet, in what Fox, Ward, & O'Rourke (2005) term the 'second moment' of 'e-pharmacy' have not been studied, despite being recognised as a potential threat (McBride et al. 2003).Such developments may stretch not only the metonymic accuracy of the term OTC, but also require a re-definition of what such supplies involve, as such supplies transcend national boundaries and attendant regulation in many cases (Bessell 2003) and may challenge the international patterns identified.

In relation to policy, this review confirms that there is a problem in a number of countries but concerns about what is being investigated – whether this is misuse, abuse, dependency, addiction or pseudo-addiction – coupled with a lack of systematic data on the scale of the problem make appropriate and proportionate policy-based interventions difficult to consider. There exists a tension between making OTC medicines available to individuals to increase their access to medicines and enabling them to self-manage conditions, and accepting that there is some degree of risk of such products being misused or abused, with potentially serious consequences for some. Raising awareness of potential problems of OTC medicines, as the recent response in the UK has illustrated in terms of making purchasers aware of the possibility of addiction, would appear a prudent response. But whilst this may arguably warn those using products for the first time, for those with an existing problem, more support may be needed in the clinical pathway.

2.3.8 Literature Review Summary

This review of the literature relating to OTC medicine abuse has revealed that there is a recognised problem internationally involving different products with potential adverse health outcomes for some. Methodological concerns have emerged in relation to the use of proxy, self-report and non-OTC specific data and the lack of qualitative research involving individual experiences of this problem. These represent urgent areas where research is needed; to explore the extent of the problem and provide insights into those affected, coupled with providing clarification of the type of problem being investigated. Such research is needed to inform policy, regulation and the preparedness of a range of health care professionals to avoid harm

The next chapter sets out the aims and objectives of the current study, and provides a detailed description of the methods used in the study undertaken.

3 METHODS

3.1 Aims and objectives

Based upon the background to this topic and the specific literature review undertaken, the aim of this research was to explore current understanding about OTC medicine addiction from a range of stakeholders, particularly those who have been previously under-represented in empirical studies.

Specific objectives were to consider:

- What are individuals' personal experiences of OTC medicine abuse and addiction? What circumstances led to their abuse or misuse of OTC medicines; what were their views of the role of pharmacists and counter assistants, manufacturers and regulators?
- What impact has the Internet had upon medicine abuse/misuse? Although identified as a concern (McBride et al 2003), this has not been studied. Do Internet supplies represent a further opportunity for obtaining OTC medicines which may be abused/misused, what forms of control of such sources are available and are the potentially unregulated nature of Internet transactions and possible identity deception further threats? (Bessell 2003; Connelly 2008). What is the relationship between misuse and abuse? Research suggests confusion amongst the public about the terms abuse and misuse ((Wazaify et al. 2005) but this has not been explored more fully in terms of individuals' understanding of, and attitudes towards, risks about medicines and their health (Bissell et al. 2001).
- Will pharmacists' changing roles in the UK, including proposals to absent pharmacists from pharmacies for periods of time and their greater involvement in clinical rather than retail activities, exacerbate OTC medicine misuse/abuse?
- What is the relationship between OTC medicine abuse/misuse and use of illicit substances?
- What has driven recent policy change in this area?

The remainder of this chapter describes the design of the study undertaken to answer these research objectives, and will provide details of the methods used, the way in which participants were considered for inclusion, and how they were selected. A qualitative design using semi-structured interviews will be described, along with details of the data collected from these interviews was analysed and presented as a number of themes.

3.2 Methodology

To answer the research aims and objectives described above, a descriptive study was undertaken, using a qualitative methodology involving semi-structured interviews. Three key stakeholder groups were the focus of the study: firstly, and most importantly, individuals who had experienced OTC medicine addiction personally, secondly, a

sample of key UK stakeholders involved at policy, academic, organizational and treatment levels, and finally, UK pharmacy staff (pharmacists and MCAs).

3.2.1 Recruitment and sampling

The approaches used to recruit and sample varied according to the stakeholder group. In relation to those involved at a policy/academic/organizational level, a purposive and snowball sampling approach was used. Firstly, representatives of key organizations including the Royal Pharmaceutical Society, the Proprietary Association of Great Britain, the Medicines and Healthcare products Regulatory Authority were approached; secondly, based on the literature review, academics working in this field were also approached; finally, as the study progressed, snowball sampling and additional contacts identified were also approached. All were contacted in the first instance by an email, either directly to the prospective participant, if this person was known, or to the organization. Attached with each email were the information sheet and a consent form. One follow-up email or a telephone call was made, to those who had not responded initially.

In relation to the pharmacists and medicines counter assistants, purposive sampling was adopted, to ensure the inclusion of participants working in different pharmacy location and type, including England, Scotland and Wales. This was undertaken as previous research suggested some differences in the reporting of OTC abuse/misuse between city centre and rural pharmacies (Matheson et al. 2002) and general variations in service depending upon the type of ownership (Rogers et al. 1998). Two counties in England were selected and from within these, a combination of randomly selected pharmacies and those known to the researcher (from previous contacts) were contacted by email or letter and invited to participate in the study. In Scotland, assistance was sought from academic contacts at the University of Aberdeen, to forward an email to pharmacists, inviting them to participate. In Wales, the same email was sent to pharmacists via a RPSGB representative. The email also contained an attached information sheet and a consent form. Initially, a quota sample of twenty pharmacies in total were anticipated but a combination of theoretical saturation of data during interview analysis (see section 3.2.2 below) and poor responses in some areas, meant that a total of eight pharmacies were included in the study, together with a locum pharmacist who participated but who had no regular pharmacy. The invitation to participate was addressed to the pharmacist, and a request was made via them to identify an MCA who they felt may be willing to participate. Pharmacists were asked to0 forward the information sheet and consent form to a prospective MCA participant. Pharmacists were interviewed from all these pharmacies (two in one case), and MCAs were interviewed in six pharmacies (one rural pharmacy did not employ an MCA, one pharmacist was a locum). All the pharmacists and MCAs in England were interviewed face-to-face in their pharmacies, whereas those in Scotland and Wales were interviewed by telephone. In all cases, a mutually convenient time was identified to conduct the interviews. The interviews with pharmacists varied from 20 minutes to over one hour, with most lasting around 40 minutes. In contrast, interviews with MCAs were much shorter, averaging around thirteen minutes.

In relation to individuals who had experienced OTC medicine misuse/abuse, two websites and associated discussion forums were used to recruit individuals. These were 'Overcount' (www.overcount.net) and 'Codeinefree' (http://www.codeinefree.me.uk/). Adapting methods used in other research with on-line discussion forums/chat-room sampling ((Illingworth 2001; Fox & K. Ward 2006) initial approaches were made to gatekeepers who are responsible for maintaining the websites, asking for permission to display an invitation to forum members. These were undertaken from 2009 to December 2010. However, responses to the invitation to participate were poor during the first twelve months of the project, and the gatekeepers were asked to repeat the messages periodically. In addition, one of the web sites sent an email to all members on their mailing list, requesting help with the research, whilst the other placed a prominent front page message, inviting members of the website to contact the researcher should they want further information about participating. The invitation will introduce the researcher and the nature of the research and then ask either for participation in on-line discussion or subsequent email contact and an in-depth interview, by telephone.

Although on-line ethnography involves concerns (Illingworth 2001) about identity manipulation, deception and rapport - the latter concern also shared with telephone interviews - the sensitive nature of the subject matter makes on-line approaches and subsequent telephone rather than face-to-face interviews a suitable choice, to help over-come fear of disclosure, anonymity and suspicion of researchers. However, it is recognised that using this sampling method may introduce possible bias towards particular respondents and limitations in generalisability. For example, on-line participants must have access to, and be literate in, computer technology, which might under-represent the poor, minority groups or the elderly, although this may be becoming less apparent (Hewson et al. 2003). Furthermore, the two proposed sites comprise many individuals who are seeking help or who have overcome their OTC medicine addiction, which might therefore under-represent those who are unaware of having a problem or who are reluctant to seek help.

Specific ethical considerations include the need for the researcher to be overt and transparent about their identity and purpose when on such on-line sites. Experience from researching other sensitive areas, like pro-anorexia sites (Fox, K. Ward & O'Rourke 2005a) suggests using the researcher's real name rather than a pseudonym and the use of a formal university e-mail address, along with appropriate measures for 'leaving the field' at the end of the research, when some participants may seek to maintain contact, are necessary.

3.2.2 Data collection and analysis

All interviews were digitally audio recorded with the patient's consent and all were subsequently fully transcribed and anonymised where necessary, removing any identifying names and replacing with pseudonyms. Any other identifiable data were also removed where appropriate, such as names of other individuals, or organizations. Analysis of interviews was undertaken as soon as possible after transcribing, to allow the emergence of any themes to be included in later interviews, as part of an iterative qualitative process of data collection and analysis. Analysis of transcripts involved an initial process of open coding, where an attempt was made to identify initial themes and

descriptive categories. In part, these were informed from the literature review themes, and also the interview schedule. Further coding was then undertaken into sub-categories, along with axial coding, which involved transcripts being read and re-read and compared using the process of constant comparison, to identify links between codes and interviewees.

3.2.3 Ethical approval and issues

Appropriate ethical approval for this research was obtained from the School of Health and Related Research Ethics Committee at the University of Sheffield (see appendix 7.3 below). During the course of the study, however, an unanticipated ethical issue arose wherein the researcher was contacted via the on-line recruitment message contact number and was asked to provide support and guidance. This occurred on two distinct occasions – one involving direct contact with an individual, and the second less direct text messaging. On both occasions, the researcher made clear their position but offered general signposting that was considered appropriate to the individuals' requests for help.

3.2.4 Non-participant details

This study was one characterized by few initial responses to requests for participants who had direct experience of OTC medicine addiction. Of those who did respond, there was a mixture of those who were offering to participate and those who provided descriptive accounts of their problems. These latter communications were somewhat ambiguous in their tone and the researcher provided individual responses thanking them for getting in touch and suggesting they respond again if they wanted to participate formally in the research.

Amongst the former, a number were not included in the study since they were resident in a non-UK country. This occurred on three occasions, involving individuals from South Africa, Australia and Eire. A further group of individuals were also not included in the study due to perceived concerns about the interview method and around confidentiality and anonymity more broadly. Several noted that they used pseudonyms on the on-line web sites and were extremely reluctant to divulge their real names, for example. This occurred for four individuals. A final group of individuals were excluded from the study since their medicine addiction occurred exclusively through prescription supplies of medicines, and there was no OTC medicine aspect to their situation or, in one case, through internet only supplies of codeine, but with only past prescription and not OTC supply.

The next chapter of this report describes the results, in terms of a number of thematic areas. This chapter is then followed by a discussion chapter, which will develop some of the themes in the data and contextualize and link them to the extant literature, as well as offering recommendations.

4 RESULTS

4.1 Introduction

This chapter provides a description of the emergent themes from the three sets of stakeholder interviews undertaken. In terms of organization, this will be done in terms of the stakeholder group with the range of individual themes set out for each group. Several common themes emerged in each of the three groups and the discussion chapter that follows will reflect in greater detail on the similarities and differences between the three groups and the emergent themes. The first section of this chapter provides demographic and other information relating to the participants in the research. The next section involves experiential accounts of those with direct experience of addiction to OTC medicines; this is followed by the stakeholder group, then the medicine counter assistants and finally pharmacists.

4.2 Demographic details of participants

A total of fifty five individuals were interviewed for this study. These included ten pharmacists and seven MCAs (Table 1 sample grid for pharmacies), sixteen stakeholders (Table 2 Stakeholder Interviewees), and twenty four individuals who had experienced problems with OTC medicine (Table 3). These individual figures total more than fifty five since two individuals were interviewed in dual roles (individuals who were responsible for on-line support forums were interviewed based on this and also their personal experiences of OTC addiction.)

Table 1 sample grid for pharmacies

Pharmacy	Pharmacy ownership	Location	Pharmacist MCAs
1	Independent	Suburban, England	1 male pharmacist 1 female MCA
2	Small group multiple	City centre, England	1 male pharmacist 1 female MCA
3	Large group multiple	Suburban, England	1 female pharmacist 1 female MCA
4	Independent	Rural, England	1 female pharmacist No MCAs working
5	Independent	City Centre, England	2 pharmacists (male, female) 2 female MCAs
6	Large group multiple	City Centre, Scotland	1 female pharmacist 1 female MCA
7	Independent	Rural, Scotland	1 female Pharmacist
8	Large group multiple	Rural, Wales	1 female Pharmacist 1 female MCA
various	Various	Scotland	1 female relief Pharmacist

Table 2 Stakeholder Interviewees

1	Representative of Medicines and Healthcare Regulatory Authority
2	Clinical director of Substance Misuse Management in Primary Care (SMMP) Group
3	Representative of Drugscope, organisation that provides information on substance misuse
4	Representative of Royal Pharmaceutical Society of Great Britain
5	Representative of the Proprietary Association of Great Britain (PAGB)
6	Member of Parliament with interest in medicine abuse, chair of all party parliamentary group on substance misuse
7	Founder and owner of on-line web site offering help to those affected by OTC medicine problems - also an individual with personal experience of OTC medicine addiction
8	Founder and owner of on-line web site offering help to those affected by codeine based medicine problems – also an Individual with personal experience of OTC medicine addiction
9	Academic researcher in area of OTC medicine abuse
10	Academic researcher in area of OTC medicine abuse
11	Academic Researcher
12	Employee of private addiction clinic
13	Employee of private addiction clinic
14	Substance misuse nurse in addiction charity
15	Director of eating disorder charity
16	Superintendent pharmacist of multiple pharmacy chain (also providing an internet pharmacy part to business)

This section provides accounts from three groups of participants: firstly, the experiences of those with direct personal experience of OTC medicine addiction, secondly, pharmacists, and finally, MCAs. There is a greater emphasis upon the first group for various reasons: they were an under-represented group in previous research, so this research particularly sought to capture and reflect on their experiences, but interviews with these participants were all typically much longer than those involving pharmacists and MCAs, so the quantity and depth of data collected was greater.

Table 3 Details of Individuals with OTC medicine addiction experience

Name	Sex	Age	Employment	Product	Dose(s) used and typology*	Current use?	Treatment(s) & support used
Serena	F	40s	Housewife	Solpadeine + diverted Solpadol	Varied, up to 12-13/day II	No	'Cold turkey', CF web site
Ailsa	F	60s	Professional	Nurofen Plus	No more than 6/day I	No	CF
Malcolm	M	40s	Unemployed	Paramol +Sudafed for short period +alcohol	Up to 36/day either 16+16 or 12+12+12 III	No	GP, DAAT (methadone), Overcount
Graham	M	DND	Professional	Co-codamol, then Syndol	Up to 8 per day I	Yes	GP, CF
John	M	30s	Professional	Co-codamol	12-14/day II	Yes	CF
Jack	M	30s	Professional self-employed	Nurofen Plus + prev. non-opiate illicit substances	Max of 60 tablets/ day III	No	GP, DAAT (Buprenorphine) CF
Glenys	F		Former health care professional	Solpadeine	Up to 8/day I	No	CF
Rachel	F			Co-codamol soluble +Rx co-codamol 30/500	Up to 16/day (max 4/dose) II	No	CFM
Theresa	F		Health care professional	Nurofen Plus	32/day (very occ. 64/day) III	No	CF + buprenorphine
Yvette	F	30s	Uni student	Feminax then Cuprofen Plus prev. alcohol	36/day III	Yes	CF
Karen	F	40s	professional	Nurofen Plus	24/day III	No	CF
Elizabeth	F	20s	Professional	Co-codamol + prescribed	Up to 8/day I	No	CF
Florence	F		Professional	Co-codamol + prescribed	up to 16/day occasionally + prescribed II	Yes	GP, Overcount
Bob	M	50s	Retired Professional	Nurofen Plus + prescribed codeine phosphate	10/day Nurofen plus + MDD of codeine III	No	Overcount
Richard	M	60s	Professional	Solpadeine soluble	very occasionally 10/day II	No	Private treatment
David	M		Professional	Phensedyl	90	No	GP, DAAT

					bottles/week III		
Mark	M		Professional	Panadol Ultra and Nurofen Plus	15-20 of each III	No	GP
Peter	M			Solpadeine	4/day I	No	Overcount
Dwain	M		Self-employed	Nurofen Plus	10/day II	Yes	CF, DAAT, GP
Abigail	F			Solpadeine	Up to 8/day I	Yes	Overcount
Jennifer	F			Syndol	Up to 8/day I	Yes	CF, GP
Bryan	M		Former health care professional	Codeine linctus, Gees linctus, stolen dihydrocodiene	Varied but much above max daily dose. III	No	CF + DAAT (methadone)
Derek	M	60s	Retired professional	Phensedyl, Actifed, Codeine linctus Diverted prescription codeine	200ml codeine linctus/day III	no	CF + GP + DAAT (methadone)
Helen	F	30s	Professional	Syndol + Nytol	Syndol: prev. up to 8/day, now 12/day in last 12 months II	Yes Syndol	Overcount
Michelle	F	50s	Professional	Feminax, then Veganin	6-10/day. Max=12/day II	Yes	Overcount + GP + Drug Action

Details of typology may be found on page 33 and Figure 2

Missing data reflects information not provided by participants

CF = Codeine Free

4.3 Individuals with OTC addiction experience - *three types of 'respectable addict'*

A total of twenty five individuals were interviewed who had direct experience of OTC medicine addiction. Two of these were also individuals recruited as part of the stakeholder group, by virtue of their involvement in one of the two on-line web sites. As Table 3 on page 17 illustrates, participants varied in terms of their background and experiences. Ages ranged from early twenties to mid-sixties and almost equal numbers of male and female participants were represented. A minority (nine) were still experiencing OTC medicine problems at the time of being interviewed, but the majority had no current OTC medicine problems. How historic these latter participant's experiences were varied, with some describing problems in the weeks prior to being interviewed, whilst others recounted problems that had begun over a quarter of a century earlier. It was apparent for several participants that contributing to the research was part of a process of recognition on their part, about having an OTC medicine problem, and several used the opportunity to contribute to explore their situation.

Several themes emerged from the analysis of participant interviews, and these will be explored in this section as they relate to the medicines used, the initial reasons for use, links to prescribed medicines, types of addiction, reasons for continued use, treatment, and associated problems. It will be shown that all the participants had experienced problems with an opiate (often codeine), and had initially used the medicine for genuine reasons, except in two cases, where intentional experimentation to exploit a side effect was sought from the outset. A typology of three types of addiction was identified, representing different levels of medicine use: at or below recommended doses, moderately above recommended doses (either regularly or on occasion), and much higher doses. All described using the medicine for uses other than that initially required or as intended by the license for the medicine – this included experiencing the 'buzz' of codeine, or exploiting sedative side effects, for example. However, what was apparent in many interviews was a theme which cut across the various themes described above and that concerned the emergence of the concept of a 'respectable addict' to describe the participants and of three distinct typologies of addiction. The term 'respectable addict' was used to describe an apparent tension between individuals recognizing their addiction, but also maintaining a professional or intelligent persona, which were thematically grouped under the term 'respectable'. This reflected active attempts on the part of most participants to present themselves as normal members of society, in contrast to frequent perceptions of a stereotypically chaotic, problematic addict, dependent upon alcohol or illicit drugs. These themes are now considered in turn, beginning with the type of medicines used.

4.3.1 Medicines

As Table 3 illustrates, a range of products were reported as being used by the participants but what all had in common was the involvement of an opiate medicine. At opiate was involved for all participants but occasional reference to decongestant and sedative antihistamines were reported by participants.

4.3.1.1 Codeine

The opiate was often a codeine-based compound analgesic (containing paracetamol or ibuprofen) in tablet form, or, from those describing more historic accounts, morphine or codeine in liquid form. The former included generic products such as co-codamol 8/500 tablets, but more frequently cited were specific branded products such as Solpadeine and Nurofen Plus. In addition, Syndol, Feminax and Paramol were also described as branded medicine that led to addiction. A key feature of the products involved was of the specific use of one product for most participants, and mention was made of substituting or changing only if a preferred brand or formulation was unavailable, as Karen noted about her use of Nurofen Plus:

> *"I had never tried anything else. I think Solpadeine is another one, isn't it? But I never ever bought it […] the other thing I did try was Cuprofen [plus], which is not a brand name. Which I think was only very occasionally when there was no Nurofen Plus available in the pharmacy and they say 'Take this, it's exactly the same, it's half price' but even then you don't think it is going to do the same and have the same effect."* Karen

For Yvette, there had been attempts to try other products and this had been prompted by the reformulation of an original medicine of choice, Feminax:

> *"I found the Cuprofen Plus and I just started taking those and it had the codeine in them. I tried other things like Paramol - dihydrocodiene - and everything else. They just didn't work for me, but the Cuprofen Plus did […] they changed the [Feminax] tablets and how they made them or whatever. I stopped feeling the effects and I knew there was something wrong with the formulation […] I just sort of correlated what was in it with other things and just ended up finding the Cuprofen Plus that gave me the same effects [...]" Yvette*

For others it was also about the need to take a specific formulation, as in Richard's case, a soluble formulation:

> *'Only Solpadeine hits the spot […] it had to be soluble. That's part of the ritual. It's strange is that because occasionally I have to go on business trips and although you can get them in capsule form, I would always have them in soluble and I got very adept at being able to take Solpadeine in the middle of a meeting without anyone noticing me doing it.'*

Such brand or formulation specificity did not appear to be associated with the dose taken and as will be described later in this section, for those taking much higher than the recommended doses, and therefore requiring increasing supplies, the choice of a specific product was still apparent. For those who described use of a generic product, there was less concern about the manufacturer but still a concern to maintain the same formulation and form, as John notes about his preference for a medicine type that must be dissolved in water before taking:

> *'No, I don't vary anymore. I am one hundred per cent co-codamol […] I'll literally do any I can get my hands on […] I'm definitely a soluble person. There is a whole feeling of ritual about it as well.'*

Serena was also very specific about her need for a soluble codeine-based medicine, and in the quote below refers to this being part of the *'ritual'* of addiction – a phrase used by several other participants:

> *"[…] it was always soluble. This is really interesting an awful lot of us get soluble tablets and wouldn't give you tuppence for the hard ones. I wonder what that is? I don't know if it's a ritual again perhaps maybe."* Serena

A minority of participants – and often those describing use that was very historic – appeared to have been flexible in the products they sought, and whilst they described a 'preferred' product, their desire to obtain the medicine mean that they would purchase different products. In all these cases, the OTC medicine addiction involved much higher than recommended doses, and, as Bryan recounts, addiction that continued over many years which had to accommodate changing trends in availability:

> *When I was out and about I was able to but codeine over the counter quite easily. In those days [the 1980s] it used to be codeine linctus and that gradually dropped off and I started using Gee's linctus […] The liquids were easier to take, that's all. The highest dose of codeine to take over the counter has got fifteen milligram per ml size […] if I couldn't get hold of codeine. I wasn't happy with co-codamol because I wasn't happy with the amount of paracetamol I was taking concurrently.*

What this interview extract also illustrates and was also clear in all the accounts presented was of a considerable awareness about the active ingredients in the OTC (and for some prescribed) products, together with awareness of other ingredients in a formulation and the doses involved. For some participants, this was manifest in terms of them offering their understanding of the underlying pharmacology of the medicines involved and, for many, an awareness that the opioid in the product they used was chemically related to morphine and heroin, which participants recognized were products associated with more stereotypical addictions, as Jack recounted:

> *"I had a thing about what would be the most effective treatment for it [joint pain] and you didn't need to look very hard to realize that Nurofen Plus is by far and away the strongest and most effective painkiller […] I am familiar with morphine from the hospital, which I think it's diamorphine in this country isn't it?"*

4.3.1.2 Other medicines

Although codeine was the main medicine mentioned in the accounts of OTC addiction, other medicines were described. In one case, this involved the use of dihydrocodeine in the Paramol product but as regards non-opiate medicines, two main therapeutic categories were identified: decongestants and sedative anti-histamines. In all these cases, the products were used as well as codeine or dihydrocodeine. Malcolm, for example, referred to various periods when he had used specifically set out to use Sudafed based on the advice of someone else, to specifically exploit the side effect of making him more alert:

> *" […] it is supposed to give you a lift or keep you awake […] last year it crept back in. I don't know why so I was taking probably about eight tablets a day."*

Two participants had described problems using Nytol, which contains a sedative antihistamine diphenhydramine. For one, this had been used in conjunction with Syndol, to help the participant sleep and for another, For Yvette, Nytol was used as well as Night Nurse - a cold and flu remedy, which contains a sedative antihistamine and paracetamol. These products were used in what appeared to be a complex polypharmacy addiction which also included Sudafed,

although her use appeared to change over time, and eventually involved only Cuprofen Plus. She attributed this use to helping her cope with certain life events (see section 4.3.3.2 below):

> *"Yeah as I said it wasn't just codeine, it was Night Nurse and the Nytol and all those other things as well [...] not anymore, but I used to take up to twenty Night Nurse a night, or I would take anti-histamines to help me sleep. So I went through a stage of abusing those as well. It is not an issue at the minute, but I have abused those as well over the years quite a lot as well [...] I was, when I was taking the pseudoephedrine that would give me palpitations."*

For Bob, mentioned having problems with Benylin Original cough medicine, almost incidentally, when describing other possible dependencies that he may have had in the past, as noted in section 4.3.3.2 below (on page 31).

Some of the compound cough products mentioned, such as Phensedyl and Actifed contained various combinations of ingredients (on page 119) such as decongestants and antihistamines. Whilst the codeine was recognised as being the key ingredient, participants such as Derek, recognised the possible synergistic effects of the combinations, and when Phensedyl was removed from sale, for example, he specifically tried to find another product that was as close to this as possible.

Having considered the ubiquity of codeine and occasional examples of other medicines and formulations, and the preferences for participants for specific brands and formulations as emergent themes, the next section explores both the initial and then continued reasons why an OTC medicine was initially used genuinely and then led to addiction.

4.3.2 Reasons for initial use of medicine

For all but two of the participants in this study their experiences of OTC medicine addiction involved genuine reasons for seeking medical treatment of symptoms or a condition. The two participants who initially experimented are described at the end of this section but in relation to those with genuine medical reasons, three different types of situation were described, and these centred on the relationship of OTC medicine use to prescription medicines. It involved three types:

- those who were *initially* prescribed a medicine or received treatment which stopped and then obtained OTC medicine supply;
- those who were *still* being prescribed a medicine, and were supplementing such supplies with OTC medicines,
- those who bought OTC medicines initially *without* any medical prescribing

The first two groups and several further variations are illustrated in

Figure 1 (on page 25). Most interviews began with participants providing lengthy accounts of their medical history and associated reasons for using an OTC product initially. Pre-existing medical problems of various types were almost always involved. Due to the involvement of codeine for almost all of these patients, there was a not

unexpected range of pain-related symptoms or conditions, including headaches and migraine, abdominal pain, period pain, pain relief following acute injury and hangover treatments.

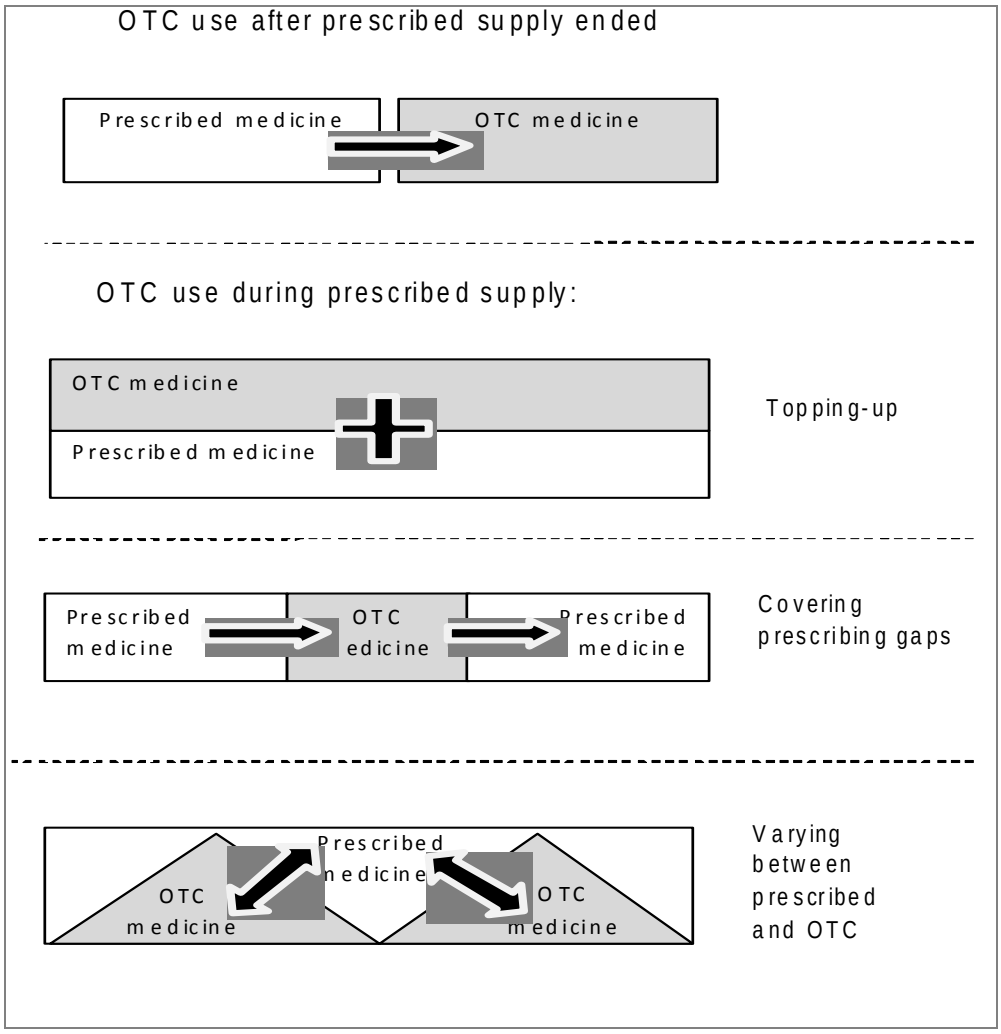


Figure 1 Different relationships between prescribed and OTC medicine use

4.3.2.1 Use after a prescribed medicine stopped

In the first category, participants described some form of medical intervention or treatment. Examples included, a GP consultation for migraines, post-operative hospital prescribing of analgesics that sometimes continued with GP prescribing for a period. Within this group, there appeared to be two broad categories of experience relating to why medical involvement *qua* treatment and prescribing had not continued; this included participant's perception that there had been a medical decision to end treatment, or in other cases a dissatisfaction with the medical care in terms of it resolving the symptoms or condition involved.

Amongst the former, there were often claims that this was not appropriate and the decision to use an OTC medicine was to *replicate* the prescribed product, as Brian notes about his initial experiences:

"It all started when my GP put me on Palfium. It is a very, very strong painkiller and it was for a trivial complaint and I found that when I had finished the use I wanted some more and he wouldn't give me any. As I had access to codeine, that's where it all started [...] I got a buzz from it. I went to the doctors with gut ache, probably colic, and he should have treated that with something like Merbentyl and so he just gave me hundred Palfium. And up to me taking the Palfium, I had no contact with any drugs whatsoever."

It should be noted that the above extract was atypical of other participant accounts in the manner in which blame was attributed to the doctor, with a suggestion that the resulting addiction had been iatrogenic in nature. More frequently, participants viewed their OTC addiction problem as *their* problem, and did not seek to attribute it to a *direct* factor, such as a prescriber. As will be indicated later, there were attempts by participants, however, to cite other events or other medical issues that they considered to be relevant to their OTC addiction.

Other accounts were more neutral in terms of describing the transition from prescribed to purchase medicine, as Theresa noted:

"I mean my story started by being on painkillers for gynaecological problems and that was when I first took codeine, but then it took a long time to realise I had a problem with it and even then you are in total denial. Then I found when I couldn't get codeine on prescription any longer it was readily available over the counter."

The latter group of participants, whose experiences involved initial medical prescribing or treatment which then ended suggested a less unilateral – medical - decision to end treatment, and these appeared linked to on-going problems in finding a treatment that worked for participants. Some of these involved headache-related symptoms, and participants described being prescribed different medicines over time, and having various specialist referrals. The use of OTC medicines in such cases appeared to represent the participant trying to self-manage their symptoms. At the time of interview, several reported that their symptoms had still not been treated effectively, as Graham noted about his various treatments for migraine-related symptoms:

"My main issue is I have a lot of classical migraines. So I get a lot of visual disturbances. I'm talking about three a week and I mean I'm now dealing with a neurology department at our local hospital. Err, I'm under their care as such and we're basically going through a big, long list of medicines and trying which ones work. Before that it was a case of I was using effectively codeine plus paracetamol and I find generally speaking that codeine is one of the things that does actually reduce the pain. Consequently, of course, when you start getting a lot of them, you start using lots of codeine."

As Glenys noted, the use of an OTC product was appropriate not just because it stopped any pain but because it was argued to have less side effects than prescribed medicines. Her experiences involved first paracetamol, and then she purchased a codeine and paracetamol product (Solpadeine), and then was prescribed a higher strength codeine compound analgesic (Solpadol) which she was not happy taking:

"Good old paracetamol just wasn't enough anymore. So I tried these blessed Solpadeine again and by heck they work. As things were then when it got worse they didn't work as well. They certainly had an effect. My GP tried me with a stronger one called Solpadol and I didn't like what they did to me. You know I want a life, not a Solpadol. [laughs] I now really felt….I had headaches, nausea. Yes it worked for the hip pain but I think I would rather have hip pain and feel alive you know. So I never really took to those."

4.3.2.2 Use whilst still on prescribed medicines

As well as the identification of OTC medicine use where initial prescribing had stopped, there was a second category of participants who were using *both* prescribed and OTC medicines. As

Figure 1 illustrates this occurred in several distinct ways, reflecting the range of different individual experiences. In some cases, this involved issues around prescribed supplies ending temporarily, with the individual using OTC medicines to cover the period before prescribed supplies were available again. For others, it was to use in a more complex way, either taking both together or alternating with prescribed and OTC medicines. Illustrating the former are Rachel's and Bob's accounts of co-codamol and codeine and Nurofen Plus respectively:

> *"Certainly I am topping up what I can get from the doctor with what I can get over the counter […] Well, I mean I suppose on a really bad day and this hasn't happened recently, but on a really bad day, I suppose I could take sixteen.*" Rachel

> *'I ended up taking the maximum number of prescribed, not co-codamol, actual codeine sulphate [sic] tablets. […] Now the doctor prescribed me those because she was concerned about the amount of paracetamol that I was taking in Tylex […] and I mean I am absolutely sure you are familiar with the slippery slope that we are talking about here. I ended up taking all those plus about ten Nurofen Plus tablets a day. That went on for some time […]'* Bob

In some accounts, there were clear negative connotations with such practices, and terms such as '*scrounging'* and '*badgering'* were used to describe how prescribed supplies were obtained from doctors.

Amongst the latter category of more complex combined use of prescribed and OTC medicines, were accounts where *'stronger'* prescribed medicines were viewed as being inappropriate at times. Echoing Glenys' comparison above, but not being as discrete in terms of ending one supply and starting another, Florence described a situation when she was in pain but decided to use OTC medicines over a prescribed analgesic:

> *"I was away this weekend and I was in incredible pain because I was out of my comfort zone and you know I didn't want to take the stronger. Which I could have because you know within safe limits I know what my limits are and instead of just taking another Tramadol I just opted to take an extra two of the co-codomol that I had because to me it seems in my head safer to take ten in twenty four hours rather than eight or six than take something like Tramadol which to me I am thinking oh that's five milligrams of morphine so actually from the pharmacological point of view, would have been safer. Well actually it would have been more effective and it could have meant that I could take less co-codomol over the day."* Florence

Another participant, Abigail, also reflected the complex interaction between prescribed and OTC medicines when she described using both prescription and OTC since the OTC version contained caffeine – which she noted '*gave me a little lift'* - and alternated between this formulation, which was also not available on prescription, and a prescribed type, especially at bedtime.

A final category of initial use that was linked to prescribed medicines involved occasional references to the use of diverted prescribed medicines – ones that had been prescribed for someone else but used by the participant. This was often a parent or a partner, but appeared to be used in both the two above categories – either to supplement

their own supplies, or used occasionally in the past before later OTC purchases were made. The former is illustrated by Elizabeth's account, and the latter by Serena's account:

> *"[…] I was taking my prescription, when that ran out…around the time mine was running out my partner cracked a rib and he got prescribed a load of them as well and he never touched them and I got through his lot as well and you know when I didn't have any of those, or when I was out, I would pick up a packet of something from the pharmacy […]"* Elizabeth

> *"[…] my mum takes Solpadol which is a bigger compound of codeine which I used to regularly help myself to with her permission which was very bad but I didn't realise that they were addictive at all. I knew there was a nice well-being sense of well-being from taking them but I won't say that I was addicted but I knew if I took them the nerves would all go and things like that and you know I'd sleep better and so I would just help myself"* Serena

In contrast to these various accounts that illustrated links between prescribed and OTC use of medicines, some participants described either no medical or prescribed element but sought OTC treatment directly, or deliberately set out to abuse a medicine. These are now considered in turn.

4.3.2.3 No medical involvement

A number of participants described genuine symptoms that they had sought treatment for, but without the involvement of the medical profession. Reasons for this included not being registered with a doctor, not having a good relationship or experiences of a doctor, or simply because the participant felt their symptoms could be self-managed using an OTC medicine. Illustrating the latter was Peter's account, wherein he recollects using a product that was already in his parent's house to treat a headache:

> *"I lived with my parents so one day you know, it was a Saturday night right and I had a bit of a dull head. A bit of a dull headache and I just went to the medical cupboard and I saw this red pack of what was Solpadine dissolvable and I had no idea what it was you know […] the next time you know I had a headache I just went straight for the Solpadine stuff. But gradually over time you know another headache came and another headache."* Peter

The use of products recommended by family was also apparent – not just in Peter's account of using medicines his parents had purchased - but more overtly in terms of being advised that a particular product should be used. Often, these could be traced back to much earlier memories such as being given a medicine to stop period pain, as in Yvette's case:

> *"When I was fourteen was the first time. I had started my periods. My Mum went out and she got me a hot water bottle and Feminax, which I took at the time and I remember the first time I took it, that feeling as the pain went away."*

4.3.2.4 Intentional abuse

In contrast to the above accounts, where there were genuine reasons for initial use, two participants described an intentional desire to exploit an OTC medicine for a particular effect at the outset, rather than genuinely control a

symptom. These involved the use of Sudafed and Phensedyl by two participants who had gone on use doses much in excessive of those recommended. In both cases, they had been told by someone else of the addiction potential of the product. In the case of Sudafed, which Malcolm used, he recalled using it, not for its decongestant use, but for its amphetamine-related stimulant properties; use which began some years earlier, then stopped and had been used again recently:

> *"I think I heard it from somebody and it was just an off the cuff comment that I heard and I thought …. that stuff you know, but I think I dallied with that in 2001 for a period of 4 months, or something like that, just taking 2 or 3 tablets and it is supposed to give you a lift or keep you awake. And it kinda did, but it wasna if, I don't know, it was just kinda messing about, so it was over before it kinda really started, but, er kinda last year it crept back in. I don't know why, erm, so I was taking probably about eight tablets a day."* Malcolm

The other participant who described initial direct attempts to abuse a medicine, Derek, also referred to the influence of a friend when he reflected on addiction that had begun several decades earlier, when he was a student. This was bound up in a period of experimentation with other substances, such as cannabis and LSD for this participant. Of interest was that Derek described the attraction of Phensedyl as being very different to the *'cerebral'* effects caused by cannabis and LSD:

> *"The thing with Phensedyl was that wonderful warm, physical feeling which I liked...a lot."*

Having so far considered the types of medicines used and the initial reasons for participant's use of an OTC medicine, the next sections go on to describe firstly the motivations for the usually subsequent addiction to an OTC medicine and then the type and extent of use, particularly in relation to the quantity taken per dose and daily.

4.3.3 Reasons for subsequent addiction

For all those participants who described a genuine initial use of a product, this led eventually to the medicine being taken for different reasons. The key reason cited related to the effect of taking codeine – often the 'buzz' – but other effects such as exploiting sedative side effects were also reported. In addition, a number of other factors were mentioned by participants, and many appeared to have insights into issues such as dealing with significant life events, other conditions and concerns about addictive personality types. What participants found more difficult to describe, however, was the exact *timing* of this change to addiction to a medicine, and when they realised that there was a problem. For some, this was understandable given the long time periods involved but several tried to locate their use and change to addiction to specific dates, or points in their lives, such as the job they were doing or an aspect of their relationship. Notwithstanding this temporal uncertainty, the emergent themes of the effect of the medicine, life events, conditions and personality are now explored in turn.

4.3.3.1 Effect of the medicine – 'the buzz' of codeine

The move to an OTC medicine being problematic occurred over different periods of time for different participants, and the main reason cited for this change was awareness that the product was being used for a different effect than initially intended, as some of the above quotes have already suggested. In relation to codeine, various descriptions were offered for the effect that was experienced, which was distinct from its analgesic effect. These were usually either described in the abstract as a feeling or sensation or in relation to the effect upon some emotion. The feeling most often described was that of a '*buzz'*, which was mentioned specifically by many participants but other phrases were also used, and the following, intentionally long list of extracts is included to illustrate the frequent use of the term '*buzz'* but to capture other positive feelings associated with codeine use:

> *"I remember when I took them that it would give you a* ***lift and a buzz****, but that lift or buzz would go and the only way to sustain that is to take more*." Karen
>
> *"I suffer with ME and this time the ME has affected me severely mentally. I have suffered with a lot of depression and how they describe, I can't remember the words they describe on the Codeine Free website, but it allows me to just zone out. So I don't have to think about anything. So if I had a really rubbish day you know for that period of time I can just* ***zone out****. Not high. But it literally,* ***it numbs me I think****. "* Rachel
>
> *"I never noticed before but if I took a couple of them it gave me* ***a buzz*** *which was quite a nice feeling. I've never taken more than six a day, never gone over that […]I don't think I ever really got that much of a buzz is was just a feeling of 'oh I* ***feel quite good'****. Sometimes I would wake up feeling awful and I would take a couple and I would think 'oh I feel better' now but it took me a long time to realise the two things were equated."* Abigail
>
> *"It would be five hundred yeah. So I would just knock back four at a time. Because that would give me that, as I say, it's not a high. Literally, I zone out. And that just makes that you know, I can then* ***zone out*** *and* ***I am able to cope with everything."***
>
> *"I can remember that not only did it cure the headache but I wasn't aware of what it was at the time but I remember it just gave you a* ***tremendous feeling of wellbeing****. So of course, needless to say, the next time you know I had a headache I just went straight for the Solpadine stuff" Peter*
>
> *"It gave me* ***the buzz*** *that I needed because as you know, you take over the counter stuff and then you take prescription stuff and you still need more and more to achieve the same effect."* Bob
>
> *"[…] that kind of* ***magic feeling****, you know that* ***buzz*** *if you want to call it. That triggered my brain"* Malcolm
>
> *"I originally took them for period pain and at some point must have got a* ***slight 'buzz'*** *from them."* Michelle.

As well as this abstract feeling being evinced, some participants noted that codeine had a more specific positive effect on them, in relation to promoting sleep, or reducing anxiety. Participants were aware that this was a different effect than the one originally sought, namely as an analgesic. For Gavin, this helped his migraine symptoms in a different way than originally intended when using the product:

> *"Yes, I think one of the things I found particularly with Syndol was that it did give a* ***soporific*** *effect and one of my triggers are sleep problems. If I have a couple of nights of broken sleep, then I tend to have more migraines or heavier ones than if I sleep properly and one of the things with taking a*

couple of Syndol was that it did help me go to sleep that could well have been the effect of the you know, muscle relaxant helping more." Gavin (emphasis added)

For others, codeine-based OTC (and for some previously prescribed) medicines allowed them to deal with symptoms such as anxiety and '*nerves'*. As Dwain noted about his use of Nurofen Plus, a combination of recognising the *'buzz'* as well as the specific effect was evident:

> *"Basically they made you feel better and then when I was going in to work I used to get terrible attacks at work. Nobody would know about it, so I found that taking some of these would help me with that, you know […] Well it made you feel high basically. It gave me that little buzz which made you feel not as anxious you know, not as nervous, a little bit more confident, that sort of thing."* Dwain

In relation to the other medicines identified in this study – pseudoephedrine (as Sudafed and as an ingredient in Night Nurse) and diphenhydramine (as the Nytol brand as an ingredient in the Benylin and Night Nurse brand specifically identified), the former was taken for its stimulant-related side effects, whereas the latter was used for the correct indication (to promote sleep) but was used at a higher dose and length of course than recommended in the case of one participants and Nytol, and for an unlicensed use in other cases in the other brands.

4.3.3.2 Life events, personality, other conditions

As well as specific effects relating to the medicines noted above, such as the codeine-related '*buzz'* or the specific effects on emotions and symptoms such as anxiety and insomnia, references were identified in interviews to a range of other factors, which participants used to either explain or contextualize their addiction to an OTC medicine. These were further divided into two broad areas: various, often adverse, life events and experiences encountered, and references to personality, and particularly concerns about 'addictive' personality and familial issues.

Life events varied but included references to bereavement and the loss of a family member for some, whilst others identified work-related or relationship problems. Common to all of these was a connection between the adverse life event and addiction to an OTC medicine. These attempts to externalize were illustrated in the following two extracts:

> *"I used to take Night Nurse quite a lot. If I split up with my boyfriend, or had a fight, or had a problem with my family and couldn't sleep, I would take Night Nurse as well. This is back when I was about fifteen. So I used to use pseudoephedrine as well which it used to be Night Nurse and that's gone on until last year as well."* Yvette

In contrast, some accounts indicated that the significant life event did not lead to the medicine being used initially, as above, but to how it *increased* use. For example, Ailsa had taken an OTC medicine, Nurofen Plus for many, years to treat headaches, but it was only when a tragic series of deaths occurred that she became aware of a different effect occurring due to the medicine:

> *"I was slightly aware probably about five years ago I think, I had some problems, my mother died and my partner and then my sister died and it was just a whole awful time and it was about that time that I noticed, I never noticed before but if I took a couple of them it gave me a buzz which was quite a nice feeling."* Ailsa

For Malcolm, his use at the point of his bereavement was still much higher than recommended – at around twenty four Paramol per day - but increased to thirty two thereafter:

> *"My mother passed away in 2001 but that didn't … maybe that was the trigger that was why it went up then, maybe it was, but I was still the same, I was still working the same, still taking the Paramol the same and that was that, you know, and I got over my mother's death fairly easily. I don't mean, I mean it was bad. but at this time the Paramol was my coping mechanism you know I had to have them, you know, I thought I couldn't function forever, but you know I just had to have them as my kind of security blanket kind of thing."* Malcolm

In relation to personality, several participants raised concerns that either their own personality may have been such that they were pre-disposed to developing a dependency, or references were made to family members who had had dependence problems, and the participants speculated whether this may have been a factor. Gavin illustrates the concern about a familial pre-disposition:

> *"[…] and I mean to be honest about this; my father is an alcoholic for want of a better term and my grandfather on my mother's side was a bit as well and they were kind of hiding things or always having it with us. Couldn't leave the house without some dependency was starting to rise and I suppose even now I find it difficult to leave the house without my anti-migraine things"*

The view that there was a particular personality type was raised by several participants, across all of the types of use considered in the next section. Several referred to excessive consumption of alcohol in the past, to illustrate their concerns that they had experienced other types of dependency and their OTC medicine addiction was not unexpected in the context of their previous use. It should be noted that the self-reported alcohol use by these participants was referred to as being higher than average or of concern, but none of the participants who referred to alcohol to explain their current use considered themselves as 'alcoholic'. This contrasted with the very modest descriptions offered by the two participants who had received treatment for alcohol dependence, Malcolm and Yvette, and considered later (4.3.4.3 below). For several participants there was an eventual realization that internal factors may be as, or more, relevant than external ones, as Michelle notes in her written account:

> *"I am familiar with the term an addictive personality. Whatever value you place on that term I am pretty sure that, if there is such a thing, I have an addictive nature. I think you know I had to be very, very strict with myself. I say to various people, I seem to have spent all my life giving things up. You know I gave up smoking in nineteen eighty […] Then of course the true nature of the codeine kicked in and I have had to be very careful about things like cough mixtures since. You know I had a very bad cough, chesty cough over the winter just. I ended up taking Benylin for a while. Of course, I found myself justifying to myself why I should say to the pharmacist, no I don't want the non-drowsy, I want the ordinary."*

For other participants there was further realization that external, life events were too obvious and underlying medical conditions may have been contributory. For some, this was because of misdiagnosis, and the OTC medicine was being used inappropriately, as in Elizabeth's case, where she continued to use analgesics but her eventual diagnosis was an intolerance. For others, psychological problems such as depression and anxiety were described. This was noted by Michelle:

> *"My father died suddenly that year so it's very easy to connect the 2 but I'm not convinced that was the reason for continual use - I think it was more a depressive mood thing which went undiagnosed and was possibly caused by a combination of periods and puberty".*

4.3.4 Typology of addiction

So far, the different medicines, types of initial use and addiction and links to prescribed medicines, and reasons for continued use have all been described. In this section, a typology of addiction is described, based on the quantity of medicine used, either in individual or daily doses. Analysis of interviews and participant's accounts led to three different types of addiction being recognised, with similar numbers of each being identified in this study. These are set out in the summary provided in Figure 2 on page 38 and further details may be found in Table 3 on page 19. Type I involved doses that never exceeded the recommended maximum in terms of both individual and daily doses; type II involved occasional or frequent use of doses that were slightly higher than the recommended maximum; type III involved doses that were considerably higher than the recommended. Two points are of note initially, before describing them in more detail. The first point is that that these types of addiction appeared relatively discrete and there was no evidence from the interviews of transitioning between doses. Obviously for those with type III addiction, where doses were considerably above the recommended, there would have been a period for many when the quantities used were at therapeutic doses and then slightly above, given the escalating use that was apparent in this type (and which will be described later). But it appeared that in the others, addiction continued as such, either at the time of being interviewed or until addiction stopped, and there was no evidence of type I addiction leading to type II addiction, or type II to type III. This was illustrated by Graham, whose type I use had never escalated, when he described having to wait, or 'clock watch' between doses:

> *"[…] if I am awake and I am in pain in the middle of the night. When I am kind of between two days if you like so effectively two periods of twenty four hours in your body clock isn't it? And I have probably had my dose and I just think no don't do it. And I can actually control that […] Whether it is knowing my limitations and my knowledge or a sense of preservation or whatever it is - Don't do that. Don't even go there."*

The second point to make initially about this typology is that it is relative to the recommended doses of the medicines involved but did not represent an attempt to impose a strict clinical definition upon those affected in a research sense. It was, instead, transparent in all the interviews that participants had an understanding of the recommended doses for particular products. In this respect, there was awareness from the individuals as to whether their use either never exceeded the recommended doses, or was somewhat higher. Understandably, perhaps, it was the first group – those who never exceeded the maximum recommended doses - who appeared to be most aware of the limits set by manufacturers and others and it is to this group that attention is now turned first.

4.3.4.1 Never exceeded recommended dose

For some participants in the study, their addiction to an OTC medicine was defined by concerns about the reasons they were taking the medicine, coupled with issues around the duration of use, and, for some, problems encountered when they tried to stop taking the medicine. In this respect, their experiences were no different from accounts of participants in the other two groups. What distinguished participants in this type of addiction was their respect for the

recommended maximum doses of the medicine and their perceptions of the harms that might occur should they take more than the recommended dose. In other respects such as their description of abusing a medicine for a different reason than initially intended, or exploiting a sedative side effect, for example, they were no different than the other two groups. Five participants referred to abusing an OTC medicine to treat headache symptoms (including migraine) with one treating abdominal pain, and another joint pain. In all these accounts, medicines were viewed in some respects as an unknown, in contrast to the detailed understanding offered by other participants who had used higher doses. The following two extracts illustrate this deference but also relative ignorance of medicines, except for the doses involved:

> *"I've never taken more than six a day, never gone over that […] Never escalated because I think I was too scared of going beyond that. I don't take anything else and I mean I'm not on any other proper drugs and when I say drugs I mean medicines of any sort and I just didn't want to take more than the stated dose, I never did* ***and then I don't think I realised there was codeine in it at all****"* Ailsa [emphasis added]

> *"I have never exceeded the maximum dose either the four hours between doses nor the two tablets nor the eight in twenty four hours […] I think that was just,* ***it was that feeling that I don't know enough about things pharmaceutical to be playing with them****. And therefore that was well enough ingrained in me somehow to make me disrespect it. It's just enough. I have never ever gone over the top. When I say over the top I mean over the recommended […]"* Glenys [emphasis added]

Another participant, Graham, was so concerned when he once accidently took a further dose of medicine too soon, that he contacted his GP for reassurance. Those in this group appeared to have gained insights from others into the extent of their use of a medicine. This occurred from reading about much higher quantities being used by other members of the on-line web sites, and for several participants, from medical opinion of their use of an OTC medicine. It was apparent that both these perspectives – which arguably appeared to play down participant's addiction – did not cause participants to change their perception that they still had an addiction. Peter illustrates the reaction of one doctor:

> *"No but I remember seeing another doctor early on in the six years and I just happened to say to him, oh by the way I have taken an awful lot of this Solpadine stuff. He says, how much have you taken and I said, well maybe x whatever a day you know. Some days I might have a bad headache and I might take up to six. Oh he says, I don't think that will hurt you."*

One final feature of participants in this group was the identification of some awareness that OTC medicines could cause harm. For two participants, this involved concerns around liver toxicity, and which prompted one to have tests, which did not reveal any problems. Emma illustrates this concern in the following extract:

> *"I am always very paranoid. I am only a little person, size wise so I am always very paranoid about overdosing or damaging my liver, or anything like that".* Elizabeth

As will be noted in the section on treatment (4.3.8 below), this first type of addiction shared similarities with the next type to be described – where recommended doses were exceeded slightly – in not resulting in specialist addiction service intervention. As Figure 2 on page 38 also shows, the first type of addiction did not include anyone with

alcohol or illicit substance misuse, but did include several participants who were still abusing an OTC medicine at the time of the study.

4.3.4.2 Slightly exceeded recommended dose

The second type of addiction identified involved participants using doses of medicines that exceeded the maximum recommended doses, but who, unlike the third type described later, did not describe their use as escalating considerably to quantities much in excess of the maximum dose. As noted above, none of these participants had used illicit substances or described alcohol dependence, although several referred to perceived concerns about past alcohol consumption. One participant described the use of Nurofen Plus but for all the others in this type, co-codamol was the product used (either as a generic, or a Solpadeine, Syndol or Veganin brands). The key difference between this group and the first described was of less of a concern about the absolute prohibition of exceeding the maximum dose, and descriptions given often did not refer to the maximum daily dose, in contrast to the previous type, where this was bound by the maximum. This was not always the case and John, for example, was conscious of exceeding the recommended doses:

> *"I am usually up to about, you take them in two's don't you, so I take about six a day. On a bad day, I'll probably take anywhere between twelve to fourteen […] I am very aware of the fact that if I go over eight it is something that fronts into my mind as a really conscious decision of, you've not just done this subconsciously and just slipped into having one or two extra. In my mind it actually physically says to me, you've had more."* John

This quote also illustrates the fact that the dose of medicine taken often varied depending on the severity of symptoms, and in this respect could be contrasted with the third type of addiction, where much higher doses were regularly taken and escalated over time. The excessive dose appeared to occur mainly in relation to the daily intake, but some participants, like Rachel below, referred to taking up to four co-codamol as a single dose when symptoms – a headache in her case - were particularly bad:

> *"Well, I mean I suppose on a really bad day and this hasn't happened recently, but on a really bad day, I suppose I could take sixteen […] So I would just knock back four at a time. Because that would give me that, as I say, it's not a high. Literally, I zone out". Rachel*

For most participants in this group, the slightly increased amounts were related only to an OTC medicine, but for three participants, this occurred because they had used a combination of OTC and prescribed medicines. Participants did appear to be aware of the possible risks in this type of use, and references were made, like the first type of addiction, to concerns about liver damage due to paracetamol.

Some describing this second type of addiction had reflected on their use compared to those taking much larger amounts, mainly, like Graham in the previous section, through reading about accounts from others on the on-line web support forums Overcount or Codeine Free:

> *"I have never taken massive amounts if you know what I mean. I know it sounds a bit silly, but I sort of count myself intelligent enough that if I had taken twenty, or thirty, or forty a day, like I have read on the internet, like lots of people, you know, it would affect my health really badly. So I have managed to stick to maybe up to ten a day maximum."* Dwain

A final similarity between this type of use and the first type was in the need to defend their use of an OTC medicine addiction which they perceived others may not view as being capable of causing addiction. This was illustrated by Serena:

> *"[…] lots of people thought 'oh you can't get addicted to 12mg or 10mg' or whatever was in the Solpadeine I was taking at that time, 'you cannot get addicted' but you can if you're taking about twelve or thirteen a day, […] I thought didn't apply to me because I'd been to the GP and he'd told me to self medicate and I was more than aware about the dangers of the paracetamol.* Serena

A noted in Figure 2 on page 38 and Table 3 on page 19, two of the participants describing this type of use had sough treatment via a specialist addiction centre. This distinguished such consumption from those who never exceeded the recommended dose, and overlapped in this respect with the treatment experiences of those in the final type of OTC addiction describe next. This is considered in more detail in section 4.3.8 below on page 51 is illustrative of the level of concern that such use raised for some participants. It was also noted that these concerns reflected more the duration than the level of OTC medicine addiction.

4.3.4.3 Significantly exceeded recommended doses

The final type of OTC addiction was identified in accounts that described either a gradual or for some very sudden rise in the amount of medication participants were taking, to regular doses that were much higher than those recommended by the manufacturer. In contrast to the two other groups, participants describing this type of use tended to be those with longer periods of use, and more historic, as relatively less of this type were still abusing a medicine as compared to the first type. Several other distinct aspects of this group were references to liquid-based medicines more often – such as Phensedyl and Codeine and Gees linctus. Problems with Sudafed (pseudoephedrine) were also described in this type, as were the only references to previous use of illicit substances and alcoholism. Nurofen Plus was more often represented in this type of addiction than in the other two types.

In terms of the quantities consumed, this included consumption of around ninety bottles of Phensedyl per week for one participant, and there were four accounts of codeine and ibuprofen compound tablets (Nurofen or Cuprofen Plus) being consumed in estimated maximum daily amounts of 32, 36, 60 and 64 tablets respectively. As Theresa noted:

> *"I used to buy a box of seventy two and I think there were eight in a strip and I would take eight in one day. But then of course in increasing amounts. Till the point came that I was taking thirty two a day. Even on really bad days, I would take a second lot of thirty two."* Theresa

For some, addiction occurred quite rapidly, as in Karen cases, which also illustrated the relationship to a genuine problem and medical prescribing initially:

> *"I was in hospital, came out of hospital and was given co-codomol or something at the time for the pain. That ended and the next thing I am downing Nurofen Plus. It started off probably taking the normal doses and the next thing, at the time you couldn't buy thirty two, I am taking twenty four tablets a day. It went on for about, you know in the beginning you get high. Three or four days later that's gone and then you are addicted to codeine. It lasted a long time. It went on for about… you know I am talking about years."* Karen

For others, the change in use was more gradual, such as Malcolm's experiences, where he recalled moving from using his mother's medication, to Paramol at therapeutic doses but later much higher doses.

Only one of the participants in this type of addiction mentioned using prescription medicines at the time of their addiction but two participants who both had professional health-care backgrounds reported stealing supplies from their respective nursing and pharmacy workplaces, as well as purchasing OTC medicines. For some in this type of addiction, multiple dependencies appeared to have occurred, including the use of Paramol and Sudafed, for example, and Nurofen Plus and Benylin, and Cuprofen Plus and Night Nurse.

Several participants in this type of addiction mentioned health-related problem – several related to the use of an ibuprofen and codeine compound analgesic. For Theresa, this involved a gastric bleed, caused by the doses of ibuprofen contained in Nurofen Plus, as they recollected:

> *"I am a nurse so I know what damage I was doing and still couldn't stop and even when I got ill and had this huge gastric bleed, I still can't believe that as an intelligent woman, after that, continued to take and I just took it as gastric protection for my stomach, so I could still carry on doing so."* Theresa

Other accounts included surgery to remove a gall bladder due to the excessive use of Phensedyl Yvette reported a range of symptoms and attributed amenorrhoea to her use of ibuprofen, as well as other gastrointestinal problems and haematuria:

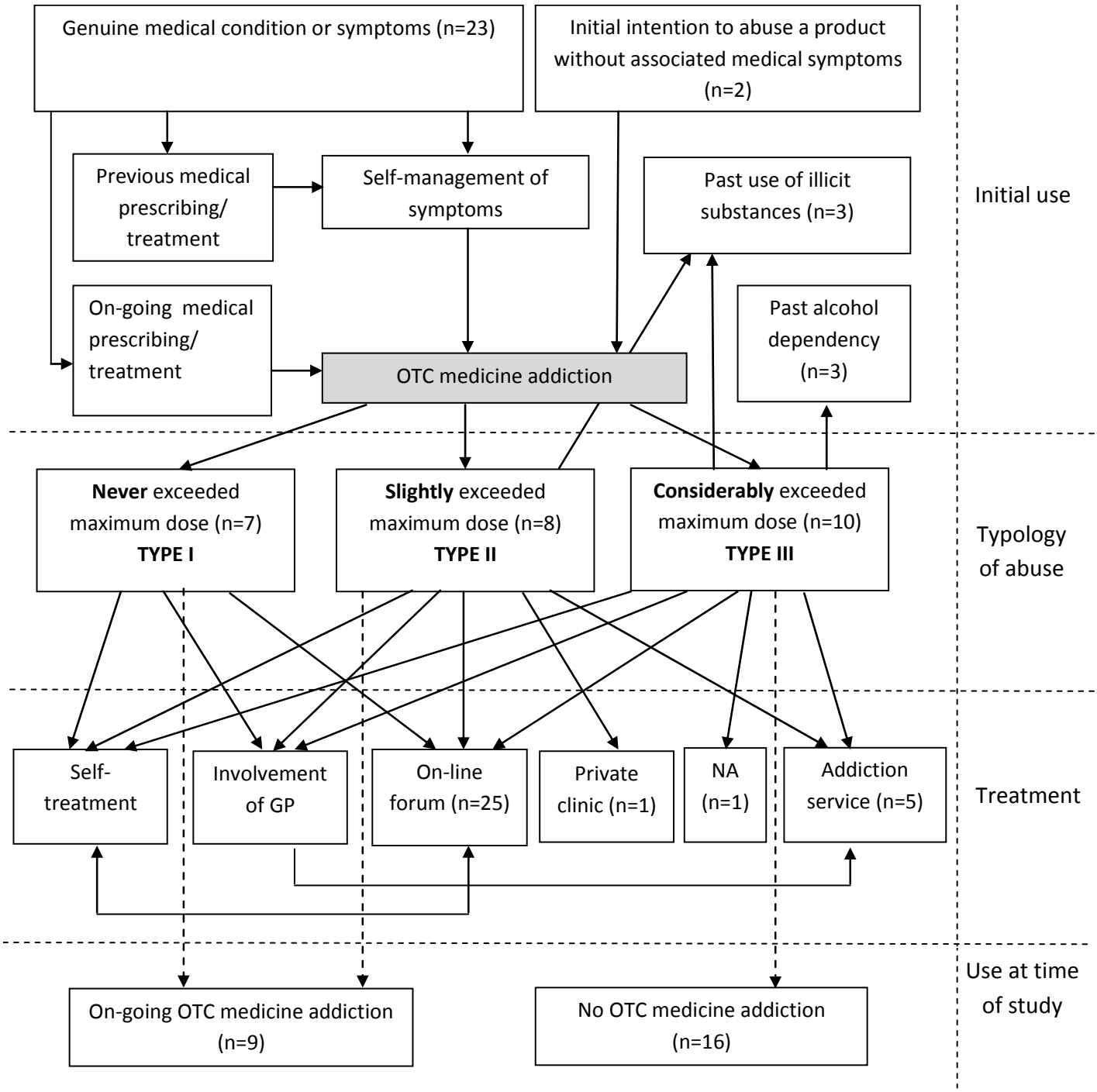
> *"My periods have stopped. I have been to the doctors to get blood tests and things like that and apparently SAIDs can cause your periods to stop so this is another reason to stop them and hopefully that will come back. I have had constipation, severe indigestion. I have had blood in my urine; lots of different things really, so yeah"* Yvette

As noted in Table 3 and Figure 2, abuse of alcohol and use of illicit substances were identified in three participants in each case respectively and, except for one participant with type II addiction, these were cases where OTC medicine addiction occurred in doses considerably higher than the maximum. For those who reported previous use of an illicit substance, this had involved LSD in one case, ecstasy in another, and cannabis in both. These had occurred historically and were not described in detail by the participants and there was no suggestion of any current use or concern that they may take such substances again.

In relation to alcohol, three participants referred to past abuse, and in all cases had been medically treated and were abstinent. As noted earlier, the accounts presented by these participants about alcohol use were considered less significant and mentioned less in interviews than others, who referred to their concerns about increased alcohol

consumption in relation to explaining their OTC abuse. In the next part of the accounts of participants who had experiences OTC medicine abuse, how they obtained their supplies are described.

Figure 2 Summary of different initial uses, typologies of addiction, treatment and current use.



4.3.5 Obtaining supplies

All participants were asked to describe how they obtained supplies of OTC medicines that they abused and the overwhelming theme that emerged was how unproblematic this was. Analysis of participant interviews suggested that this may have occurred due to seven factors, as indicated in

Table 4 below, based on participant experience:

Many participants, and especially those taking higher doses, varied where they made purchases
A number of different pharmacies were often located in close proximity to participants
Pharmacy staff often asked questions but seldom challenged participants.
Participants provided responses to pharmacy staff questions that would not lead to challenges
Occasional references were made to pharmacies that sold multiple packs.
Participants, such as those taking doses less than the maximum, did not need to visit pharmacies often.
Some evidence of ease of obtaining supplies from the internet.

Table 4 Factors facilitating pharmacy supplies

These are now considered in more detail, beginning with experiences and views about pharmacy purchases and the role of staff and pharmacists.

4.3.5.1 Pharmacies

Pharmacies, as noted, represented the most common way of obtaining supplies and few problems were described in relation to obtaining supplies, even for those consuming large quantities of medicines. Views of the pharmacy staff, and pharmacist, were often quite neutral and they appeared to be viewed as relatively ineffective, both in terms of being a source of advice or in providing a surveillance role in preventing supplies.

A key emergent theme was that considerable efforts were made to avoid detection and a sale being prevented. This involved varying where medicines were purchased, and developing particular (often fabricated) responses to possible questions from staff, so as to obtain supplies. As Yvette noted about varying her route, and also issues around shame, and deception in the following extract:

> *"But I just used to go to different pharmacies. There is one up the road where I will go in every few weeks and they will serve you […] They are okay about it, but I got very, very devious in the way that I buy them anyway. I will go to [three cities/towns in North of England] or whatever. I will circulate all the pharmacies so as not to arouse suspicion […] and the shame of the thought of going in and getting knocked back and the thought that they may think you are an addict. I had to do it. I had to go to different pharmacies and I didn't want to get knocked back. I would go in and I*

would make out that I had a toothache, so I didn't know the best thing. I wouldn't directly ask for the product, because I know that was suspicious." Yvette

Even participants who were using doses lower than the recommended maximum described conscious efforts to vary where they purchased, but this was also facilitated for most by having many different pharmacies nearby. Several mentioned using 'schedules, 'tables' or 'lists' – usually written but sometimes mental – of pharmacies they had visited over periods of time, to ensure they were not identified too often, as Michelle noted:

"I myself keep a table of all chemists I've visited with the dates I buy Veganin to ensure I don't visit the same one too often and in 36 years no-one has approached me to say they think I have a problem or refused me any product. I would be absolutely mortified if they did of course and have a 'spiel' all ready for the occasion - I'm just glad I've never had to use it!"

Linked to the above were frequent comments that there were many pharmacies within easy reach of participants, meaning it was logistically relatively easy to visit different pharmacies, as Karen notes:

"Well there are thirteen chemists within about half a mile vicinity of where I live. There are about six chemists where I work including supermarkets."

Various approaches were mentioned in terms of how participants dealt with staff in pharmacies, and particularly how they tried to persuade staff that their requests were genuine. For some, this involved rehearsing responses to questions such as whether they had used the medicine before and what the medicines was to be used for. For Theresa, there was a certain performance aspect to obtaining supplies described in the following extract along with her pattern of purchases:

"I didn't have any set routine for it and I also never hoarded it. It was part of the ritual for me to go out and have to find it every day. Also, I don't know whether it's because I am a people person or it's a personality thing, but I am very good at talking my way round things. I regularly talked them into selling me two boxes at the same time […] it's amazing if you just come across speaking intelligently and tell them you are a medical professional as well, they are easily fooled […] It's not always the same person serving behind the counter and so sometimes I would drive round to certain pharmacies to see who was serving behind the counter. Or even go during the lunch break when I knew there would be a different person on cover, because that person wasn't there."

There was also recognition that pharmacies varied in terms of their control over medicines of abuse and some described pharmacies that they avoided, or particularly chose, as they were more likely to supply them. Derek, for example, referred to a pharmacy many years ago that supplied him with several bottles of codeine-based liquid products without questioning him and Richard described the ease of obtaining supplies thus:

"[…] there were four pharmacies there and I knew that there was one that would sell you two boxes because he thought the rules were a bit stupid and he knew perfectly well that anyone wanting two boxes was simply going to wander twenty yards up the road and go into another pharmacy."

This perception of how variable supplies could be, and particularly awareness of some pharmacies who would supply more led one participant to rank pharmacies according to the ease of obtaining supplies:

"[…] I have a local chemist who are friendly, friendly with me […]. I can go to my local chemist, have a little chit chat buy me second box of twenty four for the week which I don't even know if they care they are selling me. The girl I usually talk to will say, 'They are terribly bad for you', you know and blah, blah, blah. 'I know but rough times', blah, blah. So that is my grade number one; my most reliable person. The next one is a chemist who I know to be unscrupulous […] Well it means that if I decide to go to one in [district of London] on the Monday I know that, if for whatever reason I happen to be in that vicinity by Wednesday, I can quite happily do so again […] there is kind of

third grade, which is the kind of the easiest, but kind of the riskiest. In Boots they are well trained and it's a bit mechanical, but they will say, 'You are aware of the dangers and you are not taking other medication and you can't use this and that'. Often it's a bit jobs worth. They are just saying what they have to. They have so many people coming past the till every day that they just don't recognise you." Jack

Jack's final point, about pharmacies that had staff who would routinely ask questions was a recurrent theme, and this was linked to many participant's view that many pharmacies in their experience were following a procedure and should not be blamed for not preventing supplies, as participants knew how easy it was to circumvent questions and possible restriction. As John noted about his strategy and views overall, which allow illustrated candidly how he dealt with staff questions:

"I lie. 'Do not take this for long periods of a time and no more than eight in a day' - I lie. I get that every single time and that's a consistent experience I think should be mentioned because it might appear that pharmacy comes out quite bad on this, but every single place that I go and I literally do mean this. Everyone says, 'don't do more than eight in a day. Don't do abuse'. I think that is being in terms of control of that, that's worked really, really well. The fact that I'm still a drug addict and that I'm still buying them and I lie and the way that I keep my lie workable is by not going to those again for a period." Jack

Most participants were able to recall being challenged, although this was often an isolated or indeed single case. However, such events appeared to have been memorable and negative. The consequences of such confrontations varied and for some, this simply meant not visiting that pharmacy again or certainly less often, but for others it was more pivotal. For Mark, it marked the point when he began to plan his purchases much more carefully:

"I've only ever been challenged once and it was quite a confrontational challenge and…but that was back in the days when I was taking eight a day and […] that one experience kind of altered how I did things. I started pharmacy shopping, I started varying where I went and I started to notice you know the shop workers routines […]" Mark

For Peter, a single pharmacy confrontation experience led directly to him to seeking treatment:

"I knew it would come sometime but you know to actually face it, that she had actually confronted me with it and that was really a wakeup call for me. It was then that I came home and she said, look we can't give you these quantities."

For almost all the participants, such challenges were memorable but not viewed as being inappropriate and indeed several questioned why pharmacies had not done *more* to prevent supplies. An isolated and contrasting view was provided by one participant who felt that any questioning by pharmacy staff and pharmacists was unwarranted and asking about a customer's medical history was inappropriate in a pharmacy setting:

"Of course they have turned it into some sort of public interrogation and I tried all sorts of… actually I have just lied about it. Just said, 'nay, nay, nay'. 'Have you taken them before?', 'Yes', but if one got stroppy. I mean I remember one particular incident in a chemist in [town], when this woman said: 'Well I am only doing my job'. That is a complete cop out and actually I thought to myself well actually you are not. You are like a trained parrot; you are not exercising any discretion." Richard

No participant mentioned considering asking a pharmacists or pharmacy member of staff for more specific help to treat their abuse of an OTC medicine. However, occasional comments were made about what pharmacists could do,

not in controlling supplies in the predominant way experienced by all participants but in terms of providing treatment and signposting. As Michelle noted in her written response:

> *"At the end of the day I suppose they are only selling a product but they could be the first point of contact in the chain - i.e. noticing if someone is asking for a product regularly or going through large amounts of a product and they could be the initial source for providing information on addiction and where to go for help and support."*

4.3.5.2 Internet

Although purchases through pharmacies were the paradigm route for obtaining supplies, two participants described purchases they had made via on-line internet suppliers. In one case, this was to support the abuse of a high daily amount of an OTC medicine, whilst in the other, use only slightly above the recommended. In both cases, they were able to obtain multiple packs of OTC medicines – Cuprofen Plus and Veganin respectively – and do so repeatedly, although they reported considerable variation in what different on-line suppliers would provide. Yvette noted that the more recognised 'high street' pharmacies who had on-line services would limit supplies but other 'smaller' companies would supply more. Both participants made reference to how such suppliers attempted to regulate supplies, including the use of surveys as Michelle mentioned in her summary of on-line purchases:

> *"Makes it much easier to obtain although there are more restrictions in place now I've noticed - I used to be able to buy 4 packets of Veganin but now can only generally obtain one although last week managed to buy two from one website. I also now have to complete a questionnaire each time I do to say why I'm taking them and what age I am etc. - I don't know what happens to this information or if anyone actually takes heed of it or not though?"*

For Yvette, there were obvious parallels to making purchases from physical pharmacies, such as using deception and varying where purchases were made:

> *"But I make sure I only order it once a month and I circulate the internet pharmacies as well, the same way as I go outside [...] A lot of the time I will order two packs and they will send me two packs. just lie [...] They ask you for your name and your address. Sometimes you can put in a different name or you can put in different email addresses so that you can set up different accounts, but it will ask you who is it for? Have you used this product before? What are your symptoms? But you just lie."*

For most other participants, when asked about whether they had used or considered using the internet to obtain medicines, their responses were negative and almost always related to concerns about the safety and legitimacy of on-line medicines.

This section has described the experiences and views of participants in relation to how they obtained supplies and of the overwhelming view that this is relatively unproblematic, both in pharmacies and on-line. The next section moves on to a consideration of how participants recognized they had a problem with OTC medicine abuse, and the following section describes treatment.

4.3.6 Recognising and defining addiction

This section links the previously described experiences relating to how an OTC addiction occurred, to that relating to the types of treatment and support sought that will follow. It explores participant's accounts of when they recognised they had a problem and was specifically asked in interviews. It also explores participants' views on how they described themselves and their situation. Analysis of interviews revealed that concerns about the duration of use, withdrawal symptoms, critical incidents and a loss of control were important for recognizing a problem, and that the terms 'addiction' or 'addicted' were most often used to describe themselves and their situation. These are now considered in turn.

4.3.6.1 Recognizing addiction

Withdrawal symptoms were mentioned by several participants, both in terms of when it occurred due to gaps in OTC medicine use, and, as will be described later, in terms of treatment and particularly self-treatment. The role of the two internet support forums was also linked to awareness of a problem and it appeared that these provided a confirmation that the participant had a problem.

Ailsa extract below illustrates a typical description of how a cluster of symptoms were eventually recognised that participants came to associate with OTC medicine consumption, and particularly when a dose was omitted or due, and the extract also illustrates the confirmatory effect of the internet which involved her visiting the Codeine Free web site:

> *"I was getting withdrawal symptoms between the doses. I was getting a headache because I was obviously taking tablets so I was taking the tablets that were causing the headache […] I was sort of taking them for four hours and then it was less and in the morning I woke up with a terribly screwed up stomach and I wasn't sleeping and that's when you know things just sort of start slotting into place and then I had a look on the net about it all and I thought crikey, I'm dependent on this stuff."*

Dwain illustrated the joint issues of withdrawal and also concerns about the duration of use, reflecting similar concerns amongst others about how long the OTC medicine had been used for:

> *"Yeah I was taking them for two years straight and by the end of it they weren't even dealing with my pain issues. I was taking them out of habit more than anything else and because if I stopped taking them the withdrawal would kick in. I would start getting aches and pains and I would think, oh dear, I have got a pain; I had better take my tablets again."*

For others, a critical incident appeared to have led to awareness and insights into a problem, as when Peter recalled being challenged in a pharmacy, and a counter assistant refusing a sale based on concerns about his purchases. Theresa reflected on how a gastric bleed and subsequent medication to protect her stomach had not stopped her OTC addiction *but* that a combination of other factors, culminating in a criminal conviction were important. A recurrent theme amongst several participants involved their perceived loss of control over their medicine consumption. This

occurred both gradually and suddenly for different participants, but all reflected on the need to have control as an important aspect of their lives, and that their OTC medicine use was no longer under control. As Rachel noted, who was interviewed at the point when she had very recently recognized her addiction and had made an appointment with her GP:

> *"The thing is that I am a control freak as well. So I don't like being out of control and that's where I am now, which is why I need to deal with it. Because I don't, you know I just don't like being out of control and that's why I need to see the doctor and I also process things out loud."* Rachel

Yvette echoed this concern about loss of control when she reflected on her experiences, which like Theresa's, were not triggered by problems such as indigestion, which were self-treated:

> *"I was taking Ranitidine for the indigestion and not eating, just eating cereal so I would do anything in order that I could still take the tablets and just be in denial about it and think maybe it is something else as an underlying disorder. Not really accepting, or wanting to accept that it is the tablets that is causing the problem […] When I realised it was out of control."*

Several participants made reference to their disbelief that addiction could have happened to them, and often drew upon professional intelligence status claims to argue that they should have had the understanding or insight to prevent this happening. As Karen noted:

> *"I do think we are all stupid quite honestly. I think I am stupid. I can't believe that I have done this to myself. You know I find it really hard to understand."* Karen

The influence of the two internet support groups in substantiating participant's experiences and confirming addiction meant that at the time of being interviewed for this study, they were obviously reflecting on their experiences, as viewed through this additional perspective. So, for example, references to 'rebound headaches' and indeed the use of the word 'addiction' appeared to have been acquired through interaction with the internet groups. This latter adoption of a specific term is now considered in terms of participant's definition of themselves and their situation.

4.3.6.2 Definitions

As in interviews with other stakeholders and participants in this study overall, those involving individuals with direct experience sought to explore their understanding of the problem. This has been explored in the context of actual experiences in the sections so far, but an emergent theme and one explored specifically concerned how individuals viewed and described themselves and their situation. Of particular note was that participants often referred to themselves as '*addicts*' or as being '*addicted*' to an OTC medicine and this was linked to repeated attempts to distinguish themselves from other types of addicts. As Ailsa reflected in detail:

> *"Addicted is the one that I think I would use. Yes I would say addicted. I don't abuse it, that to me I don't like the word so much, it's more of a I don't like it sort of is more of a self harm, intravenous that sort of thing you know child abuse and the word abuse I wouldn't want to be described as an abuser but I always feel abusing is you are doing it to somebody else as well whereas if you are addicted that's you and I think addicted yes, I would say I was addicted."*

A clear trend was identified in distinguishing OTC medicine addiction and participant's view of themselves, from those associated with illicit substance misuse, that was characterized visually and behaviourally as being anti-social and negative. This stereotypical 'addict' is illustrated in the following extracts, which show the contrasts being made:

> *"Addicts are people on the street who haven't got a job & I am sat here in a suit in an office, my own office with a very good career, senior manager within a very large organisation and I can't be an addict. I am."* John

> *"I'm a Company Director and all that sort of thing so you would think living in Central London blah de blah you wouldn't think oh she's a drug addict, my god […] they wouldn't say looking at me I was a drug addict, no way"* Ailsa

> *"[…] you think of addicts and you think of drink, drugs, heroin, cocaine, you know needles and all those sorts of things. I can cope with that rationally so for me, I don't think the next step is heroin or I am going to be injecting needles […] well if I was to go in [to a pharmacy] and look like their stereotypical addict, they may go, 'Oh well, you know' and call the pharmacist over. But I don't. I look like your normal middle aged woman. Quite rational and they go, 'Ok that's fine, she knows what she is doing'.* Rachel

Evident in the above extracts are the centrality of appearance and status and therefore, a perception of what others thought of them. Whilst for some this was based on opinion and a stereotypical image, for some participants, this occurred through direct experience and comparison, following their use of specialist drug and alcohol treatment centres (see section 4.3.8.2 below). Participants describe seeing different types of clients and considered themselves very different. As Theresa recalled:

> *"[…] you could see the other people who come there have got serious drug and alcohol problems and I stick out like a sore thumb. It's painfully obvious people look at me and think, 'What on earth is somebody like her doing in a place like this?' Because I don't have a can of Heineken in my hand or tram marks up my arm or stand outside smoking or anything like that and you know I don't wear a suit every day but I am clean and tidy."*

However, what was apparent alongside these visually-, status- and treatment-based ways that were used to distinguish themselves from other addicts, there was frequent recognition that OTC medicines of potential addiction were little different to addictions to tobacco or alcohol or indeed all opiates (including heroin). This reflected a certain tension between accepting their self-professed status or identity, accepting this may be similar to any addiction, but seeking to contrast themselves with a stereotypical addict. Rachel illustrated the connections made by many participants to the range of substances that could lead to addiction, and located codeine nearer other legally available products – a view that was gained from her specialist treatment service experiences too:

> *"To me I definitely have an addiction but then again I recognise that you know cigarettes and alcohol is also an addiction. And although it is not crack or heroin which people seem to know what to do with. I almost feel like a fraud because it wasn't something harder than that and actually it is something that other people would consider quite a mild drug, yet it still had that effect on me."*

Illustrating the similarities between codeine and other opiates, was Yvette's admission of what she felt she was:

> *"Yeah I am an addict, no doubt about it. As much as a heroin addict, yeah. Shameful and it makes you feel dirty and guilty, but I was an addict, yeah. Well I have stopped taking codeine before and for the past few days I have had cold sweats and had palpitations and had withdrawal symptoms.*

So the physical symptoms suggest that I am addicted to it and also the psychological. My life revolved around codeine. I could not function without codeine and just because you can buy it legally in the chemists, does not mean that it is any different from heroin. That's just a social concept isn't it, you know, no difference"

As the above extract illustrates, the degree of reflection amongst many participants was considerable in relation to their situations, and as well as these overt attempts to locate themselves as being addicted but different to some other addicts, participants had developed their own internal definitions, based on their experience. For several, this involved dependence, but there appeared to be recognition of both physical and psychological dependence, as Bob and Rachel note:

"Addiction for me is to do with what is happening inside my head. My attitude towards the substance; can I leave the house knowing I have got none. If I can't, then I know I am addicted to it. You talk about fags, you talk about codeine, you talk about Nurofen Plus. Moving about from place to place because I have lived a fairly transitory existence, when I was on the Benylin, did I take that with me? You know whether I would actually be able to exist for twenty four hours without the substance is my definition of addiction."

"But my understanding of an addict is somebody who cannot get through the day without what it is they are addicted to. Yes. I can't get through the day without taking codeine. So that's my personal definition and that's where I'm at now. So yes I am addicted to it."

In this section, then, how participants recognised and also defined their addiction was described, illustrating a range of issues but a key concern that their addiction was in some respects similar to, but in others (by virtue of status, appearance), very different from other types of addiction. In the next section, the influence of addiction on other aspect of participant's lives are explored, before going on to consider treatment and support.

4.3.7 Influence of OTC addiction

Throughout the interview accounts, participants made to how their OTC medicine addiction had impacted upon other aspects of their lives. One of the most significant for participants was health-related problems and these have been explored in the section of typology of abuse (see section 4.3.4 above). In addition, other themes included work, family and relationships, cost and illegality, and in all these OTC addiction was almost always viewed negatively.

4.3.7.1 Work

Work appeared to be a key aspect of participant's lives that they had considered OTC medicine addiction to have had an influence upon. Three types of work-related experience were identified: negative influences on work and performance, concerns about being identified by work colleagues as having a problem, and for a minority of participants, a perceived ability to cope with work.

Negative influences appeared to be centred on task performance or general mood at work, as the following two extracts illustrate from Bob, who held a senior organization role, and Yvette, who undertook bar work, illustrate. For Bob, his role meant that he could disguise his addiction, but for Yvette, this led to her being dismissed from her job:

> *"Definitely, I would take longer to make decisions. I doubted the quality of my decisions too in hindsight. It would take me longer to do the necessary paperwork perhaps. Yeah in general terms I think it slowed my thinking, without a shadow of a doubt. I was not as sharp."* Bob

> *"But I did have mood swings from them. I used to get angry or depressed or tearful, so my emotions were affected in work and it has affected m […] I was just miserable and like a zombie. I had bags under my eyes, bad skin, shaking so at the end they had to sack me and people would make complaints. They didn't know I was on drugs, but there was something wrong with me."*

Being identified at work appeared to be a concern for some, and this again linked into the theme of secrecy throughout this study. Several participants noted attempts to conceal either the physical taking of doses of an OTC medicine at work, or being concerned about their appearance and behaviour. As Richard and Peter noted:

> *"I got very adept at being able to take Solpadine in the middle of a meeting without anyone noticing me doing it. Or maybe they did and were just too polite to tell me."* Richard

> *"sometimes at work I would be reaching for the Solpadine and I would wait until everybody was out the tea room, rather than be caught taking it. That happened quite a lot actually, so again to make sure I wasn't being noticed by my work colleagues, I would scoot to the tea room where there was nobody there. But on the whole I managed to keep working, but I felt absolutely horrendous."* Peter

For John, it was a combination of both consumption and his appearance that concerned him in his work setting, which involved working in a senior position in a large organization, and also a sense of shame, which other participants also mentioned across the interviews:

> *"[…] the effect it actually physically on me now. Which isn't particularly very enjoyable at work […] You are constantly looking for a bottle of water and even if you are travelling for work purposes your ….. you've got a bottle of water. So there are interruptions and that kind of process and the kind of thing if you are with new people you hide it […] From another point of view is sometimes you get puffy eyes and all that kind of stuff, so my visual appearance changes because of it. And the other one and I think is the big thing for me is I crash. I get physically tired easier […] So I do feel a sense of shame and substantial guilt for doing it with new people and that's the reason why I do try and hide it."*

As noted, two participants made reference to the OTC medicine enabling them to function in a work context. For Yvette, she noted: '*needed them to function, so it made me be able to work'* but as noted above, this positive aspect was offset by more negative aspects of OTC addiction relating to her mood and behaviour. For Jack, this was because the medicine stopped anxiety symptoms developing, which were detrimental to his work:

> *"Basically they made you feel better and then when I was going in to work I used to get terrible attacks at work. Nobody would know about it, so I found that taking some of these would help me with that, you know."*

As well as work-related issues, participant also described the influence of others, and this is considered next.

4.3.7.2 Family and relationships

Many references were made to family and relationships more generally when participants reflected on their experiences, although such factors were not identified in all interviews. Issues that emerged related to tension between trying to keep OTC addiction a private and secret aspect of participant's lives, and the possible benefits and support to be gained by involving others. However, this did not always suggest that making others aware of OTC addiction was always positive and several accounts indicated resultant problems. These accounts were usually framed in relation to what relationships meant *for* participants: would they be discovered? Why did others not suspect? How did they help? In contrast, relatively few accounts explored directly the influence of OTC addiction *on* family and friends.

Several participants referred to keeping their addiction secret or *'hidden'* as Karen notes:

> "[…] I didn't want anyone to know. You know I don't live with my other half, but he is here often and he never knew. He never, ever knew. Why would you want people to know that you have an addiction to a drug? […] I would never have wanted anyone to know. I mean I want everyone to know now that I have come clean, but at the time I didn't want anyone to know. I felt such an idiot."

The above extract illustrates a concern theme that most participants did not elaborate on how they kept their addiction discrete. An exception was Elizabeth, who hinted at using her medical condition to explain her mood and behaviour, when she actually attributed this to her medicine:

> *"I mean they knew I was on painkillers, but they knew I was in pain, so to them it didn't link. They would just go with it. If I seemed a bit out of it, if someone said, you are not quite with it, I could quite easily turn round and say, I am not well, what do you expect"* Elizabeth

What this quote and others illustrated was a concern amongst participants that what they expected others to recognise and suspect would be a change in their mood, emotions or actions. What was seldom referred to was a concern about being caught taking a medicine too often, or having excessive medicine supplies found and questioned. Occasional references were made to disposing of supplies and these all occurred for those using significantly higher than recommended doses, where understandably quantities and hence used packaging were more voluminous. Illustrating the more dominant theme about how others might have suspected participants, Theresa contrasts her experiences in a relationship with those with her parents:

> *"I couldn't believe how easy it was to hide it from my partner. That's down to individual partners isn't it? I am sure if I had been home with my parents, there is no way they would have not noticed. You know, sometimes I would be sick a lot. I would be slurry, I would need to sleep an awful not, have mood swings […] Whereas when I admitted it to my family, they all said, oh everything makes sense now.."*

The above extract suggests positivity in involving family and this was echoed in other accounts such as the support of a husband for Serena – *'he was with me all the way'* – and family and siblings in some cases. Friends also appeared to have been supportive in some cases, as Karen's noted about benefiting from:

> *"[…] the help of my sister and the help of my friends. A girlfriend of mine went through something horrendous at the same time. The two of us spent two weeks kind of slobbing on the sofa and*

watching lots of movies so the two of us together we were going through a similar thing. That was quite helpful at the time."

The above example was also one of very few instances where a participant referred to someone not in the on-line groups who also had an OTC addiction problem. In this case, further information was not provided but it was clear that mutual support was found and was beneficial. In one other example, a participant's wife had been addicted to the same medicine, a co-codamol product, and had been successfully treated.

For others, however, the situation regarding family and friends was more mixed or negative. Some participants had either never disclosed their addiction to others, or had experienced negative reactions. Jack illustrates the former, and Michelle the latter:

"To be honest, I can't discuss it with my family. They simply wouldn't understand. It would be a horror for them. And they don't deal with things like that very well, at all." Jack

"2 members of my family know about my addiction as does my 22 year old daughter - 1 doesn't mention it and the other is very supportive - it doesn't bother my daughter unduly as having lived with me she knows it doesn't affect me negatively or have any adverse effects". Michelle [written response]

4.3.7.3 Cost

A number of references were made to the costs associated with OTC medicine addiction, although this did not appear to be a significant issue for many. Based on the other themes identified in the study – such as participant's often professional job status, and the relatively small quantities involved for some participants – this may not be unexpected. However, as some participants noted, costs were recognised, and this was often in relation to the relative price increases that occurred when pack sizes were reduced. For John, this affected his ability to purchases one hundred packs of soluble co-codamol:

"They would tend to offer the hundreds. Because they said it's more cost effective. You could actually buy a hundred for six quid. Whereas the thirty two is three quid […]"

Like John, several participants recalled being offered similar medicines by pharmacy staff that were better value for money. These were often own brand or generic versions, but in such cases, participants' desire to continue with the same product – as noted earlier – meant that this was not an incentive, as Richard noted:

"Only Solpadine hits the spot although the Boots is generic, it is a quid cheaper and has exactly the same ingredients, but it was always Solpadine."

Two participants did refer to using cheaper generic versions of OTC medicines than the branded ones, as Serena noted:

"[…] it was a big red box that I used to buy and then I got to thinking well that's expensive I'll go on to the Boots own brand because they do their own pharmacy paracetamol and codeine based things which was cheaper[…]" Serena

One participant reflected that her OTC purchases seemed illogical based upon cost, since she obtained her prescriptions from her doctor free of charge yet willingly paid to *'top up'* on Solpadeine due to their perceived benefits.

For those who were consuming much greater quantities in the third type of addiction, these purchases obviously led to greater expense. Two participants in this type of addiction stole medicines, which may have obviated the cost in at least one case, but others, like Malcolm's use of Paramol and Sudafed, were a concern, which he noted led in part to his presentation at a drug treatment centre:

> "*I went to the drug service. I can only say I did go myself, you know, I did go, cos I mean I think at that point there is financially….you know, it costs quite a lot of money You know, if you are buying Paramol, you know, because instead of paying rent, you know, using credit cards and things like that to keep yourself going and it was just all going downhill, you know, cos I don't have much, maybe 50 or 60 quid a week or something."*

Other participants in this third type of addiction did make references to selling possessions at times to fund their supply of OTC medicines but overall, issues of cost associated with OTC addiction were not considered problematic.

4.3.7.4 Illegality

Although a key feature of this study has been the perception amongst participants with direct experience that OTC medicines that they were 'respectable', occasional mention was made of illegal activity associated with OTC medicine abuse. This occurred for three participants, all of whom had used OTC medicines at doses far higher than recommended. One participant had described petty theft many years ago to support supplies, but was more ashamed of subsequently deceiving his doctor's surgery to obtain further supplies of his wife's opiate medication. The two other participants were both health care professionals and this gave them access to codeine-based products, which in both cases they stole, as Rachel candidly explains:

> *"So I found ways to get it over the counter and to get medication from my place of work. Never in large amounts to be discovered, but where there's a will there's a way. You will always find it. Because no one knew, I couldn't believe that no one could guess […] and I don't know if it was because I felt safe, but I kind of threw caution to the wind. I put myself into such a position I made sure I got caught and I ended up getting arrested for theft and I have a Police caution on my record now and will probably never nurse again."* Rachel

For Bryan, a pharmacist, obtaining supplies were unproblematic but involved obvious deception and theft, which was facilitated by being a locum who travelled to many different pharmacies:

> *"Because when I went in other pharmacies the first thing I looked for was where the DF118's were, or codeine, or codeine linctus. That's just devious and then when you are in on your own you have got a free reign. It's just what the codeine makes you do"*

As in Rachel's case, such theft had eventually been detected, although for Bryan, this had occurred through progressing to the forging of private prescriptions.

Another, unrelated example was offered by Yvette, who recalled failing her driving test due to being under the influence of alcohol and OTC medicines. This was not viewed strictly as illegality but more as a symptom of the degree to which two types of addiction had affected many parts of a participant's life:

> *"I failed my driving test unfortunately and I was under the influence [of alcohol] at that time, which I shouldn't have been. It was quite bad. Of codeine as well, that's the point I mean by addiction is that you do things that you wouldn't normally do."*

This section has identified a range of additional aspects of participants' lives that have been an influence on, or affected by OTC medicine addiction and this concludes the description of experiences up to the point where help is sought. This is now explored.

4.3.8 Treatment and support – experiences and views

All participants described how they had tried to deal with their OTC medicine addiction and it was evident that there were a variety of different options, which could be divided into either treatment or more general support. As Figure 2 indicates treatment ranged from GP consultations, the involvement of specialist addiction services (DAAT), a private clinic, counselling, and attempts by participants to resolve the problem themselves. Narcotics anonymous was used by one participant and the two on-line web sites provided both treatment advice and a support function. There was variation in the perceived benefit of the different treatment and support opportunities and with the exception of two internet groups, there was a perception that treatment was not set-up for OTC medicine addiction. In particular, GP involvement appeared to have varied considerably, and attempts at self-treatment before other forms of support had been sought were often ineffective. Specialist addiction clinics and narcotics anonymous were overwhelmingly viewed as not being set-up to support OTC medicine addiction. Also cutting across this theme of treatment and support were frequent concerns about the need for secrecy and anonymity in relation to their situation, as evidenced by concerns about addiction not being recorded in medical notes, the use of pseudonyms on internet support forums, and mixed experiences about involving others. For Theresa, this was hidden due to a lack of options and support:

> *"It is a hidden addiction because you don't know where to go for it. Even now that I am having treatment, people didn't know what to do with me."*

These various types of treatment and support are now considered in turn in more detail.

4.3.8.1 GPs

GP involvement in OTC addiction was mentioned by many participants but, as noted, led to both positive and negative comments. A further group of participants had not sought GP advice, due either to a poor relationship with their doctor or to concerns about their addiction being recorded.

Of the participants who had involved their doctor, some described their GP's attempts to treat the problem, with prescribing of codeine being mentioned for a minority but without success. Malcolm recalled an early attempt by his GP to treat his addiction, which was not successful, with the GP not appreciating the nature of addiction:

> "*I think if I go back a wee bit, my GP, he tried to detox me with the dihydrocodeine, that was probably, I don't know, might have been 1996, or something like that. But that didna work that didna work at all, so maybe that was like the first one. I mean once I got the prescription and relationship advice, I had the big bottle of tablets and I tried to do it, but I couldna you know and I just ended up taking the tablets over a week, you know, that was failure you know."*

There was a perception amongst many participants, and evidenced by the experiences they described, of doctors perceiving OTC medicine addiction to be less serious than some other addictions and being something that either the patient should not worry about, or could manage themselves. This was illustrated in the response of Peter's doctor earlier in section 4.3.4.1 on page 33 and as Dwain and Richard also recalled:

> *[…] I have mentioned it to the doctor and he sort of said, 'well it's something you handle yourself'. At this sort of level, if you know what I mean?"*Dwain

> *"[…] my own private GP […] he just laughed and said, 'don't be so stupid, stop taking them'. On the other hand, what is he supposed to say? What can a GP do?"* Richard

Others described their GP offering a referral to a specialist clinic, and in some cases this appeared to reflect a positive step on the part of the GP and in one case, the participant recalled their GP saying they had known other cases of codeine dependency and had made similar referrals. Another participant was similarly positive about their GP's response, and it transpired that the GP worked in addiction services. Bryan summarised such views as being related to a lack of understanding amongst GPs in general, based on his experience, but this was attributed to the unique and relatively unknown nature of OTC addiction:

> *"The average GP doesn't know. If you are ill you go to the doctor and you expect him to treat you. But I am afraid that with addiction it is not so bad because they do have a bit of a better clue, but with opiate addiction they just farm it off to the drug units and they are better at it, but even they don't have the where withal, because I reckon that the codeine addict is a special case […] my GP has stuck by me and he's done his best with the limited knowledge he has."*

For others, however, a negative relationship with their GP was evident and this appeared to influence their desire to either not seek their help at all, or to view it negatively. In such accounts, this relationship appeared to be an on-going concern and the participants' OTC addiction did not appear to be the trigger to the problematic relationship.

A final group of participants had actively not involved their doctor, either because of previous negative experiences or due to a desire not to have their OTC medicine addiction formally recognized:

> *"I did contemplate going to see my GP, but my concern there was again having it on my medical records. I know no-one can get at your medical records without my written permission, but to me it had to be hidden and I mean now it's on all of my medical records and I am getting treatment and everything is going really well."* Theresa

4.3.8.2 Specialist addiction services

The use of a specialist drug treatment service was mentioned by seven of the participant, with most of these being those in the third type of addiction, involving considerably excessive doses of medicine. Participants who never exceeded the maximum dose did not describe having sought treatment from such services. Routes into the use of specialist addiction appeared to be either active or passive on the part of the individual and involved three categories: referral by a GP, self-referral, and orders from criminal justice system drug or alcohol treatment interventions/programmes. GP referral was the most commonly identified and this process appeared to be accepted by participants in most cases, although two participants felt that such referrals reflected a lack of concern or understanding of the patient. Self-referrals were also identified, wherein participants had searched for services locally and made contact directly. Crime-related pathways included one participant's alcohol-related treatment order due to a drunk-driving conviction, where their OTC addiction was then identified. Experiences and views about such services were, like GP involvement, mixed. The overwhelming experience for all participants was that such services were not set-up to accommodate those with OTC addiction. Three reasons appeared to be:

- The mixing of clients with different addictions.
- A perception that specialist service staff viewed OTC addiction as a lesser problem and even self-manageable
- A lack of experience in dealing with OTC addiction clients

However, balanced against this was the finding that those who did engage with such services reported eventual satisfaction with their treatment, even if these were initially considered inappropriate and suited only for illicit substance misusers.

Section 4.3.6.2 above has already described the experiences of participants and the view that they considered themselves to be very different form a typical client of such services. In relation to the second reason, this is illustrated in Florence's negative experience:

> *"it was quite frustrating because at one point when I walked into the Drug and Alcohol Service and said you know basically 'I have got a problem with being addicted to co-codomol'. They thought I was being a bit stupid. I think they thought that you know that I should just withdraw slowly […] Actually, I was trying to tell them that it was more than that because I was clock watching and at some point I was taking more than two four times a day" Florence*

Illustrating the third reason around services not having had experience dealing with OTC addiction, are Michelle's and Theresa's accounts:

> *"I went to Drugs Action to try to get help from a professional there but they had no experience of OTC addiction - only addiction to hard drugs and didn't think they could help […] I had a couple of sessions at the Clinic but again encountered the same problem - no experience of OTC misuse - only hard drugs. I was given the same options as if I was on hard drugs and they weren't really appropriate (some of the withdrawal medicine had higher amounts of codeine than I was already taking)"* Michelle [written interview]

> *"They just don't know what to do with me because it is unusual and apparently I am the first one who has come through the door with a codeine addiction, or has a problem with over the counter medication […] there is lots of help for people who are really, really, really at the bottom. You know homeless, alcoholic, drug addicts. But if you are not quite down there yet, they don't seem to know what to do before you have got down there."* Theresa

Despite these concerns about the services, however, most participants reported being offered treatment which was successful, including Theresa above, which resulted in either a maintenance dose, or being opiate-free. The two treatments involved either methadone or buprenorphine and there was a perception that such treatments were effective overall, as the following three quotes illustrate:

> *"[…] the methadone did work. You know, from that point, that was in 2006, early 2006 until the present day. You know I've been OK […] I think that it was 45[ml], then it went down and I've tried to get right off it., but there was friction, there's no excuse, in my relationship and stuff like that. But I have sort of been back up one or two years ago and it's just basically, it will help a wee bit. Now on 40[ml] a day"* Malcolm

, > *"[…] at the moment I am on a programme of subutex - buprenorphine. I take one every other day and it takes away all cravings and withdrawings and ever since I have been on it I haven't wanted to take anything at all"* Theresa

> *"[…] they put me on quite a big dose […] And the course of treatment lasted nearly ten months. Which was excessive, but I was happy to take advantage of it at the time. It was all good and I get this free sort of drug thing, but also it has a vaguely similar effect as what I was on in the first place and it's free […] So why not? It's a funny one. It's funny stuff. It does make you feel ok, you don't get the err, you just don't really get any of the euphoria or the drowsiness or anything you know. So yeah, it was successful."* Jack

For another participant, Bryan, there was an initial concern that methadone had negative associations (as per section 4.3.6.2) although these were eventually overcome and this treatment being viewed as appropriate:

> *"I was turning up to [city in Yorkshire] drug unit for my daily dose of methadone as though I was a heroin addict. Thinking, 'What the hell am I doing here?' This is something that any treatment has got to overcome […] At that stage, I didn't think that methadone was appropriate."*

The issue of having doses supervised was raised by one participant although they were more concerned about the point when they were given weekly supplies and expected to self-medicate daily.

One additional negative experience involved a concern about the problem being added to a participant's medical notes, echoing concerns some raised about GP referral. Yvette described her experience:

> *"I did go to a place about eighteen months ago […] and they deal predominantly with heroin and methadone withdrawal. I went to see them and said 'I'd had enough and I wanted to come off it'. He said, 'Well we can look at methadone, Subutex – buprenorphine - but we can't do it anonymously'. I said, 'Well I can't do it then I am sorry'. I have managed to do it by myself, but there is just nowhere you can go if you want to be anonymous."*

Overall, therefore, specialist treatment services appeared to have been positively viewed in terms of treatment outcomes for some, but viewed negatively for others as not being experienced in, or set-up to accommodate, OTC

addiction. Yvette's comment above, however, about how she dealt with the problem after rejecting a specialist service, leads into the next section, on self-treatment.

4.3.8.3 Self-treatment

Throughout the various accounts, mention was often made of participants attempting deal with a problem themselves, without the assistance, support or guidance of anyone else. This often happened around the time when an OTC addiction was first realized, but occasionally mention was made of rejecting other forms of support, and self-managing. For those who had tried to self-manage initially, this did not include references to the internet support forums, but for those who were trying to self-manage later in their addiction, reference was made to specific terms, such as 'cold turkey' which appeared to have originated in advice they had received from the internet groups. The main approach attempted initially was a stop the OTC medicine completely and this often led to problematic effects, and reports of withdrawal symptoms. For some this was successful, such as Bob's experience:

> *"I went cold turkey as they say. I was on my own in our place over here […] and I decided that I'd had enough of basically the rounds of going to the doctors and getting the stuff, having problems may be getting the stuff and then going to different chemists."*

Others, such as Elizabeth who had never exceeded the maximum dose of an OTC medicine, also reported success by simply stopping their medicines, although she found this difficult and did need the eventual support of one of the internet groups:

> *"I had decided that I was going to stop taking these things and rather than doing anything sensible like look into that; I just stopped taking them. And after six days of feeling like hell, I thought maybe there is something I can do about this, so I Googled codeine addiction or something like that, found the forum and never looked back really."*

Others describing trying to reduce the dose of medicine themselves, again without external support and this appeared to be a difficult experience too. Karen, for example, recalled doing so when she:

> *"Came back from [holiday] and started to taper them and then I don't know […] I was at my sisters and I just burst into tears and said I feel so shit and this is what I have been doing, but I did taper then. Totally on my own, I thought, this is ridiculous, I have got to start taking less of these things."*
> Karen

One participant undertook counseling training to gain insights into her own addiction, which was linked to a desire not to involve the health care system and have a problem recorded.

4.3.8.4 Narcotics anonymous

Two participants referred to attending narcotics anonymous and several others had been recommended narcotics anonymous but several other responses were identified in interviews relating to, often forthright, views about such groups. One participant who attended sessions referred to it as helping him when he needed a 'bit more support' but

the overall impression, however, was negative. This appeared so for similar reasons to the negative views about specialist treatment services – that they were, or were perceived to be, attended by individuals who very different to those with OTC addiction, and were, or were perceived to be, not set-up to support OTC addiction. In addition, two unique issues were apparent for such support: several participants considered such group therapies to be inappropriate for their needs, and several commented on the overt religious origins of the programme offered there. Two individuals had experienced alcoholics anonymous and had developed opinions based on this too. Bryan expressed his negative feeling based his attendance at both as follows:

> *"And I turned to Narcotics Anonymous which is a complete waste of time. As all the twelve step programmes are. I don't know if you are aware, it is a cult religion […]"*

Yvette had experienced alcoholics anonymous but not narcotics anonymous, and summarized her concerns and perceptions about the group as being linked to similar concerns about the underlying philosophy of the groups and to a perception of who attended:

> *"If you go to Narcotics Anonymous there are people who are severe heroin addicts and they have been in jail and things like that and people don't want to be around that, rightly or wrongly. I think that is a deterrent with NA. So there isn't anything specifically just for codeine […] Also, with AA and NA, it's about higher power. You accept a higher power, whether you believe that to be God or whatever and things like that. That is a bit intense for some people. You know I am a scientist and I couldn't do the higher power stuff you know, which is where I struggled with AA and anything like that."* Yvette

Jack expressed his concerns about not wanting to discuss his personal problems beyond a small group, illustrating the on-going theme about the relatively secretive nature of this addiction and associated treatment when he described being advised to attend the group:

> *"Maybe I should have given it a go, but at the time I thought I had enough support from other people. Obviously not from [my doctor] but I felt that I had enough support from enough people that I didn't need to air my dirty laundry in public."* Jack

4.3.8.5 Overcount and Codeine Free

The final source of help identified by participants appeared to offer both a support and a treatment function and involved the two internet groups, Overcount and Codeine Free. No other current support groups were mentioned and many participants did refer to undertaking search engine searches initially and found them through such searches. The two website were perhaps the most positively received of all the options available to participants based on their experience. They provided treatment options, including specific ones based on on-line discussion between web site staff and participants and standardized information about the steps needed to address OTC addiction. A further function of the web sites appeared to be a 'confirmatory' one, whereby participants described the reassurance found in simply knowing this was, firstly, a problem, and secondly, others were affected. As Michelle noted, *'there are many more in the same boat, going through the same struggle.'* However, it was apparent that participants varied considerably in their use of the two web sites and for some, their benefit stopped at this confirmatory stage but for

others, specific treatment advice was sought and some continued to read and respond to messages. In two cases, participants had been motivated to become moderators of one of the web sites.

Reflecting the positive aspects, Elizabeth found that the site offered her anonymity in the first instance but an immediate benefit and actively contributed still to it:

> *"I Googled codeine addiction and found the forum and never looked back really. I started posting and everyone was very supportive and knowledgeable. It was brilliant [...] initially it was a sounding board. You know I was saying….. Sometimes you need to vent and you need to vent to people who understand what you are going through and everyone on that board in one way or another understands."*

Reflecting those who were less engaged are Dwain and Bob's accounts, where they note

> *"[…] obviously it helps some people, but I am not a one for sitting down and typing things into the internet, you know what I mean and chat rooms and that sort of thing. I do read articles. I have printed out a pamphlet […]"* Dwain

> *"I made one or two posts, mainly from the point of view of trying to offer some positive help to other people rather than myself. I didn't find it helped me much. I like to think that I helped other people you know offering my experiences."* Bob

The issue of anonymity was again identified in this aspect of participants' experiences, and several noted using pseudonyms on-line and valuing the ability to do this, as John illustrates in the following extract:

> *"[The web site] gives me the ability to anonymise myself. To experience and participate without it actually being physically me. I think where I am at right now is I need to own up who I am which probably wouldn't mean I'd take part online, but it would I think part of my process."* John

As Ailsa noted, this was bound up in issues of shame about her OTC addiction but, again, fears about identification:

> *"I was ashamed as well because you don't necessarily want to be identified as you. I think the people on there, I think it is more anonymous but then I think that's a trust thing isn't it so you know…."*

In these sections of treatment and support, a range of options have been described based on experience and also opinion, with varying degrees of endorsement from the participants. The more obvious theme to emerge from this is of the different needs of individuals and whether, for example, they want to engage formally with NHS services and have their addiction recorded, whether they think they would benefit from group discussion, what relationship they have with their GP, and their type of addiction.

The final sections relating to participants with direct OTC medicine addiction explore a range of additional views expressed about issues related to OTC medicine addiction.

4.3.9 Views on OTC addiction-related issues

All participants were asked for their views on a range of issues considered relevant to OTC medicine addiction. Several have already been described, including their views on pharmacies and different forms of treatment but in this final section a number of other viewpoints are described. These include several policy-related questions, such as

whether OTC medicines that may cause addiction should continue to be available OTC, views on pack sizes and warning labels and broader issues of where responsibility lies for this problem. The question of availability is considered first.

4.3.9.1 Availability of codeine

Most participants were in favour of the continued availability of OTC medicines that may be abused. This view was usually defended in terms of the need to balance convenient access to medicines with the risks to some, but the most important aspect appeared to be ensuring that people were able to choose for themselves. This view was advanced by participants in all three types of abuse, and was typified by Michelle's response:

> *"Everyone should have a choice what they do with their life - as long as they have the awareness of the danger then it's up to each individual what they do with that information and what path they choose."*

Other factors were also argued to be relevant including those provided by David in terms of the additional burden that would be placed on doctors to prescribe, the economic loss to marginally profitable pharmacies and an iatrogenic concern that doctors may prescribe higher strength forms of codeine:

> *"Well first of all I do not support codeine being banned and made prescription only. I think its unworkable, I think its impractical and I think it would impose an additional burden on overworked NHS GP's and it would have financial implications for small community pharmacies all across the country"*

Others, however, argued that the harm they had experienced had been distressing enough to warrant restricting supplies, to prevent others being harmed. However, this was recognised as inconveniencing those people who would never have a problem with an OTC medicine and who would benefit from their availability and the consequence of moving supply to doctors. As Karen summarised:

> *"[…] honestly from my experience I would like it banned. But that's my experience, isn't it? Whether you can inflict that on the entire nation, I don't know. But then you see if you want it, go to the doctor and get a prescription. You know, it's not saying it's banned. It's saying it is not available over the counter. It's saying if you want codeine, you have got to go and get it prescribed by a doctor."* Karen

Others drew analogies with the current availability of other substances that can cause addiction, and argued that if they continued to be available, then so should OTC medicines of possible addiction.

4.3.9.2 Warnings on packets and leaflets

Some participants in this study were interviewed before the MHRA changes (to indications, addiction warnings and packs sizes) came into place in September 2009, whilst others had continued to experience OTC medicine addiction and purchase medicines since their introduction. A key emergent theme was that such warnings were considered to be of possible benefit only to those who were not addicted. For those interviewed after the changes were introduced,

awareness of the changes to warnings appeared to be poor, not only for those who no longer consumed an OTC medicine (perhaps understandably) but also for those still using an OTC medicine. The reason for this appeared to be linked to the perception noted above, that such warnings were not of any help to those already addicted. As John noted when asked about the warnings on the boxes –*'I've not noticed, but then again I'm not looking'.* Rachel, who had only stopped taking an OTC codeine-based medicine days before being interviewed appeared similarly ignorant of the changes:

> *"I didn't even realise. I mean I am not one of these that reads all the side effects of drugs. I am afraid that comes out the packet and goes straight in the bin, But I mean if it is on there it can't be evident like it is on a cigarette packet."*

The above quote illustrated a common analogy made to warnings on tobacco, although the latter was argued to be more dramatic in terms of the imagery used and, as Karen, noted the use of mere wording may not be effective. Others were even more forthright in their view that such warning s were of no use to those already addicted, and stressed the need for changes to treatment:

> *"No - giving a warning to someone who is well aware they're addicted does nothing. There needs to be far more information, help and support for people who are already addicted to this form of medicine."* Michelle [written comment]

A final comment illustrating the motivations of those already addicted was offered by Jason, when he was dismissive of anything but the actual medicine itself:

> *"I couldn't give a toss about packaging. You just want to get it in your pocket. You don't want anyone to know that you've got them. And the only thing is the contents."*

One participant, Elizabeth, reflected on her own experience of becoming addicted on prescribed analgesics first providing yet another example where warnings on OTC packets would have been too late.

For those who were interviewed before the changes to warnings, they were still able to reflect on the potential of such warnings, but, again, these were almost all viewed as being of no benefit to those already addicted.

Other more positive comments were identified in a minority of interviews, although these all referred to the benefits of those who were not already addicted, as Bob commented:

> *"So I mean it is better than nothing certainly to have a warning on the packet. Without a shadow of a doubt, it is better than nothing and it will put some people off, but the people who need to be put off, I am not sure it would."* Bob

Participants did not appear to be aware of the changes to the indications of codeine-based products but several made comments about the issue of pack sizes. This appeared to be based on experiences for many of the previous reduction in the maximum pack sizes of codeine-containing medicines, several years prior to this study beginning. Like the warning changes, there was pessimism overall that pack size changes would influence those already addicted. As Jack noted:

> *"There is no point. You will just see people going from one chemist to the next. That's what people in my position already do. It wouldn't help."* Jack

As noted earlier, references to pack sizes were usually attributed to the slight increase in costs, rather than any deterrent effect (see section 4.3.7.3 on page 49).

Overall, then, participants' views on policy changes were viewed negatively in relation to those like themselves, who were and had been addicted already. Benefits for those first using OTC medicines were argued to be more relevant although there was a trend towards viewing warnings and pack size changes as being only a small aspect of raising awareness.

4.3.9.3 The Internet

The internet has already been considered in terms of the experiences of two participants who made successful purchases of OTC medicine relating to their addiction in section 4.3.5.2 above and also the availability of on-line help and support in section 4.3.8.5 on page 56. However, interviews revealed two additional insights into participants experiences and motivations, and this involved, firstly, concerns about the safety and quality of internet medicines and, secondly, the use of the internet to obtain further information.

Regarding the first, all participants were asked about the internet in relation to the supply of medicines and, as noted only two participants had actually made internet purchases relating to medicines to which they were addicted.[1] These two participants explained benefits in terms of being able to obtain multiple packs of codeine-based medicines, using control mechanisms that could be easily circumvented. In these two accounts, however, no concerns were raised about issues of quality or the genuineness of the suppliers or medicines, and indeed they often referred to well known companies. In contrast, many other participants *did* raise concerns about internet-sourced medicines and there was a view that medicines obtained in this way may be unsafe in terms of their quality and ingredients. As Elizabeth illustrates when asked if she would make a purchase:

> *"I never would. The idea scares the hell out of me. I think if people got desperate enough and their supplies were cut off completely, it might happen."*

Rachel described in more detail the perceived problems that could occur:

> *"No, I had never tried the internet and the only reason why is because you hear all these stories. Well, it's like everything isn't it. But well you do hear these stories about people getting the wrong stuff, or it's not effective at all, or you know it's mixed with other things and so I wouldn't only because I would just be very wary about what I was actually buying. Would it actually be Co-codomol, or could it be something completely alien."*

What the above extract illustrates is that these views were based not upon experience but received wisdom. It was also apparent in some accounts that all internet supplied medicines were perceived to be problematic and their was not insight or awareness of different types of websites, such as those that from reputable, UK-based companies, and were registered.

[1] One individual was excluded from the study who made internet-based codeine supplies (see 3.2.4 on page 28)

The second insight into the internet related to its use to provide information and although this has been considered in the specific context of the two dedicated on-line support groups, there was evidence in interviews that participants had used the internet to search for information on problems relating to codeine use in the long-term, information about medical conditions and symptoms such as rebound headaches, and for some, to support their addiction by identifying products that might be suitable based on different ingredients – often codeine. Dwain illustrates the concern about wanting to know more about codeine effects:

> *"I haven't really been able to see much on the internet about it. I mean I was having problems sleeping and things like that. Can codeine affect you in terms of sleep? You know can it stop you sleeping as well as make you sleep, if you know what I mean?" Dwain*

4.3.9.4 Whose responsibilities?

A final emergent theme in this study of the participants related to where they felt responsibility lay for the problem of OTC medicine addiction. This was raised as a question but often arose in spontaneous responses by participants in interviews. The emerging theme was one of *individual* responsibility in the main, with most participants arguing that they had initiated the use of the medicine and should have noticed the change is use. This was often linked to claims about participant's perceived intelligence and a recurrent concern that they were often very controlled individuals with successful jobs and graduate and post-graduate university qualifications, and for whom OTC addiction was in some respects atypical. The following quotes illustrate the frequency of such claims:

> *"totally* ***blame*** *myself. I have got no one else to blame but myself definitely. Definitely, definitely it is my fault I know that and I am never, ever going to do it again, so that's fine." Karen*
>
> *"You know I am* ***not an unintelligent*** *fellow and I have got access to the internet like everybody else. I knew what the consequences were, but I still couldn't stop it." Bob*
>
> *"I am quite a* ***rational, intelligent*** *person. How I didn't compute that there was something going on, I have no idea. But I didn't". Rachel*
>
> *"I sort of count myself* ***intelligent*** *enough that if I had taken twenty, or thirty, or forty a day, like I have read on the internet, like lots of people, you know, it would affect my health really badly. So I have managed to stick to maybe up to ten a day maximum."*
>
> *"I still can't believe that as an* ***intelligent woman****, after that, continued to take and I just took it as gastric protection for my stomach, so I could still carry on doing so." Theresa*
>
> *"I'm certainly not putting blame on to anyone else because I did it and that's all there is to it. Had one been aware of it earlier on, would it have made a difference? I think it possibly would have done, from the beginning it would have done becuase I would have realised that codeine was addictive […] You've got*
> *freedom of choice and nobody said to me' you've got to take them'. They may have recommended them but I carried on taking them."* Theresa

Theresa's final comment related to the pharmacies which supplied her and in hers and other accounts it is clear that whilst other factors may have been contributory for a minority – such as pharmacies who continued to supply, or a GP who prescribed inappropriately in one case, or post-operative care which did not address analgesic needs – it was ultimately a personal issue.

4.3.10 Summary

This section on the experiences and views of those with direct experience of OTC medicine addiction has revealed many important insights. These include three types of addiction based on the quantities taken, the use of codeine in almost all cases, but some reference to other medicines being problematic. Genuine medical reasons for using a medicine were identified initially in all but two cases and a range of relationships between prescription and OTC medicine used emerged. All three types of addiction involved the use of a medicine to exploit a non-therapeutic effect, including the 'buzz' of codeine or its calming or sedative effect. Withdrawal symptoms were described for many participants if a medicine was stopped or if supplies ran out; these varied from rebound headaches to emotional changes and palpitations. Many participants were economically active and made definite attempts to emphasise their professional status and also their intelligence. The hidden nature of most participants' situations was also clearly described, reflecting in a reluctance to engage with treatment services, including GPs and specialist addiction services. Such treatment options, along with support services such as Narcotics Anonymous were often viewed negatively and were argued not to be aware of the unique nature of OTC medicine addiction.

In the next section, the views of a range of stakeholders are described.

4.4 Stakeholders – *raising awareness, improving treatment*

Sixteen key stakeholders were interviewed representing a range of organizations and interests relating to OTC medicine abuse – at the level of regulation, manufacturer, treatment, support, research and supply (see Table 2 on page 18). Analysis of interviews revealed a number of similar themes, but also distinct issues and emphases, which were understandable given the heterogeneous nature of the stakeholders and their different interests. Emergent themes included issues around perceptions of the substances involved, the scale of the problem, treatment, internet supply, views on pharmacists, and policies. The medicine referred to most frequently, and for some the only medicine associated with OTC medicine abuse, was codeine. Like those with direct experience, and also pharmacists and MCAs, the majority of stakeholders were in favour of continued availability overall but emphasized the need to raise awareness and understanding amongst the public and health care professionals, and to improve treatment options. These themes are now considered in turn.

4.4.1 Perception of who is affected

A number of comments were identified during interviews that supported an archetypal individual who may be affected by OTC medicine abuse. This came from those who had been directly involved in supporting an individual, or from perceptions of those affected, but a repeated phrase identified was '*middle class'* and there were various other comments that suggested a respectable persona, as these three short extracts illustrate (with emphasis added):

> *"I think from certainly the* ***middle aged middle class woman*** *I saw the other day who came, she'd found Nurofen plus and it had really helped her"*

> *"Of course, the internet is also a problem, because if doctors won't prescribe, or a pharmacist gets suspicious err,* ***a knowing middle-class patient*** *can just go on the internet and buy whatever he likes, or she likes."*

> *"You know,* ***very middle class lady, very lovely lady*** *actually.* ***She has a husband and family and who would dream that she had a problem sort of thing****. It was just ruining her life actually, ruining her life."*

The private clinic stakeholders further expanded on this by noting that they perceived this to be an assumption made by others, such as GPs, although in their clinic, they viewed all addictions to opiates as being the same:

> *"We don't think of them as different because the people who are addicted to opiates and that's what our service is for. And you know, psychologically they are every bit as addicted as the people who are addicted to methadone are. I think in their own heads of maybe say the GP who referred them. They are a different type of addict, because they never, ever used street drugs and in addiction there is a pecking order. Do you know what I mean? So in terms of heroin, if you are an injector, you are slightly worse than people who smoke. In cocaine, you know crack users are slightly worse than people who use powder cocaine and I think they do think that they are better…"*

4.4.2 Medicines and associated harm

The main medicines referred to in interviews as being a concern were opiates, with codeine being mentioned most often, and indeed seeming to be the paradigm medicine of OTC abuse. Several stakeholders specifically referred to *'compound preparations'* such as codeine or dihydrocodeine and either ibuprofen or paracetamol as being of concern, due to the harms associated with the latter ingredients. Gastro-intestinal problems, including haemorrhage, were cited for ibuprofen, and hepatic damage for paracetamol, as a representative of a private addiction clinic noted:

> *'The physical impact on all of that because they have either been taking shed loads of paracetamol or shed loads of ibuprofen so their livers are quite damaged, or their guts are quite damaged and we have seen people as well coming in who have had longstanding addictions to ibuprofen that have had like major abdominal surgery, because of ulcers and bleeds and whatever else. You know you see people with much worse liver function than those who have been using heroin for ten years.'*

There was also awareness of an overlap between abuse of OTC opiate medicines and abuse of *prescribed* opiate medicines too, although the lower doses in OTC products were recognised. Indeed, several stakeholders raised concerns that medical prescribing was not necessarily more effective at preventing or reducing abuse, and mention was made of benzodiazepine prescribing problems as well as those relating to opiates. As the nurse stakeholder noted about an individual she had helped treat and her experiences of medical care:

> *'He [the GP] prescribed two hundred and forty, but she is topping up to six hundred and fifty milligrams a day and furthermore the GP hasn't reviewed the prescription. Also this is something else I have seen a few times now and that is that the surgeries have failed to notice when somebody is over ordering. So actually she was taking all of her tablets more or less in the first two or three days and then she didn't dare to ask for another prescription then […]'*

Several stakeholders referred to the traditional problems associated with liquid formulations of opiates such as codeine linctus and J.Collis Brown and there was recognition that this might have occurred in the case of the user of illicit street drugs who sought liquid opiates from pharmacies to supplement their other supplies.

Academics working in this field were able to identify specific medicines and therapeutic groups based upon their knowledge of the literature and, for example, one academic stakeholder was aware of the abuse of dextromethorphan by adolescents in the USA. For other stakeholders, however, non-opiate medicines and non-analgesic therapeutic groups were mentioned far less frequently. Laxatives were raised as a concern by several, including the representative of an eating disorder charity, who identified concerns around tolerance and the need for specialised medical support to reduce the dose. An academic stakeholder also identified laxative concerns, and similar issues around very specialised support, due to metabolic changes due to laxative use and weight loss:

Sedative antihistamines were not spontaneously mentioned or referred to, when participants were asked about other medicines that could be problematic. The regulatory body stakeholder did refer to both pseudoephedrine and also diphenhydramine capsules briefly, to illustrate restrictive access changes as a result of new data. One stakeholder who provided advice to an on-line forum referred to nicotine gum as being a more recent problem.

4.4.3 Scale of problem

Views on the extent of the problem varied considerably, depending on the stakeholder's perspective. These were mostly informed by perceptions or anecdotal evidence from those working directly with individuals in a clinical or treatment relationship. Other stakeholders drew upon data from the extant literature (see section 2.3 on page 3) and several references were made to the figure quoted by one on-line support forum. Several stakeholders were able to draw upon direct experiences of treating individuals with problems, as the nurse working in an addiction charity noted:

> *'I have them all written down, but I haven't got huge numbers. But then I haven't had these referrals coming to me for very long. It is growing and we have identified it as a growing trend that we seem to be less aware of until we get somebody like me to pass them through too actually. So I have probably handled about half a dozen I suppose, in the space of not many months actually. A lot of people wouldn't think to come to us anyway. You have got to bear that in mind as well.'*

The representatives of the private treatment clinic also referred to the estimated number of individuals they might treat, and expressed this in terms of the proportion of total patients admitted for all dependencies:

> *'We certainly see more patients on a monthly basis, but we are talking mainly talking ones or two's, as opposed to big numbers. I guess as a guide, on average we would admit between eight or ten patients in any one given week, so we are talking forty patients a month. And maybe only one or two of those might be. It's a small percentage. But five or six years ago we wouldn't have seen any, would we?'*

The final comment made reference to increased promotion of the clinic to those with OTC medicine problems.

Bound up in issues of the scale of the problem were concerns for some stakeholders about the different types and definitions of problems that may occur. For one academic stakeholder, this was understood in terms of intentionality, as when they noted that:

> *'[...] it comes down to the definitions of course of misuse and it always gets tied up in this area I think. I think the level of people buying it to really abuse in terms of getting a high from is pretty low. I think that's small and overplayed [but] the level of people who are misusing things in a slightly less or slightly different level of intention[...] it's quite high [...] and then there's another group of unintentional misusers [...]*

This academic identified two factors that were important in the question of the scale of the problem: the first was a view that the on-line support groups had the potential to influence the perception scale of the problem and to:

> *'overplay the extent of the problem, based on their own experience, because they are a group of people who have had a problem and so naturally they think it's a big problem, but we don't know the extent of it. Nobody knows the extent of it. It's so hard to measure.'*

The final comment linked to the academic stakeholder's second factor, namely that obtaining quantitative data in this field would be inherently difficult as they felt that individuals affected by OTC may not want to participate or admit abuse in a research project.

Further insights into the scale of the issue from the on-line support forums perspective was provided by one stakeholder involved in running a site, when he referred to inherent limitations in calculating individuals who used the

site. It was possible to calculate the number of visits or 'traffic' to the site but this did not correspond to the much lower figure of those registered:

> *'[…] the amount of people who stay and register on the forums is absolutely a tiny fraction of the people who go to the site and just get the information. The amount of traffic is grossly disproportional to the amount of people who stay and register. And of those who do register, there's only a small proportion of them that will participate.'*

Several stakeholders connected the problem of not knowing the scale of the OTC medicine abuse problem to how to design and fund relevant services, and as one drug charity stakeholder noted: *'you're not going to get any investment in treatment services unless you can get a handle on the size of the problem.'*

The scale of the problem of OTC medicine abuse is a contested one, in summary, but a range of insights including issues about defining the problem in terms of different types of use, the use of internet support for different purposes, and the formal contact that clinical services (public, private and voluntary) provide, offer opportunities for future study in this area.

4.4.4 Treatment and support

Stakeholders made reference to various treatment and support options for those affected by OTC medicine abuse based on a range of their own backgrounds and expertise, including on-line support, nursing and GP care, private treatment clinics, pharmacy interventions and charitable organization support. These are now considered in turn, although there was recognition that individuals may have experienced several of these options over time, as the individuals with OTC medicine experience in this study illustrated.

4.4.4.1 Clinical treatment experiences

One over-riding issue was of a lack of comprehensive clinical guidance, which was particularly so when compared to well-documented and established treatments for other dependencies, such as heroin or alcohol. A key aspect of treatment recognized by several practitioners was to reduce the harm associated with compound analgesic preparations. Two stakeholders in practice - a medical practitioner and a nurse specialist – highlighted the need to stop the OTC medicine and replace it with an opiate and then develop a specialsed plan to reduce the dose.

> *'I've used codeine itself a few times, but to me it's very much harm reduction. If someone is addicted to vast amounts of Nurofen Plus and you put them on codeine, okay, it's an addictive product, but they have all managed to get off it, by luck, then you are taking away the thing that's causing the medical problem'*

In terms of the choice of opiate for these clinical practitioners, a number of options were available, including the use of methadone, buprenorphine, codeine or dihydrocodeine. A key issue raised by these two stakeholders and others was, however, of the potential stigma attached to buprenorphine and methadone in particular, due to their perceived

association with illicit drug treatment. This was used to support the use of medicines such as codeine and dihydrocodeine, as these were the same medicines the individual had used initially:

> *'[…]don't switch people to other drugs if you can help it. Most people prefer to be somehow managed on whatever it is they are addicted to. So you know with all the people who are stuffing Nurofen Plus or Co-codomol, it is easier to switch them to codeine, which at least you are giving them the same drug.'* Drug charity nurse

However, the use of what the medical stakeholder termed the '*maverick solution'* of using codeine, was not unproblematic, and this included concerns about its short duration of action, meaning individuals would have to take repeated doses that could not be easily supervised, for example. This was not the case for long-acting medicines such as methadone.

A final feature of these practically-based experiences was of the need to tailor treatment very much to the individual, and there was clear recognition that the choice of medicine and duration and additional support would be decided in agreement with the individual and their circumstances.

Notwithstanding these anecdotal accounts of treatment, the broader lack of standard guidance in the formal clinical setting led to concerns about the quality and suitability of care for several stakeholders. This was perceived to be particularly the case for both general medical practice and also specialized drug and alcohol treatment centres (DAATs), as the following two extracts illustrate:

> *'There's no formalised treatment pathway for somebody who's got an addiction to over the counter drugs apart from the fact that the services are not particularly geared up particularly to those drugs they are also not geared up to the majority of people who wouldn't regard themselves as drug users or anything like that so it doesn't work at two levels. It doesn't work in terms of the problems that people have and the type of user that you are talking about would no more go to a drug treatment service than fly. You know you would have to set up particular services that looked like a GP or something you know they are not going to hang around what they see as a bunch of junkies or something […]'*
>
> *'I think overall there is quite obviously lots of GPs recognize that there are problems. A lot of them really don't quite know what to do.'*

Drug and alcohol treatment centres were, like the above quotes, frequently considered to be associated only with other types of 'drug users' and typically those using illicit street drugs and also alcohol and so, as noted, they may not attract those with an OTC problem and also therefore may not have the experience to provide help. That they were more used to treatment involving methadone and buprenorphine was also considered a factor.

There was a perception amongst those directly involved in providing services, and echoing the experiences of those individuals in this study with direct experience, of a series of referrals and unsuccessful attempts to provide support from some quarters. This was illustrated in the following extract from the medical stakeholder:

> *"She'd also - not found - she'd gone to a counsellor who happened to name me. That's why she ended up coming to me, because she'd been to her GP and her GP had just sort of said, "Well stop doing it" you know and then she'd said "Well, I can't" so he had sent her to the local drug service, who also told her well this isn't going to remit, to go away, we can offer you methadone you know but it's not only a very big problem, it's under recognised and it's…there isn't the help out there."*

4.4.4.2 Private clinic treatment

A somewhat different treatment option was described by the two stakeholders who worked at a private addiction clinic, where a week long in-patient programme was used, with follow-on medication. The clinic received individuals from all across the UK and was argued by the two stakeholders to be valued by those for whom other treatment options had failed, and was essentially the same used for heroin detoxification. As one of the stakeholders elaborated:

> *'We do a five day in patient treatments with fourteen beds and we do what is called a sedative detoxification. So we already know quite a bit about the service users before they came, because they were being referred by their GP […] So it's like sedation, so they sleep. What we are aiming for is to get people to sleep like you would do overnight. So they are going to wake up for the loo and they have lots to drink and what have you. You can't always achieve that with people who have got high tolerances. But that's what we are aiming for. Even people that can't get to sleep all the time are comfortable. So that's why people come to us because they have probably tried to do what's called 'cold turkey' and that and struggled. They might have done community de-tox's or whatever and we tend to be the last resort when they haven't managed with all the other methods. Then they will have got the funding together and then they will come to us and then we use Naltrexone the opiate blocker, so we introduce this at the end of the week to displace any opiates that they haven't detoxed and then we send them home with that. That sort of prevents any relapses. That was the programme that was designed for people who were addicted to heroin. We use the same programme very much and we do want the people who are addicted to codeine as well to go on the Naltrexone.'*

None of the other stakeholders made reference to the use of private clinics.

4.4.4.3 Internet support

All stakeholders were asked about the availability of internet support for OTC medicine abuse and the majority were aware of their existence and roles. Some referred to either Overcount or Codeine Free specifically by name, and there appeared to have been considerable interaction and communication between some stakeholders and these on-line support forums over time, reflecting not just a support role for individuals but also a campaigning one, too, at a policy level and also at the level of support to those involved in supply and clinical practice. The over-riding view was that these voluntarily run web site support forums were helpful and an important source of support for individuals. However, occasional concerns emerged in terms of the potential exaggeration of the issue, as noted by one stakeholder earlier, and of the type of advice provided. Reflecting the former, the nurse stakeholder noted:

> *'I found out about those when I went to the Glasgow Drug Conference earlier this year. Ever since then, I have been telling everybody about it, GPs, patients and colleagues here as well. I tell everybody about it. Most people don't know that it exists. A pharmacist I was talking to the other day didn't know anything about it. They are not very well advertised actually, but yeah since I learnt about it, I refer to them […]'*

Reflecting the inherent limitations of some of the advice on offer, one stakeholder, who represented a manufacturers' association, argued that the on-line support forums were limited since they could only advise on individuals' *current* medicines, and had no obvious prescribing function:

'The problem with those on-line web sites is they are still dealing with OTC practices because you can't buy codeine by itself over the counter.'

However, it was recognized that referral on to a GP was a signposting option for these web sites and this was a point clearly made by a stakeholder involved in one of the websites, when they highlighted the two key functions of the site:

'We're basically two-fold. I mean first of all we're just trying to raise the general awareness of how people can become addicted [and secondly] that when people do realize that they've got a problem, is to try and help them with the information, giving them the choices about what they can do and then supporting them with their choice.'

4.4.5 Internet supply

Stakeholders were asked for their views and experiences of internet supplies of OTC medicines and three broad themes emerged – scale, regulation and quality. In terms of the scale of internet supply, this was perceived by many stakeholders to be currently at as low level of use in relation to the supply of OTC medicines, but there was a view that this would increase over time and represent an increasing concern. For some this was seen as an opportunity to increase access in a positive way, as a drug support charity representative noted:

'Not necessarily for drug misuse but just as another avenue for getting medicines which have traditionally been under the control of pharmacists and doctors. It's going to be quite significant over time.'

However, others were less positive about the advantages of internet supplies and raised concerns about the lack of regulation of some on-line suppliers. The two stakeholders who provided on-line forums referred to various test purchases that they had undertaken together with reports from users of their web sites. Their accounts suggested that it easy to obtain multiple packs of medicines that can be abused very easily, and these stakeholders expressed correspondingly negative views about such supplies as a result:

'My personal opinion is that these shouldn't be sold on the internet because we've done test purchases [and] there is only one pharmacy that picked us up, you know the others just told. I mean in one case I managed to buy I think I bought nearly ninety Solpadeine Max and I didn't bother filling in the questionnaire […] we've actually done multiple purchases using two different email accounts so we've managed to do it.' Mark

These concerns were raised both for international web sites but also companies that were registered as official UK internet pharmacies and were displaying a Pharmaceutical Society official green cross logo:

'If you go to the UK registered pharmacy website with the logos and stuff like that there are still plenty of UK sites that will sell you large quantities [...] If you try to buy Nurofen Plus and you can actually click on the quantity and a drop down box comes up with up to ten [...] Technically right if I bought ten at my local pharmacy then eyebrows would be raised but clients actually tell me that they do this and that because they can actually buy ten at a time'

'The ones abroad, honestly I did a sort of test myself right. ephedrine hydrochloride? You can actually buy 8.6 mg tablets and they're classified as a diet supplement for weight loss. There was

one in the Canadian pharmacy [...] I had a problem with Ephedrine years ago but if I had known at the time you could buy the bloody stuff for that cheap I think I'd probably be dead by now.' David

A representative of the, then, Royal Pharmaceutical Society of Great Britain was also aware of the potential issues of internet supplies and noted that, as an organisation, it would act on any reports of inappropriately regulated supply for UK registered internet pharmacies. The stakeholder also identified further concerns about international websites, and particularly a perception that some individuals used the internet due to lower costs, which could lead to compromises in terms of quality:

'If it's being bought in the UK – if too many are being bought – at least you know the quality is there. When you buy on the internet, normally you decide...the decision on what to buy is based on price and when you buy it from abroad I would assume that, and this is a very general, sweeping statement and I don't mean this literally, but if you buy cheap the chances of that drug being counterfeit in some way are probably higher.'

Another perspective was provided by a superintendent pharmacist stakeholder, whose pharmacy company offered an internet pharmacy part of its operation. This stakeholder noted that the main interest for their company was in electronic prescription supplies but confirmed that control of this aspect of their business involved the pharmacist more than in most pharmacies:

It's a tighter control for us on the internet – we do not release any P med without clearly, a pharmacist reviewing the request. Whereas, as we know, there is a nod out there when someone is selling a P med [...] out internet business doesn't work like that, you know – it's filling a form; a pharmacists reviews it and if there are any questions he wants to ask, then it's emailed back to the patient..customer and they are asked for further questions [and...] to some people, I am sure they go off to other sites where they may not be, er, regulated as well, but I think the idea of the Pharmaceutical Society logo you know being applied to accredited sites is useful.'

The regulatory stakeholder completed the range of accounts provided about the internet availability of OTC medicines by referring to an established system for monitoring availability, coupled with a pro-active attitude to enforcement:

What we are pleased to say is that the signs are that the legitimate internet pharmacies will follow the advice that we have given and for those internet pharmacies that don't we have a very well recourses programme of test searches et cetera. We think we have had some fairly notable successes in terms of pursuiters, of potential breaches, but it's an enormous challenge.

4.4.6 Pharmacists and pharmacies

Stakeholders were asked to comment on the role of pharmacists and pharmacies to supply medicines and there were mixed responses. A recurrent interpretation of pharmacists' role and the procedures used in pharmacies was that they represented a gate-keeping or 'policing' role. This was viewed positively in some respects, since it represented a better regulated system than comparisons made to the internet or non-pharmacy suppliers of some medicines such as supermarkets. However, it was also viewed negatively, as a limited role and several stakeholders alluded to the need for pharmacists to do more to raise awareness of the problem of OTC medicine abuse and at a

professional level, to consider enhanced ways that they could support individuals. As one academic stakeholder noted about these positive and negative aspects:

> '*I mean they've got a difficult role because they've got this policing role also and that for many of these things it's the policing role that's at the fore, stopping people getting things which is fine, but really I would like to see them being used more as a gateway into treatment for people who have a problem, so making that…doing more […]*'

A further perspective was offered from a representative of the RPSGB, who argued that pharmacists were placed in a difficult situation, trying to balance a number of roles, and that the determination of some individuals would always mean purchases could be made:

> *'I think there is a danger in expecting too much from pharmacists, particularly around OTC […] if someone is determined to do something or find something – a medicine – then they are going to do it […] the lengths they go to I think they will be able to get around almost any system we bring in.'*

This stakeholder raised the possibility of using a patient's summary care record in the context of an OTC medicine sale but the above comment reflected their pessimism as to the practical potential for success of such an initiative.

There was also a perception that pharmacist standards were not always the same, and that some pharmacists may be contributing toward the OTC problem.

4.4.7 Policies

A range of views and also suggestions were raised by stakeholders about policies relating to OTC medicine abuse, and these included whether such medicines should be available for sale and what warnings should be given about the addiction potential of some medicines. The emergence of these two policy-related themes were summarised by the regulatory organisation stakeholder, who noted:

> *'In terms of the regulatory perspective, two main strategies. One is to restrict access […and] the second main area is information and awareness […]*

These two concerns are now considered in more detail, and mainly in the context of codeine which, as noted earlier, was the paradigm medicine for the many stakeholders and framed much of their interviews.

4.4.7.1 Availability of OTC medicines of abuse

As with the majority of the participants in this study overall, most stakeholders were in favour of the continued supply of OTC medicines that may be misused or abused. Again, like the study overall, this view was framed in relation to opiate containing analgesic medicines. Stakeholders defended the continued availability in terms of needing to provide convenient access to medicines for the majority of individuals, often to treat pain. This was supported by

stakeholders who had previously experienced problems personally and who also provided support to those currently affected, such as those managing the on-line support forums:

> *'I think my own view is that that is going to be physically and, I will use my own word, morally - meaning the current sort of interpretation that the society has for painkillers - impossible. If I have a tooth abscess on a Saturday morning I would personally want to be able to go down to my local pharmacists and get something strong enough to treat the pain [...]'* David

Further support for availability came from the claim that if supplies were stopped from OTC purchase, then there would be increased burdens placed upon medical prescribers, and NHS costs too. Several stakeholders also alluded to concerns that even on prescription, abuse could still occur. A further argument against restricting supply was advanced by an eating disorder charity representative, who argued that stopping pharmacy sales of laxative medicines would mean individuals obtaining supplies from less regulated or reputable internet sources:

> *'I think the difficulty with seeking to ban something is the opportunities we have now to buy things over the internet would mean that people would just find other routes, perhaps even less safeguarded routes to get these products, if they were seen as being withdrawn from the shelves.'*

One stakeholder supported availability but argued that at a policy level restriction in access to some OTC medicines would occur if manufacturers did not respond to the evidence about the potential of addiction:

> *'codeine containing products do have a place in the armamentarium of pharmacists and they have been you know, they have assisted millions of people worldwide, so we don't want to ban them. That's an extreme view, because of that usefulness, but having said that there have to be proper warnings and proper monitoring of the use of these things [...] I mean the danger is that if the over the counter industry with respect of these products doesn't self-regulate itself much better than at the moment, these products will be made prescription only which we don't want or will not be sold at all, which we don't want.'*

In contrast to these arguments in favour of continued supplies, occasional concerns were raised about availability, however, as in the following extract which described concerns about the efficacy of some analgesic products:

> *'I think people need to be able to, you know, self-manage their headaches or something. How do you do that, I don't know but things like, I mean, do we really need a combination of things like codeine plus? I mean, what is it supposed to do opposed to anything else? [....] I would go for restricted choice.'*

A similar concern was raised by one academic, who questioned the relatively smaller amount of codeine in OTC products but who, like others, felt that the issue of availability may be ultimately decided by recognising the greater number of individuals who genuinely required analgesia.

The important of using current evidence to inform any decisions about changes to access to OTC medicines was stressed by the regulatory organisation stakeholder.

4.4.7.2 Raising awareness and understanding

The second key policy related issue involved strategies that could be used to raise awareness and promote understanding of the potential risks involved in using OTC medicines which could lead to abuse. A key policy change which occurred during the research, and noted in the introduction, involved changes to the indications, pack sizes and warnings of codeine-based OTC medicines in the UK, following the MHRA's Public Assessment Report (MHRA 2009). The timing of this – in September 2009 – meant that some interviews were undertaken before (indeed just days before in some cases) the changes and so interview questions and responses about issues around warnings reflected different experiences.

In relation to raising awareness and understanding, this emerged in terms of targeting individuals who used medicines, the public more generally, together with a range of health care professionals including pharmacists, doctors and those providing specialist addiction services. In specific terms, this involved activities including the use of written warnings on, and in, medicine packs, leaflets, and training for health care professionals.

The use of warnings about possible risks of addiction – both those on the front of packaging and in associated product information leaflets - was viewed positively overall, and several stakeholders made analogies between this initiative and the use of warnings on tobacco products, to indicate other successes in promoting possible harms. As an on-line forum stakeholder noted in an interview undertaken before the pack changes had occurred:

> *"we would like to see box warning labels you know like you would see on a packet of cigarettes. We would like box outer warnings so it is just primarily raising the awareness and secondary to that is when people do realise that they've got a problem there's nowhere or no clear information on where to go or what to do to get information"*

This extract illustrates a further emergent theme from stakeholder interviews, that visual warning labels on packs should be combined with additional signposting for individuals. This was recognised as being addressed by making available leaflets in pharmacies, about appropriate choices of medicines for pain relief and as the regulatory stakeholder also made clear, changes to advertising, which they summarised as follows:

> *"you have seen our announcement about the front face of pack 'Can Cause Addiction'. You cannot get more explicit than that and I think the balance of the advice that we had from the Commission on Human Medicines was to really maximise the value of pack information as a tool. That has to be supported and reinforced and we all know that patients take in a fraction really of what they are told, so reiterating and reinforcing there will be a leaflet in pharmacy about choice of painkiller. The materials have gone out today to all Pharmacists and reinforced by the professional bodies, so at every level there needs to be the same consistent messages. The last thing to add too, is as I am sure you've picked it up, the fact that advertising will contain this warning…"*

The same stakeholder noted that these were all voluntary arrangements agreed with the medicines manufacturers, but they clearly noted these amounted to a successful form of self-regulation:

> "*I wouldn't er, ever underestimate once industry has agreed a level playing field. A self-regulatory system can be very effective and as I say the agreement to have a clear warning can cause addiction in all the adverts, is achieved with all that industry sector and the code will be rapidly*

updated to reflect that, so yes, you're right, it's not a law, but as I say self-regulation for advertising for the pharmaceutical industry is shown test of time that it works."

Despite the positive responses to these changes in the UK supply and advertising of codeine-containing analgesics, there were several concerns. One involved the unintended consequences of raising awareness of addiction potential, as they may lead to more experimentation. This was a view expressed by several stakeholders, including this academic stakeholder:

"I've no real objection to a warning going on to any packet of medication if it helps, but as long as it doesn't have the sort of reverse effect of promoting it"

Another more negative view about the value of warnings concerned the lack of benefit to those who were already addicted, and for whom the new packaging may not provide any new information. Linked to this was a concern that such warnings may go unheeded by those who were already using the product, as the pharmacy superintendent stakeholder noted:

"it's a bit like you know sticking all these warnings on cigarette packets, you know [...]It might just make somebody think when they see a packet that says, you know, be aware or you may be potentially addicted to these, but in the long run er, you know it's really down to us [pharmacists], er, we should be able to er, give better guidance to people. Deal with those things in a pharmacy and if we trained properly and we train our staff to alert us to the right people"

This extract also illustrates the third aspect of raising awareness, and that involved improving understanding amongst those providing services, such as pharmacists in the above example, but also doctors, nurses and anyone involved in providing treatment, referral, support or supply. This was clearly linked to stakeholder's views and experiences of treatment options and the role of pharmacists, wherein concerns had been raised, for example, about the negative gate keeping role of pharmacists, or specialist treatment centres focusing on illicit substance or alcohol addiction.

4.4.8 Problems

As well as the various themes that emerged and described previously, a number of additional concerns were raised in the stakeholder interviews. These included financial aspects of OTC medicine abuse, the influence of the pharmaceutical industry on policy and the use of the internet to obtain information on medicines of potential abuse.

Several stakeholders perceived there to be possible issues relating to the influence of the pharmaceutical industry on policy and regulation. This appeared to be personal opinion in such cases but references were made to the industry links and specifically non-personal links to members of bodies such as the CSM. In relation to financial issues, some stakeholders referred to the significance of the OTC medicines market in the UK as a considerable source of income, but other comments centred on how important such sales were, for example, for pharmacy income. None of the stakeholders suggested that this was a significant influence on whether pharmacists may be more likely to supply OTC medicines inappropriately to generate sales.

In terms of the internet being a source of information, the main concern centred around the provision of information either about products that could be abused, or more technical information about ways of extracting active ingredients such as codeine, from co-ingredients such as paracetamol. As one stakeholder noted:

> "*Now if you go on the websites you'll find kids putting up on, I don't know if it's called Facebook or some of those social chatrooms, you will find that they advise you to crush them, several tablets probably in a pestle and mortar. Grind them as fine as possible into a powder. Shake the powder with moderately hot water, the codeine preferentially dissolves the Ibuprofen preferentially precipitates. Filter it through a handkerchief and drink the residue which is predominantly codeine. It's there on the internet. So the street abuse is already well known."*

A further example was provided by an academic stakeholder, who recalled seeing on-line postings by American teenagers about dextromethorphan abuse:

> *"[...] dextromethorphan, you know the cough suppressant that's supposed to be non-abusable. Well I would have been doing the sort of internet searches there was a lot of sort of postings on-line from teenagers, mostly in America [...] A huge amount of, you know, they were all saying extreme things basically. This cough bottle, this is the one you have to buy and it doesn't taste too bad. So much of this, or so much of that and this is what will happen [...]"*

4.4.9 Summary

This section on stakeholders has identified a number of emergent themes including issues around products involved, the scale of the problem, treatment, internet supply, views on pharmacists, and policies. Like the section on participants with direct experience, the medicine referred to most frequently, and for some the only medicine associated with OTC medicine abuse, was codeine. Also like those with direct experience, the majority of stakeholders were in favour of continued availability overall but emphasized the need to raise awareness and understanding amongst the public and health care professionals, and to improve treatment options. These were linked to concerns about the inadequacy of formal, evidence-based treatment options. Stakeholders held mixed views about pharmacists and their role, and viewed the internet availability of medicines as a currently small but significant future issue. There was evidence of co-operation between regulators, manufacturers and those representing support groups.

4.5 Medicine counter assistants - *monitoring and referring*

Seven MCAs were interviewed across six pharmacies and they varied considerably in the length of time they had worked in pharmacies. This ranged from three months to thirty two years – all were female. There were many recurrent themes amongst the interviews with them, and these could be grouped into concerns around procedures, products, perceptions of customers, the commercial environment, and problems associated with the misuse or abuse of OTC medicines. The most significant theme throughout the interviews, however, related to their references to the *frequency* of purchases. This appeared to be used as a key monitoring and surveillance tool, and assisted in defining certain customers as potential misusers or abusers of medicines. Linked to this were repeated references to referring customers on to pharmacists. These themes now considered in turn, using examples to illustrate them.

4.5.1 Procedures

The MCA interviews gave detailed accounts of the procedures that were used in relation to OTC sales. This was manifest in terms of legislation and also less formal forms of recording and surveillance that were undertaken at individual pharmacies, linked to referrals on to the pharmacist. There was an evident aware of, and apparent readiness to conform to, procedures in relation to the sale of OTC products, and particularly those liable to misuse or abuse. The recent changes to pack sizes and indications of codeine, and those relating to pseudoephedrine were cited by several as being an important control over what they supplied:

> *"We are warned particularly with something like pseudoephedrine and how it was being very much misused to make something else. So that was very much brought to our attention."* Irene, Wales

There was frequent mention of the rule relating to the supply of no more than one packet of thirty two tablets of a codeine containing medicine, which appeared to be viewed authoritatively by the MCAs. Similarly, as Irene noted, there appeared to be heightened awareness of the need to restrict the quantities of pseudoephedrine sold, in line with official guidance. In contrast, and illustrating a more pharmacy-specific approach, was the example in one pharmacy, where the MCAs and pharmacists permitted a regular customer to purchase two bottles of a liquid product – Kaolin and morphine, used traditionally to treat diarrhoea. This was explained by the pharmacy having received a genuine note from the customer's doctor, saying the doctor was aware of this and did not consider it a problem.

The use of a formal, written note, as in the above example, was in fact a procedure used by the pharmacies to *record* sales of medicines to customers where the potential for misuse or abuse was considered present. This was not used in all the pharmacies but in those that did it involved a customer writing their name in a book. As Margaret and Janet noted:

> *Janet* *"We sort of think, 'oh, he's been in a bit too often for this product so we report it, don't we – to the pharmacist.*

Margaret: *"Yea, because we've got like a folder now that we keep you know and when they come in we have to take their details down and then report it to the pharmacist and then it's up to them if they are willing to sell it.*

[…] *"So we do a log of it now because we are having that many people come in and obviously with use being open 'till ten we have that many different change of staff."*

In one pharmacy, this recorded transaction was then added to the computer record for the customer, if they were known to bring prescriptions to the pharmacy too. Several MCAs mentioned instances where such recording was being actively used, and indeed linked to other forms of commercial technology, as Irene noted:

> *"We have something called Chest-ease Dodos. They have theophylline in them, and we are trying to be very, very stringent that it is not the same people who are coming in and buying them on a regular basis and we have one name in particular that we are all looking out for because we do think this lady is overusing. […] Luckily because [this company] operate a loyalty card system, the lady has a very unusual surname. […] and we are keeping an eye out."* Irene, Wales, City Multiple

Irene also referred to a further technology used in her pharmacy, which involved restrictions on sales by the tills, so that if an attempt was made to scan several packs of an item restricted in quantity, the till would refuse them.

Another key procedural activity mentioned by all the MCAs involved the intervention of pharmacists and MCA's role in alerting pharmacists. This referral procedure was argued to provide more authority to MCA's concerns about a customer's use of a product and appeared to be a valuable mechanism for dealing with concerns, which worked well in pharmacies. One MCA, however, noted a problem relating to the use of locum pharmacists in her pharmacy, and of her preference to have greater pharmacist oversight:

> *"I've mean I've worked with pharmacists who want to know everything that you're selling – even if it's cotton wool balls! You know, they want to know everything and I've worked with other pharmacists who have been sort of 'you're fine, you know what you're doing.' You know, you see it from both sides really […] I feel more confident with somebody who will lean over mean and say 'err, what you selling.'* Theresa, England, Suburban Multiple

Several MCAs referred to alerting other pharmacies in their area, although this was also considered a problematic activity, both in remote areas, where there was not obvious or immediate 'other' pharmacy, or conversely, in cities, where there were too many pharmacies to contact individually. As Theresa noted again:

> *"It wasn't the fact that he was trying to buy the codeine. It was the fact that he was quite nasty. So we rang [the nearest other pharmacy] just to say that, you know, he was round and about and he was getting a bit shirty and then they rang us back and he had been in there trying to buy you know […] they don't realize that you are all sort of connected. I know [the other pharmacy] are nothing to do with us. But they'd do the same."* Theresa, England, Suburban, Multiple

Several MCAs referred to having received training and updates on medicines, particularly those in large organization pharmacies. Training packs (including electronic learning) and staff newsletters were specifically mentioned, and these appeared to provide information for staff, and formal assessment was mentioned. This was viewed positively, although one MCA noted that *'The training didn't really bring out about misuse[…] It was mentioned [but] in passing.'*

4.5.2 Perception of customers

MCAs distinguished between regular and non-regular customers, and although this appeared to be easier in rural pharmacies, MCAs working in city pharmacies also referred to regular customers. This distinction was one based mainly around frequency and repeat visits and was applied to all sales and not just those relating to OTC medicines of misuse or abuse. The frequency of purchases, however, took on heightened significance in relation to those medicines which were considered liable to misuse or abuse (see 4.5.3 below) and all the MCAs made reference to how often a product was being used. As Jane noted in the following two extracts from her interview:

> *"We had someone who's quite addicted to Benylin [cough medicine containing sedative antihistamine]. Er, and we kept saying to him, you know you're using this medication a bit too frequently, and he said 'Oh, but the doctor's said this or he's said that 'and eventually [the pharmacist] had to say to him, 'No, I'm sorry but we're not selling you any more. Because he was buying like 300ml bottles every week, and you just don't get through cough medicine that fast.'*

Many of the MCAs had developed perceptions about what could be inferred from a customer's response, and, for example, some viewed a negative reaction to a refused or referred sale, as being suggestive of abuse or misuse, as Jane argued:

> *"I think the ones who are getting dependent on it are the ones who don't accept it and argue. Normal people who use it for medication, you'll find will just say 'Oh, okay then', you know?'*

However, one MCA perceived the reverse to be the case, and felt that customers who did not challenge or argue were of concern too. Another perceived clue to suspected abuse was over-familiarity on the part of the customer, and this was manifest in terms of customers knowing, for example, where a product was specifically located in the pharmacy or to the use of specific products and brands by name:

> *"[…] they know exactly what they want as well. That's a giveaway. I would not have known, unless I worked in a pharmacy […] they know all the brand names you know or what's in it, but they do tend to more ask for brand names rather than the drug itself, to sort of throw you off."* Theresa

> *"You get to know your customers and once people have been in two or three times, you, know, you sort of start remembering what they're buying - which is the key thing. And if somebody spots somebody, if they've been in a couple of times and are buying the same thing. They know exactly where it's kept. They know exactly what pack size it is. Then alarm bells will start to ring."* Jane, England, city pharmacy

Many perceived the use of deception by some customers to obtain medicines that were being misused or abused and examples, and MCAs described their belief that customers were lying about what a product was to be used of, and by whom, as first Margaret, then Margaret and Janet noted about two customers:

> Margaret *"When I worked in another pharmacy, there was a woman who used to come in for two bottles of kaolin and morphine and she always used to say 'Err, can you put them in separate bags because one is for me, and one is for me neighbour' and we used to cotton on to her and watch her. And she used to walk out of the shop into her car and drink off the morphine off the top.*
>
> *[…]*
>
> Margaret *"Yea, there's always a story with it. Oh, and then that woman with Paramol, when she comes in.*

Janet	*"Yea, she always says it's for work doesn't she?*
Margaret	*"She'll say 'Can I have thirty two Paramol [the larger pack size available], because they're for the office'. 'Have you had them before?' 'Yea, they are for the office.*

Evident is such accounts were considerable suspicions about the information provided by some customers, which, coupled with issues around frequency identified too, contributed to a perception that a customer was abusing a product. Also evident in the above extract is an example of not only procedural surveillance, as identified above, but also physical surveillance, too, of watching a customer after leaving a pharmacy. In the next section, the range of products identified by MCAs is considered.

4.5.3 Medicines

A wide range of different products were identified by MCAs as being suspected of being misused or abused and these included those in the four broad categories identified in the literature (see chapter 2), namely: codeine-containing analgesics, decongestants, laxatives and sedative anti-histamines. Specific brands were often mentioned, such as Solpadeine, Nurofen Plus, Nytol and Sudafed, although generic medicine names were also cited, such as co-codamol (particularly with reference to the withdrawal of the soluble one hundred size packs) and pseudoephedrine. Codeine-containing analgesics were the product that were often first mentioned, when MCAs were asked about products who considered to be liable to misuse or abuse. In addition, however, several referred to liquid-based codeine-containing products, such as codeine linctus and kaolin and morphine, which were viewed as being historically problematic but now not stocked (as the earlier example of the customer who drank the separated parts of the medicine illustrated). One MCA referred to an example of a customer purchasing large amounts of a tooth repair kit and this was revealed as being due to the abuse of the alcohol in one of the constituent parts of the product.

4.5.4 Problems

Overlapping with many of the issues already presented, were a number of problematic aspects for MCAs in relation to OTC sales and those associated with potential misuse or abuse. These involved issues such as customers becoming aggressive or challenging, part-time staffing, through to more general concerns about the commercial environment and consumer choice.

In relation to abusive or challenging behavior, many of the MCAs recalled instances where there had been dissatisfaction from a customer in relation to a refusal to sell a medicine, either due to concerns raised by the MCA (or more often pharmacist, as per the referral procedure used) or due to legislation changes beyond the control of the pharmacy staff.

Concerns about staffing levels in pharmacies involved concerns particularly around part-time staff and them not being aware of all pharmacy transactions. This was argued to mean that the surveillance of repeat customers was undermined, as staff changed over, and so did not know what had happened at other times of the day:

> *"[…] the trouble Is with me only being here in the afternoon, I don't know what goes on in the morning. This is the problem. So she was coming in and buying suppositories, and she was asking about those diet pills […] if I'd have been here all day I'd have known myself […] so we are just keeping a note of it now, for what she comes in for, and when."* Jasmine, England, suburban, independent

There was a perception amongst some that this could be exploited by those seeking to abuse or misuse products, as Janet noted: *"they are starting to get a bit wise and come in at different times'* and as Theresa noted, in her suburban pharmacy:

> *"[…] I have seen him look through the door and see us on the counter and you know , ' I wonder if I'll be able to?'But you see we tend to tell each other as well."*

A final cluster of company concerns for MCAs centred around the commercial setting, and perceptions of a consumer culture. For some MCAs, the inherent commercial nature of pharmacy business meant that customers *qua* customers could visit different pharmacies with relative ease. There was a perception that this is what happened, but only limited evidence (based on contacting other pharmacies) that this occurred. Several MCAs referred to the influence of consumer culture and their belief that customers felt they *should* be able to purchase medicines in an unrestricted manner. Several referred to the availability of medicines from non-pharmacy outlets, such as supermarkets, as undermining the case for monitoring sand restricting sales in pharmacies. Another argued that increased advertising of medicines led to demands by customers that were not matched with an appreciation of the regulation and risks of such medicines.

This section has presented a number of themes in relation to experiences and views of MCAs, and has highlighted in particular MCAs' reliance of the frequency of purchases, coupled with a range of perceived motivations and strategies used by customers, to inform and justify various forms of surveillance of customers in pharmacies.

In the next section, the experiences and views of pharmacists are presented.

4.6 Pharmacists – *Uncertainty and lack of information*

A total of ten pharmacists were interviewed for this study, representing a range of organizational types, ages and locations (see Table 1 on page 17). In most cases, the pharmacist identified an MCA who was also interviewed after gaining appropriate consent, but one pharmacist was a relief pharmacist and her location varied so identifying an MCA was not possible, and one pharmacist worked in a rural pharmacy where no MCA was employed.

Thematically, many of the same themes emerged as in the MCA interviews, in terms of the types of products used, problems encountered and perceptions of customers. However, pharmacists appeared to be able to draw on wider clinical issues and opportunities to signpost and refer, and were less pre-occupied with procedures per se, but rather broader mechanisms for dealing with such issues. Pharmacists were asked about possible changes to their profession but apart from broader views that issues such as remote supervision were unwelcome, did not make links to OTC addiction and possible changes. Key features of pharmacists' accounts were those of uncertainty and lack of knowledge, and these were manifest in relation to treatment and signposting options, details of customer's medical history, current medication and customer's use of other pharmacies. These topics are now explored in turn, beginning with pharmacists' understanding of definitions of misuse and abuse.

4.6.1 Definitions

Pharmacists varied in their description of what constituted the misuse or abuse of medicines, when asked in interviews. For some, their responses were immediately to consider specific products and no attempt was made to consider the terms in the abstract. For others, however, more nuanced definitions and descriptions were advanced, and some distinguished between the terms misuse and abuse. There was recognition by several pharmacists that misuse of an OTC medicine involved inappropriate use and, for example, ignorance of the indication or licenced use of a medicine. However, many definitions centred around the abuse of medicines, and for several pharmacists this was linked to over-use and to the frequency of purchase, linking into MCAs' concepts about frequency. As Sharon notes:

> *"To me it means people who are overusing over the counter medication. So obviously things like co-codomol, Paramol® sleeping products, laxatives, but basically overuse or inappropriate use of anything. […] I mean to me misuse means that it is inadvertent, but abuse suggests to me that someone is setting out to do something."*

As the above quote also illustrates, the concept of intentionality appeared significant for several pharmacists in describing the *abuse* of medicines, with *misuse* being considered an *unintentional* process in contrast. One pharmacist referred immediately to customers *'coming in surreptitiously to try and get round.'* However, some pharmacists were are also able to identify a more complex situation, with 'intentional' and 'unintentional' and 'conscious' and unconscious' differences being attributed to customer motivations to purchase OTC medicines:

> *"Either consciously or not consciously, not necessarily they are meaning to do it, but because of the condition they've got. I guess you know back pain, things that are only relieved by painkillers. They are I guess subconsciously abusing them."* Ranjit, City, Multiple, England

> *"Mostly intentional but also partially not, in that people are not aware. Although having said that, ever one I have ever questioned are quite clear that they perhaps are taking too much of a certain thing and they just leg it and run."* Rachel, England, City, Independent

For one pharmacist, there was recognition of a possible transition between these amongst customers and he identified a progression from use or misuse to eventual abuse, either from an OTC product initially or a prescribed medicine:

> "*Obviously around codeine, so maybe it wasn't intentional to start with, but effectively not taking it within the dose and the licence and all that kind of stuff because of addiction. From whatever that has come from, whether it was from non-intentional to start with, you know and it kind of creeps yup and we certainly come across quite a bit of that here […]"* John, England, City, Independent

4.6.2 Dealing with misuse and abuse

A range of strategies and procedures emerged in relation to how pharmacists managed misuse and abuse in their work. These ranged from immediate responses such as advising customers or refusing sales, through to occasional signposting and involving GPs, and occasional example of contacting other pharmacies. These illustrated the emergence of themes relating to uncertainty, and a lack of complete information relating to a customer. This theme relating to responses to misuse and abuse highlighted two groups of pharmacists: those who viewed their interventions positively, and those who felt their interventions were of little help in this area. For the latter, this was often associated with concerns about not having enough information and an assumption that customers would inevitably visit other pharmacies for supplies. One of the most important aspects of dealing with customers was around the decision as to whether to refuse a sale or supply. These are now considered turn.

The most commonly identified way that pharmacists dealt with misuse and abuse was to intervene in some way in person. This almost always occurred from a referral from an MCA or from a pharmacist over-hearing a transaction, and no examples were identified of pharmacists being involved in sales initially. Pharmacists emphasized the need for such interventions to be carefully managed, in terms of using the right approach and tone of voice, to avoid problems. As John noted:

> *"Well, I spoke to the lady; said you know, politely as possible: 'Pou know, you don't want to be using as much of these, because they can be, you know, can be addictive and you might be wanting them for pain and stuff, but maybe you should just try paracetamol' […] and they did still buy them, but it was more sort of every few months."*John, Suburban, Independent, England

Also reflecting the need to be sensitive to how any advice or information was given, was Ranjit's approach to communication in such cases, which illustrated a more positive belief about pharmacist's role in such cases:

> *"What I try and do is talk to them in a way that is not accusing them as such, but saying, 'Ok,I feel, I know the reason why you are buying these, but perhaps this is not the best option for you'. So to*

try and approach it in that direction rather that to say, 'You are buying too many, you are abusing them'.Non-judgmental […]and I think they understand why. Why we take a bit of extra care. I can't recall anyone ever saying to me 'Are you accusing me of being a junkie, or are you accusing me of abusing them?'

In terms of what was being communicated, this ranged from advice about the dangers of using a product too often, as the two examples above illustrate, to exploring more about the clinical aspects of a customer's situation. This was most evident in the case of analgesics, and several pharmacists noted that they would routinely explore underlying conditions and symptoms, such as headache or muscular-skeletal pain, to try and advise customers best. These attempts to explore clinically relevant factors were also viewed as giving additional weight to decisions not to supply, and to, for example, refer the patient to a GP. Pharmacists also relied upon their therapeutic knowledge to communicate to some customers that a product was not appropriate and therefore could not be supplied. This was particularly evident for what were referred to a traditional medicines, such as kaolin and morphine, where there was no longer an evidence-based reason to use them:

"There have been cases where I've had a long chat with a person and refused a sale at the end of it. Mostly, it's for kaolin and morphine, because it's much easier to get around that. There are better preparations available. You should be using loperamide and Dioralyte[…] Some people stand there quite patiently, they know they are going to hopefully get it at the end of it, so will just nod their heads and spin a long story about grandpa says I should have it." Rachel

Still linked to pharmacist intervention was the most definite decision, namely whether to supply or not. As noted, this often involved obtaining more information and potentially advising the customer of the abuse potential of a medicine, and examples were given of denying a sale – which was described as the *'gatekeeper'* function by one pharmacist, but also of making supplies based on different factors. Some centred around giving customers the benefit of the doubt, if perhaps this was the first occasion, but as noted later, the indirect influence of the doctor appeared to be relevant, and so too, did the use of limited supplies. This occurred in some pharmacies in terms of simply monitoring that purchases were not too frequent and appeared to not involve a concern about signposting or gaining more information about the customer, as in the case of John's example above. In other pharmacies, however, there was a more conscious attempt to provide more frequent but controlled supplies, which was defended on the basis that the customer may obtain completely uncontrolled supplies without support from other pharmacies and so supplying regularly at their pharmacy was best. In one pharmacy in Scotland, the pharmacist noted:

"You can march out there and say 'no, you are not going to get any you are obviously an anorexic and I am not selling you any more and you bought a packet last week;. They will go to the pharmacy down the road. Do you actually think you have helped that person? In the old days, perhaps ten to fifteen years ago, I would have refused a sale. Just said 'No, you can't have it.' I don't see that now as particularly helpful […I] try and get a bit of a dialogue going here and […] if they come in for another small packet the next week, then that is your opportunity to have a wee chat." Vanessa, city, multiple, Scotland

In another city centre pharmacy, two pharmacists described their approach to continued supply:

"The Nytol man, I feel it is actually better to supply him, because in my mind, trusting mind, is that if I don't supply him then he will go elsewhere anyway. Whether he does go somewhere else even though I have supplied him, if I supply him then he knows what he is going to get and I think there is an almost mutual

> *[trust] – that's all he is going to get, and every so often I'll try to see how he's doing."* Rachel, city, independent, England

> *"I guess traditionally in pharmacy we kind of look at it as a big problem. I think some people think that they should police it [but] we should be trying to help them. Whether that is referral on to other agencies or other places […] or where the pharmacy can help, or help people to self-help."* John, city, independent, England

Rachel's response reflects a more immediate practical response to how to respond, but John's is more inspirational and views a greater pharmacy involvement, that moves away from a 'policing' or 'gatekeeper' function. This extract also leads into the next strategy referred to be pharmacists, namely various forming of signposting or involving others. There was considerable variation in understanding of what signposting opportunities there may be, with one pharmacist not being able to think of anything beyond an immediate pharmacy intervention. However, three other forms of signposting were referred to. The first was to suggest the involvement of the customer's doctor and this occurred either in terms of a customer being advised to do so, or in a more pro-active way, of instances where a pharmacist had contacted a patient's doctor to indicate concerns or let them know about OTC requests. This strategy was not unproblematic, however, as many pharmacists noted that in most cases, the customer's doctor was not known, and so advice was merely given to contact their doctor, or via a care worker in one case:

> *"An elderly lady who was very confused about her medicine and the only thing it turned out she was taking was sleeping tablets. Then she was asking for Nytol and various things […] I think the doctor must have spoken to her and I think it's sorted itself out […]"* Whilhemina

Clear in the above example was the difficulty in identifying who to contact, and also more accurate information about the patient. Such problems were particularly evident in customers of city centre pharmacies, where it was less likely that a customer would also be someone who brought a prescription in. In contrast, pharmacists in several rural pharmacies noted that customers had no choice but to bring their prescriptions to the same pharmacy where they made medicines sales and this meant a customer's GP could be identified. As Sharon noted, this led to a more specific clinical assessment:

> *"Well we have had people buying a lot of co-codomol. I have spoken to a patient and with their permission contacted the doctor and kind of raised my concerns that they are not having adequate prescription analgesics, say because you know these people were using them for pain, but they were coming in every couple of days because you can only buy a pack of thirty two. So yeah just raised that with the doctor and said do you know that Mrs Such and Such is using regular co-codomol. 'Oh no, I didn't know that'. So it is just getting the GPs to do a proper assessment of their pain and get them sorted out".*

The second was to consider the involvement of a specialist centre, where drug addiction was known to be managed. Pharmacists specifically referred to drug and alcohol action teams, or DAATs, but in all but one example, this represented awareness of them only. This may have been linked to many pharmacists' concerns that such services were not set-up for customers with OTC medicine problems, as John noted when reflecting on both GP and specialist referral:

> *"I suppose you can always send them back to the GP, but then they are not going to divulge to the GP, I don't think, so it would be better to send the, on somewhere, but if it's just codeine addiction or you don't know how much of an addiction, or a slight addiction in a way, then there's lots of*

different departments you could send them to [...] or is it too much to send them to you know a drug counsellor? It probably is. Then the drug counsellor probably wouldn't want to know because they have a lot more serious cases to deal with."

This extract that illustrates the perception that OTC abuse may be perceived of as a lesser problem than other forms of addiction.

The third form of signposting involved awareness amongst pharmacists at two pharmacies of the on-line website support and associated information made available by CodeineFree. However, in both these pharmacies, the signposting had been to provide written information produced by the website, rather than suggest a customer go on-line and visit the web site for help. As with specialist treatment centres, pharmacists appeared not to have much knowledge of the on-line support available:

*"The next step I guess would be asking them about whether they are, do they feel they are addicted to it. Which, I probably not at that stage yet, you know, I'm not comfortable and then it would be 'Do they need signposting to sort of drug misuse and that kind of thing'? [...] I'm not sure, the last time I looked on the Codeine Free website, I think it talk about things like that on there as well."*Ranjit

What was apparent in the interviews and is reflected in the above descriptions is of a considerable degree of uncertainty amongst pharmacists about what to do, over and above intervening directly in sales and making a judgment about whether to supply or not. This appears related to informational inadequacies – in terms of the customers and what pharmacists knew about them, and also in terms of what pharmacists knew about other options.

A final strategy mentioned by a minority of pharmacists was the occasional use of contacting other pharmacies to warn them of their suspicions of a customer who may be abusing a product. However, other pharmacists argued that this was not possible due to the time involved and the numbers of other pharmacies:

"Where do you decide where they are going to? I mean from here, there's pharmacies in all directions. I mean, I don't think it would be very practical really." Whilemina, independent, rural, England.

4.6.3 Views of medicine counter assistants

Pharmacists were very supportive of their staff, and praised their ability to oversee the volume of medicine and other sales in their pharmacies. There was recognition that they undertook an important surveillance role and were able to bring to pharmacist's attention, suspected concerns about, almost always, increased frequency of purchases. Training was identified by several pharmacists as being important, either by themselves, in independent pharmacies, or by more formal company training activities.

Pharmacists varied in the degree to which they wanted to oversee OTC medicine sales, however, with some arguing that the volume of other work they undertook, such as dispensing prescriptions, meant this was not possible, and others arguing that proper training should enable staff to make responsible sales and only alert pharmacists if there was a problem. Others, however, preferred to be more involved, as Ranjit noted:

"I think the assistants, certainly in my experience in here, they are quite clear on, I hope, what is expected of them. I like to, not oversee but overhear, what is going on […] but they are very good, because they are here on a daily basis, as opposed to myself. So they spot people, and they will say to me 'He or she came in on Monday, it's now Thursday and they are wanting some more'. So then it's up to me to go out and say 'Look you know it has been noticed that you came in' and have a brief chat with them."

4.6.4 Medicines

The same four broad product groups were identified by pharmacists as in the MCA interviews and the wider literature: codeine-based products, sedative antihistamines, laxatives and stimulant decongestants. However, pharmacists referred much more to liquid opioid-containing products, although for some this was to highlight the changing trends in availability and requests. It was widely recognized that these products and formulations, which included codeine linctus, Gees linctus, Kaolin and morphine and several proprietary products were previously abused but had since been removed from supply in pharmacies:

"Traditionally, it was codeine linctus and what was it? Collis Browne mixture and these sorts of things. They had codeine or morphine in. Kaolin and Morphine was the other thing we all used to go 'Oh, dear can't have any more of that.'"

However, requests were still made by customers, particularly for kaolin and morphine, although this was argued to be related mainly to misuse of the product by older customers. As well as references to liquid opioid containing medicines, codeine- and dihydrocodeine-containing analgesic were also frequently mentioned. These included generic descriptions, such as co-codamol, through to brands such as Solpadeine and Nurofen Plus. One pharmacist noted, that more recent products to treat migraine, such as Imigran, could be subject to misuse.

Pseudoephedrine was recognised as being a problem, but this appeared to elide actual experiences of pseudoephedrine being abused with the change in legislation about it's supply and heightened awareness of its *potential* for abuse.

The specific branded product, Nytol, was mentioned by many pharmacists, in terms of its misuse and abuse potential as a product to aid sleeping.

4.6.5 Perceptions of customers

Pharmacists, like MCAs, appeared to hold various assumptions about customers, and there was a sense that certain customers would use a variety of tactics to obtain supplies of medicines. These included sending in other people to make purchases on their behalf, lying about who a medicine was for, or for what use, and there was a perception from several pharmacists that some customers had '*rehearsed*' their responses in such a way as to allow a sale to go ahead. Linked to the previous issue about a lack of information and also the problem of a customer reacting negatively, was a difficulty, however, in knowing if and how to challenge a customer's response. Several examples

were given of patients denying taking other medicines, but where a pharmacist clearly knew the customer was also a patient, as the following example indicates:

> *"There was a regular methadone patient that came into the pharmacy he hadn't actually presented with a prescription for a few days. He'd been without and he came in and asked for some Kaolin and Morphine, told we didn't have any. He went through all the morphine containing products that you can purchase over the counter and so I asked him 'are you on any other medicines at all? And he said 'no' I said, 'are you sure about that, because you get a prescription here. I can go and look at your records now. He said 'no I'm not on anything else. So in that instance I did ring the prescriber. Just to let them know that he was trying to make a purchase of an opiate based medicine and probably needed them to get in touch with him."*

Several pharmacists referred to customers in general as lacking knowledge of the dangers of medicines, and suggested that this may be problematic in terms of them misusing or abusing a medicine.

4.6.6 Problems

Pharmacists identified a number of challenges, including some already addressed in this section such as a lack of information about customers and a lack of time to deal with problems. Several others emerged from the interviews and these included challenging customer requests, commercial conflicts, the retail environment and medical authorization.

Challenging customers was identified by all the pharmacists as being potentially difficult. Reasons for this included customers' anticipated negative reactions to being given advice or refused a purchase, and linked to this, a concern that the pharmacist may be accusing them of abusing a product, and creating a situation in a shop environment where other customers could observe it. As Vanessa noted:

> *"So telling somebody that they are addicted is really quite awkward. Which it is, even for a pharmacist to say, 'and by the way, madam [laughs], this is your third packet this week, and you can't have any more.' It is quite difficult."*

Unlike the MCAs, however, the pharmacists did not appear to make inferences from customer responses. The commercial nature of the pharmacy shop meant that consultations were often not in private and this meant any negative reactions from customers were visible to other customers, to the embarrassment of the pharmacist. For one pharmacist, this was more of a problem in her smaller, rural pharmacy, with many regular customers:

> *"In some ways it is hard to deal with people who you know. I wouldn't say more intimately, but you know them as part of the community [and] because we are a small community if there is anyone else in the shop and you are sort of going and saying, 'No I am not happy to sell you that', you do kind of get other people looking. So you do have to be sensitive to that sort of issue, but perhaps if I were working in a Sainsbury's supermarket or something, perhaps I wouldn't be so worried about it."* Sharon, Wales

Another issue was that relating to medical authorization, wherein pharmacists described customers who had requested medicines and, when challenged, stated that their doctor was not only aware of their use, but did not consider it a problem. As Tania noted:

> *"There was a gentleman this morning actually, who purchased some Nytol, and I asked him if he was on any other medicines and I know who he is, because I do his prescription and he said 'no' and his hand was shaking as he gave me the money. He said 'My doctor says it's all right, I only take half a tablet and I won't use it for longer than a week […] so I authorized the sale […] so I have got no say in it. It does put you in a difficult situation."*

Similar examples were cited by other pharmacists and there appeared to be a passivity and view amongst these pharmacists that they could not challenge the authority of the doctor, even when communicated indirectly through the patient as a customer.

A number of commercial issues were raised and these included tensions for those employed by larger organizations that promotional activities could conflict with their professional views. A common example given by several pharmacists related to promotions for codeine-containing analgesics, and where the company had instructed pharmacy branches to display material and set prices in a way that the pharmacist felt was inappropriate. In both these cases, pharmacists were concerned but felt unable to challenge the marketing and passively accepted them:

> *"We do keep Solpadeine in stock and I just feel bad about sort of putting them up as you know this month's marketing. I don't know if you are familiar with [the company] but they have counter packs, counter display units and they will say 'Put Solpadeine in there'. They are pushing it in people's faces or Paramol or whatever. I would be in trouble if I didn't do that marketing […] I don't know how much attention people pay to them but it just feels like the wrong message to be sending but we do it anyway."* Sharon, rural, multiple, Wales

A similar concern was expressed by Ranjit:

> *"I mean we have had promotions on Solpadeine products, particularly the Solpadeine soluble, when they used to be in the sixty pack and yes, I did, you know my colleagues and we had sort of a discussion and we were a bit uncomfortable but we never did anything about it."*

Another pharmacist felt that the trend towards medicines being displayed more openly in clear perspex shelf covers encouraged a perception amongst customers that all medicines were readily available.

Perhaps the most significant problem relating to the pharmacy environment was the ready access to different pharmacies for many patients. This had two different concerns. The first was that this was sometimes used by customers to make demands of a pharmacist, by claiming they should be supplied either because another pharmacy has done so, or they will visit another pharmacy with their custom if refused. The second links back to the initial point raised about a lack of information about customers in terms of where else they might be going and of a concern that it was not possible to monitor the use of medicines by customers if they could freely visit other pharmacies. Of interest was that the locum pharmacist interviewed and also other pharmacists who had been locums in the past, or who covered different pharmacies, had identified the same customers in different pharmacies:

> *"so they're coming in once a week or more than that and quite often going to a number of pharmacies, and I've been able to pick up on that, with being on relief in different shops."*Rebecca, relief manager,

5 DISCUSSION & RECOMMENDATIONS

In this final chapter, the results are briefly summarised and considered in relation to the three groups of participants. The study findings are also reviewed in the context of the original aims of this study. The significance of this current study and its relationship to previous research are then considered, particularly in terms of the unique data generated from this study relating to identity, typology, treatment, medicines involved and definitions. In particular, the theme of the 'respectable addict' will be developed in terms of a concern about identity, as well as reflection on a number of emergent tensions, including those between:

- Protecting individuals from the potential harms of medicines whilst ensuring convenient access,
- Viewing an OTC medicine as less harmful than a prescription medicine, but still capable of causing addiction,
- Reconciling very different types of OTC medicine addiction based on significantly different levels of consumption.
- How to provide addiction services to a 'hidden' and secretive group of individuals who perceive themselves to be respectable and professional.

It is argued that to some extent the very nature of OTC medicines may explain some of the findings and, for example, that since OTC medicines are often lower strength and consumed in smaller amounts in some cases than prescription medicines may explain why health care professionals view them as a lesser problem. Furthermore, that they are chosen because they are available in pharmacies that do not record personal details and hence facilitate the hidden nature of this addiction. This chapter ends with a number of recommendations, based upon the results in this study and a brief conclusion is offered.

In relation to those with experience of OTC medicine addiction, this study has revealed that this occurs in three different ways for individuals, ranging from doses below the maximum recommended, those slightly above recommended maximum doses, to considerably higher dose addiction. Codeine was involved in almost all cases, but occasionally other medicines. Shared characteristics of all types of addiction were the use of the medicine for non-therapeutic effect such as the 'buzz', calming or sedative effect of codeine. A complex relationship with prescribed medicines existed, and genuine reasons were present for initial use of an OTC medicine, except in two cases where intentional abuse was planned. The 'respectable addict' emerged to describe the identity presented by those affected, who often continued to be employed, and who viewed themselves as informed, intelligent, requiring anonymity, and very different from stereotypical substance misusers. Treatment and support options included on-line support, self-help, GP involvement, specialist drug services and narcotics anonymous. On-line web sites were used by all participants with OTC addiction experience but interaction and benefits ranged from it solely confirming the problem, to obtaining support from others, to personal treatment plans. The role of pharmacists and staff was sometimes praised but more often viewed neutrally, as being unable to prevent sales occurring in the large range of UK pharmacies, using simple questioning. The internet was recognised as an emerging issue, and two individuals

reported obtaining relatively unrestricted supplies but most affected by OTC abuse raised safety concerns about internet medicines.

The wide range of stakeholder groups provided different insights and backgrounds but many common themes. Interviews revealed concerns that the scale of the problem was not known and may be difficult to determine given the hidden nature of this group, coupled with definitional issues Emergent themes included issues around products involved, the scale of the problem, treatment, internet supply, views on pharmacists, and policies. The medicine referred to most frequently, and for some the only medicine associated with OTC medicine abuse, was codeine. Like those with direct experience, and also pharmacists and MCAs, the majority of stakeholders were in favour of continued availability overall but emphasized the need to raise awareness and understanding amongst the public and health care professionals, and to improve treatment options. These were linked to concerns about the inadequacy of formal, evidence-based treatment options. Stakeholders held mixed views about pharmacists and their role, and viewed the internet availability of medicines as a currently small but significant future issue. There was evidence of co-operation between regulators, manufacturers and those representing support groups.

For those working in pharmacies, OTC medicine problems were often referred to in terms of the phrase abuse rather than addiction and were focused on the type of medicine and the frequency of purchases overall. The *frequency* of purchases by customers appeared to define who MCAs considered to be abusing an OTC medicine, reflecting a monitoring and surveillance approach. A range of products were implicated and referring customers to pharmacists was a key activity in this area, which avoided confrontation. Pharmacists identified a wider range of medicines as being abused, but appeared to be uncertain about signposting options and were often not aware of how and where to refer them. Many identified the lack of information about customer's medical and current medication history and use of other pharmacies to be a key barrier to doing more. Pharmacists could be grouped into those who were negative about pharmacy involvement in supporting OTC medicine abuse or addiction, and those who, despite current problems, felt pharmacists could do more. Both pharmacists and MCAs recognised that OTC abuse was facilitated by having many different pharmacies that did not communicate with each other.

5.1 Comparisons between three groups of participants

The data presented in the previous chapter has indicated a number of areas where the three distinct groups of participants overlapped but also contrasted. Several similarities were apparent across the results, including views about availability of OTC medicines, the internet, the paradigm medicine involved, treatment and the type of individual who may be affected. A striking finding was that all three groups of participants were in favour of the continued availability of codeine-based OTC medicines along with others that may cause addiction overall. This is explored further below but it is telling that not just those from particular positions, such as pharmacists and those representing manufacturers, who might be thought to support their availability, but also those with experience of the associated harms – based either on being personally affected or being involved in treatment were in favour, overall, of continued availability. Similarly, the internet was regarded by both the stakeholders and those with experience of

OTC medicine addiction to be currently not a significant problem. However, concerns were identified about the lack of regulation and safety-related concerns about products available. One interesting similarity concerned the type of individual associated with OTC medicine addiction, and the stakeholders often referred to those affected in terms of their normal outward appearance and social position, and this was broadly the case for those who participated in this study. Codeine appeared to be the paradigm medicine in relation to OTC medicine addiction and was identified in all the participants with experience accounts and many stakeholder interviews. Pharmacists and MCAs tended to describe a range of medicines, although codeine was often mentioned, but other medicines appeared to have heightened significance, such as pseudoephedrine. This was of course mentioned by several participants with OTC medicine addiction but arguably the concern for pharmacists had arisen due to the high profile change in pack sizes, following MHRA guidance. Views about treatment and support also appeared similar in many instances and, for example, both stakeholders and those with direct experience of addiction perceived there to be a need for better services. That those affected did not consider pharmacists to be a possible source of help was not unsurprising given pharmacists' uncertainty about how and where to signpost in many cases.

Differences between the groups arose variously and included the definitions and terminology used and views about the pharmacy control of OTC medicines. Those with direct experience and also several stakeholders – particularly those involved directly with individuals – specifically used the terms 'addict' and 'addiction'. This could be contrasted significantly with the terms misuse and abuse used by some of the academic stakeholders, for example, and also pharmacists and, as noted previously, the literature more generally. A further contrast was identified in relation to pharmacy experiences, with those working in pharmacies and especially the MCAs presenting accounts that suggested successful surveillance and identification of customers, whereas those with direct experience presented relatively unproblematic accounts of obtaining medicines. That they described using many different pharmacies and had prepared responses to pharmacy staff questions may explain this disparity in accounts.

In the next section, the significance of the findings of this study is considered in relation to the extant literature described in chapter 2 above on page 2.

5.2 Comparisons with other OTC addiction literature

This study has been argued to address the almost complete absence of qualitative approaches to understanding OTC medicine addiction which was apparent in much of the previous research in this area. Using such an approach has revealed several unique insights as well as others that support other findings in other studies. A key issue that relates to the literature regards the definitions of the problems and specifically the emergence in this study of the term 'addiction'. This may be argued to perpetuate the conflation identified by Akram (2000) of different types of medicine consumption – such as misuse and abuse – but in defence of its use in the study, it was the term specifically used by those with direct experience. However, this study did identity two instances of participants who set out to exploit an OTC medicine and this may be argued to conform to the definition of intentional 'abuse' advanced by Temple (1996 and Wazaify & Shields (2005) amongst others.

As noted earlier, there has been a trend away from the use of the term addiction and in particular 'addict' to avoid issues of stigma (Reay 2009; Dean & Rud 1984; Erickson & Wilcox 2006) and also shame (O'Connor et al. 1994). Linking to the broader literature reveals the use in DSM-IV (American Psychiatric Association 2000) of both the terms abuse and dependence, which reflects a distinct, orthogonal relationship between pharmacological dependency and broader social, legal and psychological abuse (Hasin et al. 2006). Abuse in this sense is clearly broader than that used in some of the OTC medicine abuse literature, which uses it only to indicate experimentation or exploiting side effects. There are also lay perspectives on the terms and the perception that addictions can occur for many activities (gambling, sex, shopping) and may occur for long-term use of medicines as Britten (2008) notes;

> "*The terminology can lead to misunderstandings. For example it is clear that lay understandings of the terms 'addiction' and 'dependence' extend beyond the pharmacological meanings of these terms. Lay people express fears about becoming addicted to antibiotics, drugs for epilepsy, hypertension and rheumatism as well as tranquillisers and other psychotropic medicines."* (Britten, 2008 p.47)

The issue of definitions in this area appears to be unresolved, and this is illustrated by recent exchanges in relation to the choice of either the term 'addiction' or 'dependence' in substance misuse disorders in the DSM-IV (Erickson & Wilcox 2006; O'Brien et al. 2006). This study suggests that addiction is a relevant term and, as section 5.5 below indicated in relation to the rival identity claims and the 'respectable addict', participants did not automatically view it as stigmatising in the sense of all addictions. It is interesting to note, however, that despite this distinction, several participants in this study did refer to a sense of 'shame' in relation to their addiction and this is recognised in the addiction literature (Dean & Rud 1984; Wiechelt 2007). As Wiechelt (2007) notes, the relationship between shame and addiction is complex and potentially cyclical, as both pre-disposing individuals to addiction and being a result of addiction itself. It may also be linked to issues identified in this study such as control over individual's lives and consumption, as Wiechelt notes:

> *"In the process of developing the addiction, the individual feels increasing shame and humiliation associated with their loss of control."*(Wiechelt, 2007, p.403)

This may also have implications for the management of OTC addiction, in providing health care professionals and those providing support further insights into the emotional experiences associated with OTC addiction.

This study also confirms the variation in the type of medicines involved and reflects very different trends in the UK as compared to, for example, the USA. A key one, for example, was the lack of any mention of products such as dextromethorphan in this study except for some academic stakeholders, and certainly no direct experiences were reported. In contrast to qualitative studies such as those by S Nielsen, J. Cameron, & Pahoki (2010) and Peters et al (2007) which focused singularly on codeine and dextromethorphan respectively, this study did not impose such as restriction. As a result, examples of addiction to a range of medicines were identified and, although this was almost always codeine, dihydrocodeine was reported in one case, as well as pseudoephedrine and sedative antihistamine-containing cough medicines and sedatives. This matches three of the four broad categories of medicine identified as being of concern in other empirical studies (Orriols et al. 2009; Matheson et al. 2002). Laxative use was identified in

stakeholder accounts but due primarily to the recruitment methods in this study (see section 5.6 below), direct experiences of laxative addiction were not reflected in this study.

In relation to the doses identified in this study, these reflected variations seen in other studies (Frei et al. 2010; Orriols et al. 2009) supporting claims that problems can occur at relatively low doses. This study identified some serious adverse health outcome as a result of the addiction, such as gastrointestinal haemorrhage in one case, but the absence of such adverse events in other accounts in this study may reflect both the use of lower doses in two of the types of addiction, and also the use of codeine alone in liquid form in earlier accounts. This may be contrasted with the emergency department admissions cases identified by Dobbin & Tobin (2008), Frei (2010), Nielsen, Cameron, & Pahoki (2010) where morbidity was usually associated with much higher doses.

The qualitative nature of this study also meant that it was possible to explore not just the experiences of those with direct OTC medicine addiction experience but also more depth of understanding about pharmacists that were not possible in previous, often quantitative survey method, studies. Of particular interest was the issue of the uncertainty amongst several pharmacists about what to do and how to signpost individuals, coupled with concerns about the lack of any information about customers visiting pharmacies. Attempts to explore ways of recording OTC medicine sales have been attempted in the past, and included the identification of links to dispensing computers (Cooper 2007b) and use of electronic patient records (Cooper 2007a). Whilst this was occasionally referred to by stakeholders, and would provide pharmacists with the information they currently lack, this study reveals that there may be considerable opposition from individuals, given the reluctance identified to have this problem recorded formally. The unique inclusion of MCAs in this study adds a further perspective not considered in other research in this area, and this reveals further details of how OTC medicine sales were undertaken, particularly in the areas of surveillance and referring on to pharmacists. It complements other research which, like the concerns raised in this study about the inadequacy of simple questioning protocols, that there are more complex types of interaction in pharmacy encounters (Banks, Shaw & Weiss, 2007). The other key qualitative study identified in the literature (Nielsen et al. 2010) did identify findings that were strikingly similar to this study, but also important differences. Similar findings emerged in relation to a complex understanding of the similarities but also differences between OTC medicines and illicit and also prescribed medicines amongst those affected, and the identification of similar pathways to addiction and codeine-related harms and a broadly negative perception of pharmacy involvement from those affected. An interesting and key difference, however, that that whilst a typology of three different kinds of use was also proposed, only two of these types corresponded with the three in this study. In the Australian study, there was therapeutic dependence (characterised by not exceeding the maximum dose), non-medical or recreational use (to exploit euphoric effects of codeine), and high dose dependence (characterised by serious adverse effects, rapid escalation and progression from therapeutic use). Of interest in comparing the two studies was that the first and third types are very similar but Nielsen, Cameron and Lahoki did not specifically identify the second category of addiction identified in this study, involving slightly higher than recommended doses, and their second category did not involve quantity but reasons for use. Arguably in the present study, the second type of use identified in the Australian study – involving those who sought to exploit a side effect – was identified for *all* three types of use, with the buzz of codeine

being frequently reported, as well as sedative and calming efforts. In addition, the two individuals who deliberately set out to experiment with an OTC medicine in this study were grouped into type III addiction, involving significantly higher doses.

5.3 Context of study aims and objectives

This study had six specific objectives in relation to OTC medicine addiction and the data obtained has informed all of these. The first and most important objective was to explore individuals' personal experiences of OTC medicine addiction and this was been achieved in terms of an extremely detailed account of the different initial uses of medicines, symptoms involved, types of medicines described, typology, treatments and where supplies were obtained from.

The second objective was to explore the impact of the internet and this has been seen to be considered a relatively insignificant medium for supply, both for those with experience of OTC addiction and key stakeholders. Concerns were raised about the quality of internet medicine and the internet did appear to be used as a source of information and support. For some stakeholders, there were concerns that information about medicines and addiction could lead to experimentation but for participants with direct experience, this often involved searching about medical symptoms or obtaining on-line support.

The third objective was to explore the relationship between misuse and abuse and this study has revealed a different interpretation for the main participant group in terms of the term ‘addiction’ which did not involve specific reference to misuse, abuse or dependency. Two examples of individuals intentionally seeking to experiment with a medicine from the outset were reported, which has been suggested in the literature. No participants who were addicted to illicit substances and were topping up on OTC medicines were reported in this study, although the design relied upon those visiting the two UK internet support groups. However, occasional pharmacist comments suggested this may still be occurring. A different design, involving for example recruitment from a specialist addiction service may have revealed different insights in this respect. Regarding the terms misuse and abuse often used in the OTC medicine literature, this appears to involve awareness or intentionality on the part of the individual, with misuse involving a lack of awareness or unintentional problems in use, whereas abuse appeared to involve the intentional seeking of a specific effect. In this sense, the participants in this study appeared to describe abuse, since they all at some stage in their medicine use described the positive effects of a different property of the medicine from that originally intended, and were aware of this. What appears less clear is if there was a definite misuse stage, but it was evident that a genuine use and initial medical issue or symptoms were evident in almost all cases. As well as the term ‘addiction’ and ‘addict’ being chosen because this reflected what the main participants in this study referred to themselves and their situation, a term such as abuse was rejected since it appeared to involve not just a pharmacy-based definition, as above, but also a diagnostic one, based on criteria such as the DSM-IV. Referring to this, it was evident that participants did conform to some of the criteria for abuse, in their OTC medicine use affecting other activities for some, and involving significant amounts of their time, and also dependency, in the sense that withdrawal symptoms

were described, as well as tolerance developing, for example. However, as noted, the aim in this study was not to use specific clinical diagnostic criteria as either an inclusion criteria for participation, or as an analytic framework. One additional and related point was the recent emergence of the term 'pseudoaddiction' in the literature (Weissman & Haddox 1989) which was identified in cases where medically initiated pain medication and inadequate control of pain resulted in increased requests for supplies, and issues such as clock-watching. This was identified in several accounts in this study – with those with direct experience, occasional pharmacist concerns and some stakeholders - and illustrates the broader concern about the adequacy or otherwise of pain medication for some individuals. This has been identified in terms of increasing public understanding and the British Pain Society developed a leaflet specifically to provide additional information for pharmacy customers (see appendix 7.6 below). Whilst this study provides isolated but further evidence of such symptoms occurring, pseudoaddiction has, like much of the terminology in this area, been the subject of critique. For Bell & Salmon (2009), for example, pseudoaddiction risked '*reifying the distinction between the 'deserving pain patient' and the 'undeserving addict'* and was a complex set of claims that needed to balance moral claims to treatment with clinical perspectives.

The fourth objective was to consider the influence of pharmacists' changing roles but the relatively minor role that pharmacist and MCAs appeared to have in relation to OTC medicine addiction rendered this question mostly redundant. Pharmacists interviewed were opposed to changes such as remote supervision, but did not identify this as a specific OTC medicine addiction problem. The fifth objective was to explore the relationship between OTC medicine addiction and use of illicit substances and this has already been noted as not been identified in terms of the category of topping up, except for occasional pharmacist comments. However, it was apparent that some participants had used illicit substances in the past, and two of these had developed Type II addiction. A more significant and semantic link between OTC medicines and illicit substance use involved the general perceptions of individuals of who had direct OTC addiction experience. This is considered in the section on the 'respectable addict' below and was explored in section 4.3.6.2 above (on page 44) but involved these participants considering themselves very different from illicit substance addicts. The final objective was to consider the drivers for recent policy change in this area, and a number of issues emerged. There appeared to be evidence of communication and co-operation between regulators, manufacturers and internet-based support groups, but ongoing uncertainty about the scale of the problem, which was a fundamental problem in assessing the proportionality of policy-based decisions.

5.4 Tensions identified relating to OTC medicine addiction

As noted above, this study reveals a number of tensions in relation to OTC medicine addiction and these arise in at least five areas. Two arise in relation to the potential harms associated with OTC medicines and relate to balancing access for medicines for the public and the relationship between OTC and prescribed medicines. The majority of participants in all three groups in this study were not only in favour of the continued availability of OTC medicines, including those with addiction potential, but many often defended this with the benefits overall for most people in having medicines available to treat symptoms promptly. For most, the tension between possible harm and availability

was resolved in terms of the former, and this was often justified by noting that adequate information about risks should be available to individuals (although elsewhere in a minority of accounts, such warnings were considered ineffective). This reflects a classic liberal individual position, which can be traced back to John Stuart Mill's writing on the legitimate restrictions that may be imposed on individuals. Indeed Mill (1998) specifically referred to the control over medicines and, whilst framing his example in terms of 'poisons', he clearly sets out a defence for un-regulated access as long as adequate warnings were given:

> *"when there is not a certainty, but only a danger of mischief, no one but the person himself can judge [...] labelling the drug with some word expressive of its dangerous character, may be enforced without violation of liberty: the buyer cannot wish not to know that the thing he possesses has poisonous qualities. But to require in all cases the certificate of a medical practitioner, would make it sometimes impossible, always expensive, to obtain the article for legitimate uses."*

However, a tension always exists despite this liberal rejoinder, and this is reflected in the evidence-based approach used by the MHRA, for example, in informing policy on current medicine safety and efficacy data, using the expertise of groups such as the Commission on Human Medicines (CHM). The review of codeine is just such an example of this (Medicines and Healthcare products Regulatory Agency 2009). The related tension about the harm of OTC medicines, is that which occurs primarily in relation to comparisons to prescribed medicines. In particular, the potential concern that notwithstanding the above – and that some risks are permissible – it is not unreasonable to consider OTC medicines to be broadly less likely to cause harm than those on prescription. Although the details of medicines regulation is complex (Britten 2008) and involves decisions about diagnostic issues as much as the inherent potential for some medicine to cause harm, comparisons between prescribed and OTC medicines are inevitable. That identical medicines are available but in different doses may contribute to this perception (such as the different licenses doses of codeine permitted in OTC medicines compared to prescription). It is argued that this distinction contributes towards an overall perception that OTC medicines are less likely to cause harm (Raynor et al. 2007; Bissell et al. 2001; L. Hughes et al. 2002). The tension is that this study and much of the empirical data described in chapter 2 above *do* indicate that OTC medicine-related harm, including significant morbidity, can occur. This represents an on-going concern about how to inform the public that OTC medicines – and particularly those that have addiction potential – can result in harm to individuals.

A further contextual point relating to this second tension about the addiction potential of medicines that are perceived to be relatively safe concerns the broader medical anthropological understanding of medicines. Specifically, this involves recognition that there are complex relationships between medicines and individuals and that to some extent medicines and those who consume them are mutually constructed (Whyte et al. 2002). This draws on related work to medical devices such as inhalers (Prout 1996) and develops concerns that individuals can be changed by material objects (like medicines) and vice versa, thereby challenging a presumption that material objects are neutral or unable to exert powerful influences over individuals. Viewed from this additional perspective, and notwithstanding the recognised harms identified for several in this study and the literature more generally, OTC medicines *qua* non-prescribed and non-illicit medicines of often reduced strength do have the potential to affect individuals in significant ways and also take on heightened significance themselves.

The third tension concerned the definition of the three different types of OTC medicine addiction identified in this study (based on different doses taken) and the belief amongst individuals that these were all 'addiction'. In particular, with the first and second type of addiction identified, do sub-therapeutic or slightly excessive doses still represent addiction, if the doses do not escalate over time, and in some cases only amount to doses on a less than daily basis? Answering this, one issue is that for all three groups, non-clinical uses of the medicine were sought in all cases (such as the 'buzz' or relaxing effect of codeine, rather than its analgesic property) which suggest some issues, and another is that relating to the loss of control and the broadening definition of addiction in terms of this (Reith 2004). This latter point is considered in more detail later.

A fourth tension relates to surveillance of OTC medicine sales and particularly the monitoring and recording of sales of those medicines which may cause addiction. For pharmacists, this would satisfy their concern that customers are currently able to make multiple purchases from different pharmacies almost with detection, and allow them to make more informed decisions about supply. For those who are addicted to an OTC medicine, however, this study suggests a considerable resistance for many to any form of monitoring and threat that information about them will be recorded and stored. This is considered in the later recommendation section.

The final tension to consider is that relating to the hidden and secretive group of individuals who perceive themselves to be respectable and profession, and specifically how to reach such individuals and provide services and support for them. In this respect, individuals with OTC medicine addiction represent a hard to reach group, who require support and treatment often but who do not engage with health care services. Issues identified elsewhere about fear of their problem being medically recorded, or made public appear central for many, and this may also explain the attraction of internet-based support involvement. As Britten notes about such self-groups more generally, there is a potential for membership of such groups to threaten *'people [who] many want to keep their disease status hidden or at least marginal to their identity'* (Britten, 2008, p.153). However, the unique nature of internet support may be important: and:

> *"It is possible that one of the appeals of internet-based groups is the possibility of separating one's life as a member of a disease community from the rest of one's life.'* (Britten, 2008, p.153).

The findings of the APPDMG (Reay 2009) recommended that such on-line groups be given greater recognition and support. A consequence of this hidden and secretive identity, except for internet involvement, is that health care professionals may not gain an understanding of such individuals and hence may not be able to provide the most appropriate services. Viewed in this way, the involvement of the medical, nursing and pharmacy professions amongst others may be paradoxical.

5.5 The 'respectable addict' and identity

A key emergent theme from this research has been what was termed the 'respectable addict' to describe participants. As noted previously (4.3.6.2 above), participants with direct experience were spontaneous and candid in their use of the terms 'addiction and 'addict' to describe their situation or themselves. This occurred for many through

awareness and insight into their continued use of a medicine, experiences of withdrawal and use of a medicine for reasons other than initially used or licensed. Several others factors appeared to support participant's sense of themselves as being addicted. The first was the influence of the two internet support groups, and the confirmatory function that they appeared to provide for many participants. Many accounts involved reference to participants with OTC addiction experience describing internet searches and finding websites such as Overcount and Codeine Free. Another was the experiences of those with alcohol, in one of two categories. Some openly referred to alcohol dependence in the past, and recognised in their OTC medicine use similar patterns which confirmed addiction. Others referred to what they considered to be harmful levels of, usually past, alcohol consumption, and this again confirmed in their OTC medicine use, a sense that this was an addiction. A final substantiation of the 'addict identity' was raised by several participants when they recognised that codeine was an opiate, and hence no different in terms of its pharmacological effect than morphine or heroin. Although such insights involved some errors and misunderstanding, the similar nature of all opiates meant that codeine-based medicines were capable of causing addiction. A key contrast was made, however, between the consequences of OTC medicine addiction and that related to stereotypical substance or alcohol misuse for many. These were often associated with chaotic individuals, who were visibly different from them, and who carried a significant negative social identity. For some, this was confirmed by attendance at specialist addiction centres, where other clients were observed and considered very different from OTC medicine addiction individuals. Several comments were also received that treatment options that were routinely used for illicit opiate problems (such as methadone and buprenorphine) were not appropriate for OTC In addition to the emergence of an addict identity and the contrast with perceptions of stereotypical addiction, were a range of explicit professional and other social identity claims. These were often articulated in terms of intelligence claims, or professional and successful employment and social standing. Linked perhaps to the above point about the pharmacological knowledge espoused by several, there were attempts in participant interview to demonstrate knowledge and understanding of the issues. This appeared to represent a control or mastery of their situation for not only those who were not currently experiencing OTC medicine addiction but for some who were still taking medicines. Again, visual differences were invoked, such as participants being well-dressed, or presenting themselves in a way that would not arouse suspicion. These three rival identity claims are summarised in Figure 3 below and there were degrees of overlap in various aspects

For example, the rival professional and addict identity claims shared features such as the need to project and manage a respectable appearance, to keep addiction hidden to avoid disrupting the professional identity, and to issues around family and disclosure to them in particular. It is argued that from this inter-relationship, the concept of the 'respectable addict' or 'respectable addiction' legitimately appears to reflect a unique type of experience and individual that shares characteristics with addiction and perception of a 'normal' social identity. In developing this concept of the 'respectable addict' as a distinct identity, the aim is not to cause further proliferation of the range of 'addictions' and those affected, as per Hacking's concern about 'making up people' (Hacking, 1987) for example and the widening remit of types of addiction, such as recent examples around activities such as gambling, shopping and sex (Erickson & Wilcox 2006; Reith 2004).

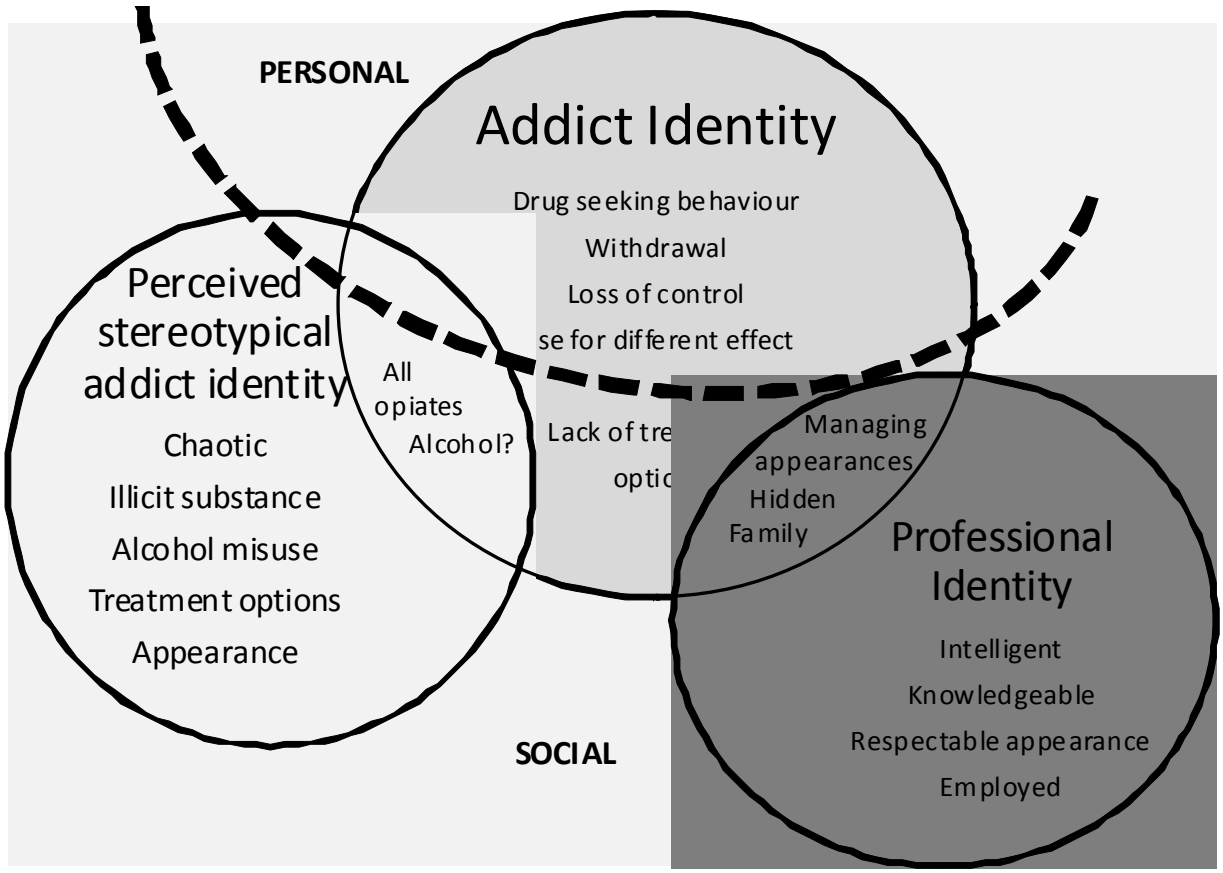


Figure 3 Different identity claims

Rather, it is possible to view the development of this term as being linked to treatment and support narratives, loss of control and also an explanatory role – and that all of these justify its use. In terms of narratives, McIntosh & Mckeganey (2000) (McIntosh J & McKeganey N 2000) note that recovery narratives may be important in defining how individuals come to re-define their own identities and his may be important in treatment. The issue of identity is also one often bound up in the context of treatment, particularly for other types of addiction and the development of this specific 'respectable addict' identity to accommodate overlaps but differences between the different identity claims may be important for treatment. For example, sociological perspectives on addiction treatment have explored Goffman's (1990) concept of the 'spoilt identity' to argue that the negative effects of addiction can eventually be seen as conflicting with those related to other aspects of an individual's lives – distinct from that addiction. This study suggests that the frequent identification of the respectable addict and both professional, intelligent and rival addict identity claims means that there is accommodation rather than antagonism between them. Related to this study and as noted above, the influence of the two internet support groups – Codeine Free and Overcount – may have a significant role in this process.

In relation to control, Reith (2004) has argued that the widening of the definition of addiction is linked to concerns about individual loss of control rather than the traditional concern about the absolute harm associated with a substance:

> *"Initially the figure of the addict was constructed as the outcome of the interaction between the properties of specific substances as dangerous and powerful, and the consumption patterns of certain disruptive social groups. However, along with the development of new techniques of governance associated with the shift to post-industrial, neo-liberal societies, 'addict identities' have increasingly come to be defined in terms of subjective, individual evaluations of* ***loss of control****."* (Reith, 2004 p.284) [emphasis added]

Such concerns about control were certainly identified in this study and appeared linked to issues of how to maintain a professional identity. Finally, it is argued that the emergence of this identity – the 'respectable addict' – the issues of respectable addiction is also explanatory and can be used, along with issues of control, to explain the perception of addiction for those, for example, consuming relatively small doses of medicines, in the first two types described in this study.

Offering a striking degree of overlap with the emergent identity concerns in this study, Rødner (2005) described the construction of identity amongst a group of drug users in Sweden. Her study identified individuals who clearly defined themselves and their situation as being different from some types of drug abuse. Rødner uses the term *'normalized drug use'* and although relegating this discussion to a footbote, defined this thus:

> *'The term normalized drug use refers to drug use by people who apart from their drug use lead lawful lives within the boundaries of normative expectztions such as having a job and being a student.'*(Rødner 2005, p.333)

These Swedish participants considered themsleves 'users' and not 'abusers' of drugs and this was explicitly linked to ideas, like Reith's above, about control, and also wider concerns about confidence. Clear in these interpretations was a difference between 'self' and 'other', drawing on psychological assumptions that can be traced back to Mead (1972) and a recognition of how individuals consider themselves to be understood by others. For Rødner, and of interest in this study, is that her data suggests focusing treatment and prevention on a model which views at least some individuals as striving to maintain control and free will relating to drug use, and to avoid a self-fulfilling prophecy of '*addiction styles of conversation.'*

In the final sections, limitations of the study are considered, followed by a number of recommendations and a brief concluding statement.

5.6 Study limitations

This study provides only a UK perspective on OTC medicine addiction and reflects the medicines, pharmacies, services and policies available in this country. However, many of the medicines available reflect those in other countries in Europe and Australia, for example. The sampling of participants with direct experience of OTC medicine addiction was purposive but represented a self-selecting group and therefore reflects only those who responded to

invitations to participate. Furthermore, sampling occurred through two internet support groups and this reflected individuals who had internet access. Finally, one of the internet groups focused on codeine and in the other, this medicine dominated too. The study design precluded recruiting participants with experience related to laxatives.

5.7 Recommendations

This study and the emergent data and themes presented have several implications for practice, policy and public in relation to OTC medicine addiction and also supplies more generally. These are summarised in Table 5 below (on page 104) and include raising awareness and improving treatment, which were concerns raised by many stakeholders explicitly. These are argued to impact upon a range of stakeholders and, for health care professionals for example, lead to a greater understanding of the different types of addiction (particularly those at lower doses which may hitherto have been regarded as unproblematic, self-manageable concerns). It is also argued that understanding more about the hidden and secretive nature of OTC addiction is important in terms of identifying individuals at risk who may benefit from interventions, treatment and support. Opportunities for doing this could occur variously through continuing professional development routes, awareness in under-graduate training, professional journal publications and through professional bodies. Raising awareness amongst consumers of medicines through continued use of warnings on packets, leaflets and advertising is argued to be necessary, as this represents a relatively low level of intervention proportionate to any inconvenience in customer choice. Arguably, such warnings could be considered for not only opiate-based medicines, but others such as sedative antihistamines and sympathomimetic stimulants such as pseudoephedrine. Whilst dextromethorphan appears to be a problem medicine in countries such as the USA, there appears to be no evidence as to its abuse in the UK. This study revealed that some participants did not notice warnings, so increased use of leaflets and other promotional media may also be warranted. However, it should be noted that despite many participants in this study stating that warnings on packets and leaflets should continue, there was also pessimism that this may not be enough in itself, and not be of assistance to those already affected by OTC medicine addiction. Furthermore, previous studies have suggested that OTC medicines are considered to be a lesser risk than prescription medicines (L. Hughes et al. 2002), and as Raynor et al. (2007) note:

> *"There is some evidence that OTC medicines (which do not need a prescription) are perceived as safer and that people are less likely to give priority to reading information about these medicines."* (Raynor et al., 2007, p.85)

Hence, considering a wider range of awareness-promoting strategies may be appropriate. One obvious suggestion is for pharmacy staff and MCAs to provide this, but, once again, the data from this study and others (Britten 2008; Salter et al. 2007; Nielsen et al. 2010) suggest that pharmacists' role in information provision may be variable and, for some, not required. There is also a need to evaluate such warnings in the context of addiction, to explore their effectiveness.

Improving treatment and support options was another key issue identified amongst stakeholders and those with direct OTC medicine addiction experience. Whilst there appear to be a range of treatment options (including

methadone and buprenorphine pharmacotherapy), other issues related to treatment such as health care professionals' awareness of the different treatment options will permit more appropriate referrals from ,for example, GPs and pharmacists. Research to explore the effectiveness of such treatments in the context of OTC medicine addiction are also required.

Identifying the scale of OTC medicine addiction remains a key aim which qualitative studies such as this were not able to address. Robust, well designed studies that can capture valid data about not just the extent of OTC medicine addiction in the UK and internationally, but also details of those affected, will be invaluable in making policy-based judgements about continued availability. Linked to this are two further forms of data collection: one is to explore the viability and, crucially customer acceptability, of recording sales of OTC medicines that may cause addiction. This would address the key pharmacist concern about the lack of information about customers and their purchases from different pharmacies. As noted earlier, however, this represents a tension between satisfying pharmacist's desire for information about other purchases and relevant clinical information (such as previous dependencies, for example) and respecting customer's wishes not to have their purchases recorded and their details made available. As Cooper (2007a) noted, public acceptability relating to the use of a summary care record in the use of medicine sales, as proposed in several countries, may be resisted in terms of concerns about confidentiality, privacy and surveillance. One other form of data that is collected concerns the substances that individuals report who present to NHS addiction treatment services. These can include not only illicit substances but also those relating to prescribed and OTC medicines. The National Drug Treatment Monitoring System (NDTMS) in the UK collects such data relating to OTC medicines, as it would be recorded formally, but such data is currently not collated or analysed (personal communication 2011). The National Treatment Agency (NTA) is currently exploring the possibilities of analysing and reporting this information and notes:

> *"The NTA and the Department of Health began work in the summer of 2010 to determine the scale and implications of the use of addictive medicine."* (National Treatment Agency 2010)

This represents a potentially important source of quantiative data relating to OTC medicine addiction, although important issues may be in adequately describing the wide range of OTC medicines available, as both brands and generic names (Gonzales, Brecht, Mooney, & Rawson, 2010 and see also (Matheson et al. 2002) and separating the recording of prescribed and OTC medicines, as was not apparent in some data sources, such as emergency department admissions in US, for example (Gonzales, Brecht, Mooney, & Rawson, 2010; Substance Abuse and Mental Health Services Administration, 2004)

Monitoring of internet sites that sell medicines is currently undertaken and a further recommendation is that this continue and to be responsive to rapid changes in technology.

A final recommendation is that there be continued collaboration and communication between different stakeholders. This was evidenced by collaboration over the addiction warning changes by the MHRA, with involvement of groups such as the PAGB and the internet-based support groups. This is a welcome activity, which permits a range of different views to be included, including those from regulation, manufacturer but importantly, the individual.

5.8 Conclusion

OTC medicine addiction in the UK centres on codeine and its non-therapeutic effects mainly stemming from usually genuine medical reasons for treatment, often with either initial or on-going opiate prescription supply. Stakeholder perceptions and direct experience suggest a secretive 'respectable' addict who may be receiving varied and sub-optimal treatment and support, from pharmacies that are often blamelessly unable to prevent addiction and limited internet purchases, which raise additional safety concerns for different participants. Continued availability of OTC codeine and other medicines was widely supported across all participants, to ensure the public had the ability to choose medicines based on information about possible risks. Raising awareness of OTC addiction and improving treatment and support options are key to managing this issue.

Table 5 Summary of Recommendations

Recommendations	Impact (or responsibility) upon:						
	Health Care Professionals			Public	Those already addicted	Researchers	Policy makers
	General Practitioners	Pharmacists	Specialist drug service staff				
Raise awareness of OTC medicine addiction/abuse	Need to recognise that addiction can occur with differing doses of medicines; to understand implications of opiate prescribing decisions (on-going and when stopping). Understand hidden nature of OTC medicine addiction.	Need to understand different types of addiction not just based on frequency and dose. To recognise hidden nature of OTC medicine addiction. Provide in-pharmacy information.	Need to recognise the different types of addiction, and particularly those who may be using relatively low doses.	Public need to be made aware of addiction potential of OTC medicines.	May help develop insight into personal addiction.	Study the impact of warning advice on packets and leaflets.	Continue to require codeine addiction warnings. Consider for other medicines (sedative antihistamines, pseudoephedrine) Consider other means of communicating risks.
Improve interventions and treatment and awareness of them	Understand treatment options. Appropriate referrals made. Consider pain management reviews.	Consider use of brief interventions. Know where to signpost.	To consider specific treatment needs of OTC addiction clients.		Successful cessation of OTC addiction.	Evaluate clinical effectiveness of compound opiate analgesics. Evaluate interventions in referring and treating.	
Identify the scale of OTC medicine addiction and study clinical harms						Robust quantitative UK & international studies needed. Study extent of harm caused by compound opiate medicine.	Make regulation proportionate to scale of the problem. Report OTC medicines in NDTMS data analysis.
Monitoring internet sites that sell medicines				Safe and appropriate supply of medicines	Safe and appropriate supply of medicines		Continue process of monitoring internet sites that sell medicines
Explore options to record OTC medicine sales		Ability to monitor frequency of sales accurately		Personal information recorded	Personal information recorded	Evaluate impact of monitoring on medicine use, & impact of recording	Consider feasibility of adding OTC sales to summary care record
Continued stakeholder collaboration							Ensure different viewpoints represented and mutual goals agreed

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7 APPENDICES

7.1 Interview schedules

Stakeholders

1. In what capacity are you or your organisation involved in this area of medicine use?
2. What is your understanding of the extent of the problem of OTC medicine abuse/misuse?
3. What current strategies are being used to deal with this issue?
4. In your view, what more could be done?
5. Are there particular areas of concern about OTC medicine abuse/misuse that you have?
6. What impact do you think the internet supply of medicines is having or will have on possible medicine abuse/misuse?
7. What role do pharmacists and pharmacy staff have in dealing with this issue?
    a. In your view, do you think they have the skills and understanding to identify and appropriately deal with possible OTC medicine abuse/misuse?
    b. What additional training could be given?
    c. Would co-ordination between pharmacies be of value? How achievable?
    d. Could electronic health records have a role in reducing medicine misuse?
8. Will developments within pharmacy in the UK such as remote supervision and the responsible pharmacist have an impact on possible abuse/misuse?
9. Do you feel that legislative change could have a role (prompt: restricting codeine-based medicine pack sizes, P to POM move).
10. Are you aware of on-line self-help groups? Do you feel they have a role to play?
11. Could you comment on the recommendations from the recent APPDMG
    a. Training for nurses and doctors (NB pharmacists not mentioned)
    b. Combating fraudulent on-line sites and use of RPSGB logo
    c. MHRA to reduce codeine product pack sizes from 32 to 18.
    d. More support for local and on-line support groups.
12. Do you feel that customers should still have access to, and be given a choice about using, medicines of potential abuse?

Overall, do you feel that the emphasis on tackling the problem of OTC medicine abuse and misuse should be upon high level (macro) policy change, local (micro) strategies within pharmacies, other approaches or combinations?

7.2 On-line invitations to participate in research

POSTED BY DAVID GRIEVE- OVER-COUNT PROJECT DIRECTOR

Over-Count is helping Dr. Richard Cooper, Lecturer in Public Health at
ScHARR, University of Sheffield, with a Research Project studying the problems associated with OTC addictions and abuses.
Dr. Cooper would like to speak, in total confidence, to anyone who has experienced problems with an OTC product, for use in the study.
Your experiences and identity would be treated as anonymous, under strict University Ethics code, and unlike media writers, he does NOT require your photograph !!

Could I urge anyone affected by problems taking an OTC product, to consider speaking to Dr. Cooper, as this is a serious study into the whole problem, and may help form policies for dealing with sufferers in future years.

You can email, phone or write to Dr. Cooper, using his direct contact details shown below.
Your participation would be really appreciated, thanks,

CONTACT DETAILS :

Dr. Richard Cooper
Lecturer in Public Health
ScHARR, University of Sheffield
Sheffield, S1 4DA, UK
0114 2220683 Email- Richard.Cooper@sheffield.ac.uk

Can you help with an academic study into OTC medicine dependency?

Richard Cooper is a lecturer at the University of Sheffield, and is researching problems related to over the counter medicine misuse and abuse in the UK. He has been conducting confidential interviews with those affected to help represent their views and experiences so that more is known and understood about this subject. If you are able to spare some time to talk by phone or in person, please contact Richard by email or phone 0788 993 2626 or 0114 222 0683.
Any help would be greatly appreciated by Richard and all responses are kept confidential and anonymous.

Unfortunately, Richard is unable to help with support enquiries.

7.3 Ethical approval

The University Of Sheffield.

Cheryl Oliver

Ethics Committee Administrator

Regent Court

Telephone: +44 (0) 114 2220871

Fax: +44 (0) 114 272 4095 (non confidential)

Email: c.a.oliver@sheffield.ac.uk

Our ref: /CAO

26 March 09

Richard Cooper

ScHARR

Dear Richard

Understanding over the counter medicines abuse and misuse in the UK

Thank you for submitting the above research project for approval by the ScHARR Research Ethics Committee. On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that the project was approved.

If during the course of the project you need to deviate significantly from the documents you submitted for review, please inform me since written approval will be required.

Yours sincerely

Cheryl Oliver

Ethics Committee Administrator

7.4 Empirical Literature

Authors	Study Aims	Design	Sample	Participants	Results
Paxton and Chapple (1996)	To establish numbers and kinds of people affected by OTC medicine misuse, medicines involved, pharmacists' concerns and policies.	Postal questionnaire (no details provided)	All 60 pharmacies in Northumberland, England in 1994	39 pharmacists (65%) responded	69% of pharmacists considered there to be some form of OTC medicine misuse in their pharmacies. Female customers were perceived to be more likely to misuse, and Gee's linctus,codeine linctus or tablets, kaolin and morphine and laxatives were the most commonly cited medicines involved. Most pharmacists had 'concerns' about OTC misuse and 62% of pharmacists reported having associated policies including pharmacist interviews, not displaying medicines and refusing sales. Around two thirds of pharmacies did not communicate with other pharmacies
Mattoo, Basu, Sharma, Balaji, & Malhotra (1997)	To study socio-demographic and clinical profiled of patients seeking treatment for codeine-based cough medicines in India	Observational case series; semi-structure interview. No pilot stated.	Patients seeking treatment in hospital addiction centre in Chandigarh in 2004-05	All 46 eligible patients identified from total of 126 opioid abusers participated	Participants with codeine based cough medicine dependency were all male, from mainly urban backgrounds (80%) and completed school education (85%). Initial use was most commonly through friends (89%) with 11% citing pharmacists or doctors as the source of their supply. Curiosity was the most common reason given for initial use (63%), followed by substitution due to non-availability of another medicine (22%) and treatment of symptoms (15%). Participants reported a range of pleasurable effects, including alertness, cheerfulness and subsequent drowsiness. 92% experienced withdrawal symptoms.
Hughes, McElnay, et al. (1999)	To investigate the abuse of OTC products in Northern Ireland	Cross-sectional postal questionnaire. One follow-up mailing Piloted, with minor amendments made	All 509 Northern Ireland community pharmacies in 1997	253 responses (49.7% response rate)	112 different OTC products identified by pharmacist respondents as being abused in NI, with mean of 6.8 products noted per pharmacist. Opioids were the most common group mentioned (on 878 occasions) and Kaolin & Morphine mixture was the most commonly named product (81.4%, n=206). Antihistamines were the next most frequently identified (364 times), followed by laxatives. Clients suspected of abusing in the last 3 months ranged from 0 to 700, with a median estimate of 10 and a mode of 6; 55% of such clients were considered regulars. No statistical link to pharmacy location and extent of OTC problem. Hiding products, contacting other pharmacies were reported as strategies to deal with the problem and when asked about pharmacists' role in OTC abuse, 67.2% considered referral to a GP appropriate, 40.3% to a drug and alcohol team appropriate and 64.4% felt pharmacists should be involved in a dedicated harm-reduction programme.
Hughes (1999)	To assess the attitudes of GPs regarding the appropriateness of OTC medication use by their patients	Cross-sectional postal survey. No pilot stated.	Stratified random sample of 500 GPs in Northern Ireland. One repeat mailing	202 GPs responded (40.7%)	Majority of GPs (97%) believed OTC medicines were valuable for self-limiting conditions. 91% were concerned about abuse/misuse potential of OTC medicines and 73.3% felt these consequences were as severe as prescription problems. Almost 80% of GPs felt they required training in such issues; increased communication between health care professional was identified.
MacFadyen, Eadie, & McGowan	To explore type of OTC medicines being abused & pharmacist attitudes,	Cross-sectional postal survey. 2 reminders, one follow-up survey sent in 1998. Survey informed by	All 110 pharmacies in one region of Scotland	Eighty six responses obtained	58% reported occasional and 31% frequent misuse, with more problems reported in urban than rural pharmacies. Perceived prevalence of misuse varied with 45% reporting only 1-2 patients per typical week, 21% reporting 3-4; estimated mean was 5.63. Nytol (79%), laxatives

(2001)	management and training needs.	unreported qualitative study		(79%)	(58%), paracetamol and codeine products (55%) commonest products involved. Frequent requests (100%), counter assistant concerns (78%), particular products (64%) and suspicious behaviour (45%) identified as alerting factors by pharmacists. Interventions always or often made by72% of pharmacists, using information provision, removing products from sight, communicating with other pharmacies and medical referrals. More support wanted.
Wazaify, McElnay, & Hughes (2002)	To develop a harm-minimisation model for identification and treatment of OTC medicine abuse/misuse by community pharmacists	Retrospective study of all queries and sales of OTC medicines recognised as having abuse potential (opioid, antihistamine, laxative)	8 pharmacies in Belfast	N/A	Over 7 weeks, average of 6.8 clients per pharmacy suspected of abuse, and 4.8 of misuse. Opioids (n=25),most commonly identified (and were most often requested by male clients), then antihistamines (n=11) and laxatives (n=5) (all requested by women).More than half (58.5%) of clients were regarded as strangers rather than regular customers.
(Matheson et al. 2002))	To identify 5 year trends in local misuse of OTC medicines	Two cross-sectional postal surveys in 1995 and 2000	1091and 1162 Scottish community pharmacists	864 in 1995 (79.1%) and 969 (83.4%) in 2000	Extent and pattern of misuse unchanged over period – 67.8% (n=586) in 1995 and 68.5% (n=669) of pharmacists considered there to be OTC abuse in their area. Nytol remained commonest product and was cited by around half of all pharmacists, then Feminax and Kaolin and morphine. Hiding products, registers of sales, increased pharmacist intervention identified as sales policies.
Pates, McBride, Li, Ramadan (2002)	To investigate pharmacist perceptions of OTC misuse, identify products used, alerting factors and strategies used.	Survey of all pharmacies in Welsh health authority in 2000	180 community pharmacies	161 (89%) responded.	66% of pharmacists believed there was current OTC misuse, 19% disagreed; mean of 4.5 attempts to misuse OTC product per pharmacy identified in previous month. Opioids most commonly suspected (57% n=217), then sleep aids (16%, n=61) and laxatives (10%, n=37). Frequency of request (85%, n-59), customer behaviour /state (11%, n=18) or appearance (11%, n=18) identified as alerting factors. Refusals or out of stock excuses commonest strategy (63% n=66), then counselling (32% n=33). Referral to GP, removing stock, monitoring or limiting sales also mentioned.
McBride, Pates, Reem Ramadan, & C. McGowan (2003)	To explore expert views on OTC abuse, current, future strategies and best practice	Modified 3-stage Delphi design using postal survey.	164 international experts	109 (66%) recruited and 47 completed all stages	Consensus reached in key areas such as improving staff training, access to information, and concerns about non-pharmacy and internet supplies, and commercial pressure. Improved co-ordination and communication essential to implementation. Barriers included staff changes, time pressures, gaining full co-operation, lack of deterrence to those addicted and industry factors.
Myers, Seigfried and Parry (2003)	To provide community-level surveillance information of OTC and prescription medicine misuse	Retrospective study of patients attending substance abuse centres over 6 months periods (1998-2000) using form to collect patient data, drugs used and use patterns	9063 forms collected from 23 centres in Cape Town, South Africa		710 (7.8%) of cases included OTC, prescription or unspecified medicines. Of these, 239 (33.7%) used medicines a s primary drug of abuse, and OTC specific use of codeine was identified in 17 cases (29.8%) of these. With 25 (43.9%) being from prescription and 15 (26.3%) being unspecified.
Akram & Roberts (2003)	To determine how pharmacists respond to requests for over-the-counter (OTC) medicines by patients on a methadone maintenance programme.	Cross-sectional postal survey	All 213 community pharmacists in Glasgow health board, Scotland	153 of 167 pharmacies providing methadone responded (92%)	Methadone patients sought advice on colds, GI problems and headaches most frequently, and requested codeine/paracetamol analgesics, other analgesics and antacids most frequently. 62% of pharmacists (n=93) had refused sales, with Nytol (diphenhydramine) the most common, but also codeine-containing analgesics and codeine linctus. Night Nurse, Sudafed and Benylin also denied. Fifteen percent (n=23) of pharmacists had supplied abusable product to avoid problems/trouble. Pharmacists perceived methadone patient requests not to be genuine on occasion.
Fleming, McElnay,	Develop and pilot a harm-	Observation of model developed	2 pharmacies	N/A	18 clients identified during one month of pilot (10 in one pharmacy, 8 in the other), of whom 3

& Hughes (2004)	minimisation model for identification and treatment of OTC medicine abuse/misuse by community pharmacists	using expert conference discussion local stakeholders consultation; records analysed from participating pharmacies trained in using model.			were already known to the pharmacist as being suspected of abusing medicines. 14 were challenged and some success reported in initiating change; no clients were successfully enrolled into the harm-minimisation scheme.
Hughes, Pillitteri, Callas, Callahan, & Kenny (2004)	To estimate the amount of misuse of and dependence on nicotine gum in OTC setting.	Cross-sectional telephone survey, eliciting views on past and current use of nicotine gum in 1st study and questions based on dependency diagnostic criteria from DSM-IV and ICD-10. No pilot mentioned	Public and pharmacy customers in 5 US states in 2000 approached via adverts	In 1st part of study, 351 contacts led to 266 participants. In 2nd study, 139 contacts leds to 100 participants	Around half (46%) of respondents in study 1 had used gum longer than 3 months; 20% of those using gum for more than 90 days attributed use to addiction. In 2nd study, 66% of respondents met DSM-IV dependency criteria and 74% the ICD-10 criteria. Overall incidence of dependence of nicotine gum was estimated as 0.7-1.4% using data from another study.
Agaba, Agaba, Wigwe (2004)	Use and abuse of analgesics in Nigeria	Cross-sectional community survey using structured face-to-face interview. Pre-tested in pilot	2 stage random sampled using residents of Zawan B ward district of Jos, Nigeria	600 subjects enrolled, but 80 invalid responses	312 (60%) of participants reported regular (twice a week for two months or greater) use of analgesics; 76% obtained by self-medication. Commonest indications were for rheumatical complaints (89%) and headache (67%). Paracetamol commonest medicine (58%), with 28.9% reporting compound analgesic use. Analgesic abuse (defined in study as cumulative lifetime use of > 5000 doses) was identified in 22.6% of participants.
Sweileh et al. (2004)	To obtain information from Palestinian community pharmacists about perceptions of OTC medicine abuse, suspected customer types & solutions.	Questionnaire, section related to demographics and descriptions of customers suspected of abuse.	All 111 pharmacies in Nablus district, Palestine	97 valid responses obtained	Two thirds of respondents perceived an increase in suspected OTC misuse or abuse due to instability in region, and that majority were not regular customers. 80% of pharmacists identified anti-tussives as being of misuse/abuse potential, 70% identified analgesics, 41% antihistamine problems and 67% laxative misuse/abuse. Male customers were perceived more likely to abuse or misuse OTC medicines in all categories except laxatives and the 20-40 age range was most commonly identified. Informing the customer's doctor, hiding products and informing customers of abuse potential were identified as strategies to reduce problem.
Wazaify, Shields, Hughes, McElnay (2005)	To investigate general public's opinion and perceptions of OTC medicines	Cross-sectional survey using structured interviews	1000 members of public interviewed in 10 shopping centres over 10 weeks in 2002.	N/A	OTC purchases were cited by 11.3% of participants as reason to visit pharmacy. 76.4% of participants reported painkillers as always being kept in stock at home ; 14.7% of participants strongly agreed, and 65.2% agreed that some OTC medicines could cause dependency or addition if take over time. Almost a third (n=298) reported having personally encountered OTC abuse (based on personal experience, knowledge or observation). Younger participants were more likely to report this. Paracetamol (n=106) was the most reported medicine liable to abuse, followed by Paracodol (n=37) and co-codamol (n=30).
Bryant-Waugh, Turner and East (2005)	To determine the availability of laxatives and pharmacists' and other retailers' awareness and responses to laxative misuse.	Cross-sectional survey of retailers (pharmacies, supermarkets, health food shops) of laxatives near to eating disorder treatment centre	293 retailers sent survey by post. No date specified	53 retailers (18.1%) responded	20 retailers (37.7%) reported selling laxatives, including all pharmacy respondents but only 1 of 31 convenience or newsagent categorised retailers. Awareness of abuse potential varied and was not limited only to pharmacies. Only 3 pharmacies had a protocol for supervising sales of laxative, but 18 retailers had at least one policy, and these included age restrictions, limiting quantities sold and involving the pharmacist routinely. Responses to suspected misuse involved limiting supply rather than advice.
Steinman (2006)	To estimate prevalence of adolescent micuse of OTC	Census of students in US county using survey in 2003. Focus		39,345 students	4.7% of students reported misusing OTC drugs occasionally (which included responses to either one or twice a year or used, but not in past year), with a further 2.1% reporting misuse

	drugs, identify misuse of other substances and demographic/psychosocial characteristics of OTC misuse	groups used to address validity. Frequency of OTC medicine misuse assessed with one question.			in the previous month. Females misused OTC medicines more than males, as were those who also reported using alcohol and other illicit drugs. Depressive affect and violent behaviour were positively associated with OTC misuse, and Native American youths reported the highest level of OTC misuse, with African Americans reporting the lowest.
Ajuoga et al. (2008)	To investigate use and misuse of OTC medicine in HIV-infected patients and determine related adverse drug events (ADE)	Cross-sectional self-administered pre-piloted, questionnaire (demographic & attitudinal data) and semi-structured interview (on medicine use, frequency, side effects). Expert panel judged on abuse.	HIV-infected adult patients at Houston, US hospital. Convenient sample of every 3rd clinic patient having prescription filled	215 patients responded from 338 approached (63.6%)	Analgesics/antipyretic OTC medicines were the most commonly used (64.2%) and non-steriodal anti-inflammatory the most common type. 80 (37.2%) respondents misused OTC medicines on 149 reported occasions, as judged by the panel, by duration (46.3%, n=69), dose (45.6%, n=68) and condition (8.1%, n=12) misuse respectively. 16.7% (n=36) of participants reported ADEs.
Orriols, Gaillard, Lapeyre-Mestre, & Roussin (2009)	To explore feasibility of pharmacoepidemiological methods to investigate misuse of self-medicated drugs	Cross-sectional pilot survey of patients requesting medicines from pharmacies assigned into one of five therapeutic groups (codeine, dextromethorphan, pseudoephedrine and antihistamines, and control)	74 pharmacies (from 228 solicited in one French region) distributed 817 surveys over 2 months in 2007	530 participated (64.9%) with 491 valid surveys	48,9% (n=240) of patients had used the medicine in previous month, with 49.2% having informed their doctor of such use; 38.8% had started use on medical advice, 27.5% on pharmacist advice. Of those who used codeine-based products in the last month, 15% (8/53) were misusing, 7.5% (4/53) were abusing and 7.5% (4/53) dependent – all statistically significant. No abuse identified for dextromethorphan, one case for pseudoephedrine, and none for antihistamines,
Björnsdóttir, Almarsdóttir, & Traulsen (2009)	Mapping Icelandic people's definitions of drugs/medicines.	Focus groups	Members of the public in Iceland , identified as rural/urban dweller, and lay/educated (teaching, ICT, midwifery)	42 participants in 8 focus groups; 4 lay, 5 urban, 4 rural. 4 professional.	Slight variation in definitions of medicines emerged but participants recognised categories such as OTC, prescription, illicit, vitamin/herbal although often chose to conflate drugs as being from any source. Some participants expressed concern about side effects and abuse and misuse potential of medicines, including OTC medicines. More information about medicines was suggested as being needed. The internet was identified as a source of medicines but rejected, and considered suitable for information in the main.
Nielsen, Cameron, & Pahoki (2010)	To understand who is at risk of developing dependence to OTC codeine, and how products are used	On-line survey of codeine users, qualitative interviews with codeine dependent people and key experts		800 valid survey responses (from 909 respondents), 20 interviews with codeine dependent people and 14 key experts	17% (n-138) survey respondents were codeine dependent, and around three quarters had not sought help. Doses at ten times the recommended maximum were reported. Interviews suggested three types of codeine user: therapeutically depednent on doses not above recommended maximum, recreational users, and high dose dependent users. Participants viewed OTC medicines as different to other drugs, and themselves as different from other drug users. Key experts perceived older females to be typical, pharmacists used appearance to describe those affected and barriers to treatment involved user's lack of insight. Raising awareness, training pharmacists and over-coming barriers to treatment recommended.
Albsoul-Younes, Wazaify, Yousef, & Tahaineh (2010)	To investigate abuse/misuse of prescription and non-prescription drugs in pharmacies in Jordan	Cross-sectional survey using structured questionnaire in 2005-06	Random sample of 405 pharmacies in Jordan		Most respondents (94.1%) suspected some abuse/misuse in their pharmacy, with decongestants, cough/cold products, benzodiazepines and antibiotics most commonly cited. Current controls are ineffective.
Major and Vincze (2010)	Survey self-reported use of OTC medicines and understanding of abuse	Structured face to face questionnaire of 25 questions. No details given. Piloted with 50.	2000 surveys distributed at 25 geographically varied	1486 completed surveys and	81.7% of respondents thought OTC medicines could be abused and more than half (782) were not able to suggest solutions: 1089 named at least one product or category, 180 named 2, and 45 named 3. Most frequently identified were painkillers, sleep aids and cough

	potential amongst people who visit Hungarian pharmacies		Hungarian pharmacies in 2008	65 returned not valid	medicines. Almost 1/3 of respondents identified specific brands. 536 respondents reported having personally encountered OTC medicine abuse; women were statistically more likely to identify weight loss medicines.
Gonzales, Brecht, Mooney, & Rawson (2010)	To examine treatment admission patterns to addiction system for primary abuse of prescription and OTC drugs, differentiating between adolescents and adults	Cross-sectional descriptive study using data captured for all treatment admissions to public addiction services. Data included drug use and demographic information	216,716 admissions were identified in this period for individuals aged 12 or over in California, USA, in 2006-07.		Prescription and OTC medicines accounted for 6,841 (3.2%) of admissions, with adolescents (12-18 years old) accounting for 1.5% of overall admissions. OTC medicines represented 1.9% (n=139) of total of prescribed and OTC medicine admissions and were statistically more likely to be reported by adolescents, who were more likely to cite 'self' for referral to treatment than older clients, who cited 'others' more often.

7.5 UK proprietary product details

Product or class	Packs sizes	Active ingredient(s) per dose	Indicated Use	Mentioned in this study by:
Actifed linctus	100ml	Pseudoephedrine 30mg/5ml TriprolidineHCl1.25mg/5ml	Cough/cold	OTC experience
Benylin chesty original	100ml 300ml	Diphenhydramine 14mg 5% v/v ethanol	Cough/cold	Pharmacists
Co-codamol tablet		Codeine 8mg Paracetamol 500mg	Analgesic	OTC experience, stakeholders
Codeine linctus	100ml	Codeine 15mg/ml	Cough/cold	OTC experience
Codis tablets		Codeine phosphate 8mg Paracetamol 500mg	Analgesic	OTC experience
Feminax tablets (before reformulation in 2006) Later formulations contained only NSAID		Codeine phosphate 8mg Paracetamol 500mg Caffeine 30mg Hyoscine HBr 0.1mg	Analgesia	OTC experience
J.Collis Browne mixture		Morhpine (anhydrous) 1mg/5ml Ethanol (alcohol) 2.3%v/v	Diarrhoea	OTC experience
Kaolin and Morphine mixture	200ml	Morphine 0.46mg/5ml Kaolin 1g/5ml Ethanol (alcohol)		Pharmacists, MCAs,
Laxatives		CLASS		Pharmacists, several stakeholders
Nurofen Plus		Codeine phosphate 12.8mg Ibuprofen 200mg		OTC experience, pharmacists, stakeholders
Nytol		Diphenhydramine 25mg		OTC experience, pharmacists, MCAs
Paramol tablets		Dihydrocodeine tartrate 7.46mg Paracetamol 500mg		
Phensedyl (discontinued UK)				OTC experience
Solpadeine Max		Codeine phosphate 12.8mg Paracetamol 500mg		
Solpadeine Plus		Codeine phosphate 8mg Paracetamol 500mg Caffeine 30mg		
Sudafed tablets		Pseudoephedrine 60mg		Pharmacists, MCAs, stakeholders
Syndol		Codeine phosphate 10mg Paracetamol 500mg Doxylamine 5mg Caffeine 30mg		OTC experience
Veganin		Codeine 8mg Caffeine 30mg Paracetamol 500mg		OTC experience

7.6 Examples of leaflet

PAGB/British Pain Society leaflet

What side effects do painkillers have and what are the risks of taking painkillers in the long-term?

Side effects

All medicines can cause unwanted side effects. Used in the short-term these are not generally troublesome but if painkillers are used long-term, then the extent and severity of side effects can increase. If you have any unwanted side effects or if you have any concerns, you should seek advice from your doctor, pharmacist or other healthcare professional.

Paracetamol is a safe drug, except in overdose when the liver can become damaged, sometimes permanently.

High doses or long-term use of NSAIDs may lead to indigestion, bleeding from the gut, kidney problems, high blood pressure, fluid retention, and slight increased risk of heart attack and stroke. They may also affect blood clotting and worsen asthma in about 10% of asthma sufferers. Aspirin must not be given to children under 16 years because of a very rare illness called Reye's syndrome which can be fatal.

Prolonged use of painkillers containing codeine or dihydrocodeine can lead to constipation, "chronic daily headache" and addiction.

Chronic daily headache

If you are taking painkillers for 15 days or more a month you run the risk of getting daily or near-daily headaches that last, on average, for more than four hours. These headaches are often linked to overuse of painkillers. Unless the overused painkillers are completely discontinued, the chronic daily headache is likely to continue. If you suffer from this then you need to see your doctor who can help you.

This leaflet is available to download from www.pagb.co.uk and www.britishpainsociety.org

ADDICTION

Although, addiction to codeine and dihydrocodeine is rare, if it does occur it is a serious problem. **Never take painkillers containing codeine or dihydrocodeine for longer than three days without medical advice.**

You may find it helpful to read *'Pain and substance misuse: improving the patient experience'* published by the British Pain Society which can be downloaded from www.britishpainsociety.org

How do I know if I am addicted?

Ask yourself:

- Do you feel that you need to take the codeine/dihydrocodeine products for longer periods of time than instructed on the pack?
- Do you find yourself buying more and more pills?
- Do you feel the need to take more than the recommended dose?
- Do you feel very unwell when you stop taking the medicine but you feel better if you start taking the medicine again?

If you answer **"yes"** to any of these questions then you need help in managing your symptoms and it is important that you talk to your doctor. If you take the medicine according to the instructions on the pack, it is unlikely that you will become addicted to the medicine.

THE BRITISH PAIN SOCIETY

Managing your pain effectively using "Over the Counter" (OTC) Medicines

We all know what pain is. Sometimes we hardly notice it. However, other times it is so severe that we ask a doctor or pharmacist for help. Sometimes we take a painkiller (analgesic) to lessen the pain until it goes away.

Short-term (acute) pain relief

Most of us have had occasional headaches, muscle or joint pain, or in women, period pain. Short-term pain does not last long and tells the body that something is wrong.

Short-term pain can be treated by painkillers that can be bought "over the counter" (OTC) either from a pharmacy or other shop, such as a supermarket or corner shop.

Long-term pain relief

Long-term pain, sometimes called chronic or persistent pain, is present everyday or comes and goes. Some people with long-term illnesses need to take painkillers everyday to manage this.

You may find it helpful to read *'Understanding and Managing Pain'* published by the British Pain Society which can be downloaded from www.britishpainsociety.org

SAFE USE OF PAINKILLERS

- When taken at the right dose, OTC painkillers are safe and effective medicines.
- When you have short-term pain it may be best to take the painkiller as recommended on the pack to stop the pain from building up and becoming intolerable.
- If you need to take painkillers for longer than three days you should see your doctor or pharmacist for advice.
- If you feel the dose of a prescription medicine isn't enough, don't 'top up' with painkillers bought over the counter - Talk to your doctor or pharmacist.
- Speak to your doctor or pharmacist if you need advice.

MANAGE YOUR PAIN EFFECTIVELY AND SAFELY WITH OTC MEDICINES

- Paracetamol
- Aspirin
- Ibuprofen
- Diclofenac
- Naproxen
- Dihydrocodeine in combination with paracetamol
- Codeine – only available as a combination with paracetamol, or aspirin, or ibuprofen

Always read the instructions and do not take two products containing the same active ingredient. Codeine or dihydrocodeine containing painkillers should only be used for short-term treatment of acute, moderate pain which is not relieved by paracetamol, ibuprofen, naproxen, diclofenac, or aspirin alone. Some OTC painkillers can only be used to treat specific conditions.

ALWAYS READ THE INSTRUCTIONS AND INFORMATION IN THE LEAFLET AND PACK

- It can be dangerous to take more than one painkiller with the same active ingredient. Make sure you know the ingredients of the products that you are taking.
- If you have conditions like asthma, any stomach problems or if you are taking certain medicines, then some painkillers may not be suitable for you and you should speak to your pharmacist or doctor about which painkiller would suit you best. Always read the instructions and information in the leaflet and pack.
- Some people may have side-effects when taking medicines. You can help to make sure that medicines remain as safe as possible by reporting any unwanted side-effects via the internet at www.yellowcard.gov.uk or through your pharmacy.

UNDERSTAND WHAT YOU ARE TAKING

- Keeping a pain and medicine diary can ensure that you are using your painkillers most effectively.
- Never take painkillers more frequently than it says on the instructions on pack or in the leaflet.
- Always read the names of the ingredients and information on the leaflet and pack.
- Never take another product sooner than you should.

Your pharmacist and their assistants can advise you on an appropriate choice of product.

You do not always need painkillers to relieve pain

- Applying heat to the skin can help some types of pain. Use compresses or products such as sprays, creams, ointments, gels and patches to help swelling and inflammation.
- Support from bandages or compression hosiery can help with sprains and strains.
- Acupuncture or Transcutaneous Electrical Nerve Stimulation (TENS) are alternatives to medication for pain control. Ask a healthcare professional about these treatments.
- Rest if your body tells you to.
- Exercise gently as soon as you are able to.

Ask yourself what is causing the pain. If you do not know, if the pain persists for more than three days, or if you are unwell, always seek medical advice.

What kinds of pain can be helped by OTC medicines?

- Headache, migraine
- Toothache
- Period pain
- Minor injuries, strains and sprains
- Backache, muscle aches, joint pains

How do different painkillers work?

Aspirin, ibuprofen, diclofenac and naproxen come from a group of drugs called nonsteroidal anti-inflammatory drugs (NSAIDs). NSAIDs work by changing the body's response to pain and swelling. They are particularly helpful for acute strains and sprains, muscle and joint pains.

Codeine and dihydrocodeine are similar to, but weaker than morphine, and work by blocking pain messages in the brain and spinal cord.

Paracetamol works in a different way to NSAIDs and codeine. It is particularly helpful in reducing fever and relieving pain.

Because each type of painkiller works in a different way to relieve pain, there are some products available that contain more than one type of painkiller. For example aspirin, paracetamol or ibuprofen can be combined with codeine and/or caffeine.

What do the other ingredients do?

Some painkillers contain caffeine as it may improve pain relief. Caffeine, also in coffee and tea, is a stimulant. It increases blood pressure and speeds up the heart. There is about 75 mg caffeine in a small cup of coffee and about 50 mg in a small cup of tea, similar amounts to some OTC painkillers. Increasing caffeine intake may increase the risk of nervousness and dizziness.

Doxylamine, a sedating antihistamine, has muscle relaxing properties thought to be beneficial in headache.

Does your pain affect your life?

Long-term pain can often affect your quality of life. **Ask yourself:**

- Do you need to take this medicine continuously for more than three days?
- Do you have low moods?
- Do you suffer from a lack of sleep?
- Are you tired and irritable often?
- Do you find it difficult to concentrate?
- Does the pain make it difficult for you to exercise?

If you answer **"yes"** to any of these questions then you need help in managing your symptoms and it is important that you talk to your doctor. Although it may not always be possible to get rid of pain completely, there is a range of different treatments available.

BEWARE! MEDICINES HAVE MORE THAN ONE NAME

A brand name is the name chosen by a manufacturer (e.g. Panadol®, Nurofen®, Voltarol®, Feminax®). Each drug may have several different brand names. The "active ingredient" describes the drug (e.g. paracetamol, ibuprofen, diclofenac and naproxen). **Always read the instructions and do not take two products with the same active ingredient. Make sure you know the ingredients of the products that you are taking. These will be clearly marked on the pack.**

Weldricks Pharmacy Leaflet

New guidelines for Codeine-based Pain Killers

The Medicines and Healthcare product Regulatory Agency (MHRA) have recently announced new guidelines for codeine-based painkillers to minimise the risk of overuse and addiction.

How will this affect you.

The changes will include adding addiction warnings to packaging, restricting quantities that can be purchased and making certain medicines only available on prescription.

As a responsible pharmacy and in response to the new MHRA guidelines, Weldricks will no longer offer price promotions on any codeine-based medicines.

If you have any concerns regarding these new guidelines or about effective medication for pain relief please speak to our Pharmacist.

WELDRICKS PHARMACY

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