Opioid painkiller dependency(OPD)
An overview

A report written for the
All-PartyParliamentary Group
on Prescribed Medicine Dependency

By
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Note: unlike other medication covered in the remit of the APPG, potentially problematic opioid painkillers (OP) can also be bought without a prescription over the counter (OTC) at chemists and other retail outlets so OTC painkillers are also considered as part of this report.[2]

Summary

- The growth in the use of OP across many western countries and the subsequent rise in OP dependency and overdose has become a major health concern for international agencies and especially in the United States
- In the UK, the subject of OP dependency is chronically under-researched. Despite having some of the highest levels of OP use and sales in the EU and a wealth of anecdotal evidence from individuals, patient group representatives and clinicians about OP dependence, the estimate of those who might be OP dependent varies wildly from tens of thousands to nearly a million. But whatever the figure, it is clear that a significant number of people in the UK are battling with an OP dependency while being 'hidden in plain sight.'
- Home Office figures released in 2015 revealed for the first time, a cohort of people across the age ranges using OP that were not prescribed to them, often for recreational purposes. This potentially heightens the risk of dependency and overdose among naïve users and is a further indication of the overall level of availability in the community.
- Until the publication of the All-Party Parliamentary Group on Drugs report *An inquiry into physical dependence and addiction to prescription and over-the-counter medication* in 2009, little interest was shown in this issue either from government or professional medical organisations. This has begun to change with, for example, guidelines from the RCGP, the development of assessment tools, professional calls for regular reviews on repeat prescriptions and reductions in packet size for OTC painkillers with additional patient health warnings.
- Most people will use their OP in accordance with medical instructions and patient leaflet information. But while in theory anybody could become dependent on their medication, research is establishing that some people are more vulnerable to OP dependency than others.
- In the main, those suffering from OP dependency are not willing to attend established community drug treatment centres, but find that there are few specialist treatment options.

[2] The primary Prescription-Only OP are those containing the following: morphine, fentanyl, tramadol, buprenorphine, oxycodone. Codeine will also be found as a POM, but in higher dosages than an OTC equivalent. For example, co-codamol contains 30mg of codeine as a POM but only 8mg as an OTC product, although both contain 500mg parcetamol. The main OTC products are all codeine-based and include Nurofen Plus, Solflex, Paramol and Solpadeine.

- Research has shown that GPs and pain specialists are often uncertain as to the best way forward in treating OP dependent patients – and have differing perceptions of the groups most at risk - but new initiatives from drug treatment services are pointing the way towards primary care being the most suitable environment for treatment where GPs work in shared care arrangements.
- Growing public and professional concerns about OP dependency has resulted in a consequential increase in patient advocacy and help groups demanding action at both a local and national level.
- It is encouraging that steps are being taken to address this issue at a local and national level, but there is still much to be done.

Introduction

Since the early 1980s, the extensive professional, political and media discourse about drug misuse and addiction has centred on the use of a wide range of illicit drugs such as heroin, cocaine, cannabis, amphetamine, and ecstasy. There is also a public and professional awareness about the dependency potential of tranquillisers and antidepressants highlighted, for example, by class actions brought against pharmaceutical companies, media reports and articles, popular and medical books, TV documentaries, and guidelines produced by the medical profession to advise against over-prescribing. That said, the very existence of this APPG indicates continuing and very real concerns not only about the startling level of prescribing of tranquillisers and antidepressants[3], but also the lack of specialist help underlined by the recent closure of some of the few charitable helping agencies that do exist.

In recent years too, there has been a growing awareness of the dangers of OP, most notably dependency and overdose. The evidential base is most developed in the USA where celebrity revelations including Michael Jackson, Burt Reynolds, Melanie Griffiths and Jamie Lee Curtis have served to foreground the risks demonstrated by the epidemiological evidence and clinical case reporting.[4] It has been suggested that much of the problem has derived from the progression from only prescribing OP for acute pain and cancer treatment to more generalised chronic pain conditions which has led to more widespread misuse and rising mortality in many Western countries.[5]

In the UK, public and professional awareness in the UK of the potential dependency and overdose risks of OP has been patchy. Despite some sporadic press coverage going back into the 1990s, the subject really didn't hit the headlines until 2009 with the publication of the All Party Parliamentary Group on Drugs report, *An inquiry into physical dependence and addiction to prescription and over-the-counter medication.* The remit covered tranquillisers, anti-depressants and OP and MPs took evidence from campaigners, doctors, clinical researchers, government agencies and the pharmaceutical industry. Even then, it has to be said that the government response to the report was originally lukewarm; there was no commitment to improve service

[3] Council for Evidence-Based Psychiatry, *The harmful effects of overprescribing benzodiazepines, antidepressants and other psychiatric medications.* March 2015. See also, Davies J. (2013) *Cracked; why psychiatry is doing more harm than good*. Icon.
[4] For example, Volkow et al. (2014) *Medication-assisted therapies –tackling the opioid overdose epidemic.* N. Eng J Med 370: 2063-6 Center for Disease Control and Prevention (2013), *Addressing prescription drug abuse in the United States: current activities and future opportunities.*
[5] Dhalla, I et al. (2011) *Facing up to the prescription opioid crisis.* BMJ, 343:d5142

provision and the low presentation rate to drug treatment agencies of those with medicine dependency issues was cited by ministers as an indication that this was only a minority health issue when in fact the profile of those most in need was very different from a traditional heroin/crack-using drug treatment client. It would be fair to say though that since 2010, issues surrounding addiction to medicines have become more prominent in professional and political circles – and since 2012, there has been a noticeable increase in national and local print and broadcast media coverage. [6]

UK prescribing and purchase of opiate painkillers.

It is not easy to get a comprehensive picture of the overall situation regarding the prescribing of OP and the purchase of codeine-containing OTC formulations, but piecing together the evidence from various datasets reveals that the UK population is consuming considerable and increasing amounts of OP:

- In 2012, some ten million people in the UK were prescribed an OP, more than double the next nearest EU country France at four million[7]
- In 2013, the UK had the highest sales of morphine by volume than any other country in the EU[8]
- In 2013, the UK had the highest sales of opiates like codeine by volume than any other country in the EU and between 2010-2013 the UK had a 6% growth in sales, against the next largest margin increase in the EU.[9]
- In 2011, Northern Ireland has highest annual prevalence of prescription opioid use in the world (8.4%)[10]
- In the period 1994-2009, Tramadol prescribing increased tenfold and all OP showed significant increases in level of prescribing during this period with the exception of dihydrocodeine. Just in England, the number of prescriptions rose from around three million in 1991 to 23 million by 2014.[11]
- Defined Daily Doses for Tramadol in England have increased from 5.9 million in 2005 to 11.1 million in 2012.[12]
- Between 2001-2011, prescriptions for co-codamol almost doubled from 8.8 million to 15 million[13]

[6] Media examples include articles from the *Daily Mail*; 9th April 2004; 13th February 2007; 27th December 2012; 29th September 2014. *The Mail Online* 22 July 2013. *The Independent* 25th August 2011. In 2013 a character in *EastEnders* developed an addiction to painkillers as did one from *Emmerdale*. The actor and comedian Mel Smith declared an addiction to Nurofen Plus. The most publicised case in the UK was that of Cathryn Kemp whose story was widely reported and who went on to write a book, *Painkiller addict – from wreckage to redemption: my true story (*Piatkus 2012) and set up the website www.painkiller-addict.com.

[7] IMS Health audit sales data

[8] ibid

[9] ibid

[10] Data from the International Narcotics Control Board supplied to the Pain and Policy Studies Group, University of Wisconsin

[11] National Treatment Agency *Addiction to Medicine,* 2009; Health and Social Care Information Centre, *Opioid analgesics dispensed in the community 2010-2014*

[12] Advisory Council on the Misuse of Drugs (2013). *ACMD consideration of Tramadol.* The Defined Daily Dose is a measure of prescribing volume maintained by the World Health Organisation based on the assumed average daily dose used for its main indication in adults. As a result of its deliberations, the ACMD recommended that Tramadol become a Class C controlled drugs under the Misuse of Drugs Act 1971.

[13] *Daily Mail* 22 July 2013

- Following a voluntary reduction to 32 tablets per pack of branded codeine-containing OTC products in 2005, sales of that pack size more than doubled in the period 2006-2008 from 5.3 million to 11.1 million[14]

Online pharmacies

From 1st July 2015 anybody selling medicines online in the UK to the general public must register with the Medicine and Healthcare products Regulatory Agency (MHRA) and be on its list of registered online retail sellers. The site must by law also carry the EU common logo. Pharmacy Sales and Prescription Only Medicines can only be dispensed against a prescription. While current UK online pharmacy sales are relatively low compared to, for example, the USA and Germany, analysts predict a substantial growth in the UK online pharmacy market.[15]

However the darker aspect of internet sales (which has been well documented) is the ease with which it is possible to buy all types of medicines including powerful OP from unregistered online pharmacies across the world without any prescription needed. It is reasonable to assume that as prescribing guidelines tighten, more people will be tempted to buy online to top up legitimate prescriptions. The MHRA has an ongoing operation to close illegal sites, primarily those offering fake or counterfeit medicinal products.

Overdose

A key measurable harm from the rising number of OP prescriptions and volume of OTC sales is the concomitant increase in the overdose statistics. Mortality trends in the USA show a relentless rise in the number of deaths from OP overdose; in 2010 the figure of 16,500 was more than double the number for 2002 and more than twice the number of deaths from heroin and cocaine combined. While the figures for the UK are nowhere near as dramatic, a similar trend can be discerned. For example, in 1996 there was just one death record for Tramadol in England and Wales; by 2011 that figure had risen to 154.[16] and according to the Office of National Statistics drug-related death figures for England and Wales 2014, the figure for Tramadol is now at 240. In 2013, there were 757 deaths where an OP was mentioned on the death certificate, almost as many as for heroin and morphine (765) and rose by 30% from between 2012-2013, again similar to the increase in heroin and morphine-related deaths for the same period. For 2014, the figure for all opiate deaths apart from heroin, morphine and methadone was 760 while the figure for heroin/morphine rose

[14] Proprietary Association of Great Britain data cited in Reed, K et al, (2011) *The changing use of prescribed benzodiazepine and z-drugs and OTC codeine-containing products in England: a structured review of published English and international evidence and available data to inform consideration of the extent of dependence and harm.* Study conducted by the National Addiction Centre and the University of Bristol.

[15] Sempora Insights (2013). *Sempora market survey: the UK retail pharmacy market 2012 – consumer internet purchasing behaviour.*

[16] Giraudon, I. et al. (2013) *Prescription opioid abuse in the UK.* British Journal of Clinical Pharmacology, 76 (5), p823-824.

significantly to 952.[17]The latest mortality data from Scotland[18] revealed that from a list of selected drugs reported, the numbers of deaths from codeine, dihydrocodeine and related compounds rose from 69 in 2010 to 107 in 2014.

Opiate painkiller dependency

Chronic pain is one of the most distressing and debilitating of conditions and attempts to alleviate it go back thousands of years to very early finds of poppies in Neolithic sites from 4200 BC and evidence of opium cultivation found in ancient Sumerian sites from 3500 BC. And right up until medical science progressed sufficiently to identify the causes of disease, all that was available was symptomatic pain relief in various formulations such as laudanum and OTC patent medicines, which became a hugely profitable industry in the 19th century once morphine (and from that heroin) had been extracted from opium (and cocaine from coca leaves). Alongside the use of opium-based medicines has come myriad accounts of addiction from Thomas De Quincey's *Confessions of an Opium Eater* (1821) to the ubiquitous stories of heroin dependency which continue to proliferate in the media.[19]

So it should come as no surprise to learn that medicines such codeine prescription and OTC drugs whose 'parent drug' is opium should have the potential to cause dependency both physical and psychological. At the stronger end, as well as alleviating pain, these drugs have a euphoric and calming effect, distancing the user from reality and so cushioning them not only from physical, but also psychological pain. The press headlines emanate from the fact can this be a dependency originating not from a street drug dealer, but your own trusted GP prescribing legal drugs in a legal manner– and that the victims are not chaotic street drug users, but 'normal respectable people' with jobs and families.[20]

It should be pointed out that most people will be using their OP in accordance with medical instructions and/or the information given in patient information leaflets driven by the very real fear attached to the notion of 'addiction'. But the cohort of people who are likely to be most affected are also most unlikely to present to a traditional drug treatment agency and so are 'hidden in plain sight' making it impossible to determine the size of the problem in the UK.

Estimates vary widely; from the number of calls, the drug charity Overcount extrapolated a dependent population of 30,000. Then again, the ITV programme 'Tonight' (broadcast 10th July 2015) surveyed a cross-section of 2000 people of whom

[17] Office of National Statistics. *Deaths related to drug poisoning England and Wales 2013* (2014) and *2014* (2015)
[18] National Records of Scotland (2015). *Drug related deaths in Scotland 2014.*
[19] The search for the non-addictive analgesic is something of a Holy Grail within the pharmaceutical industry. See for example 'Are painless painkiller possible?' The Fix 29th March 2015. http://www.thefix.com/content/are-painless-painkillers-possible

[20] In America, while overprescribing by doctors was clearly the genesis of the current epidemic, figures from the 2009 National Survey on Drug Use and Health showed that family and friends (70%) were the primary source of OP for non-medical use. Because of all the adverse publicity, the increasing reluctance of doctors to prescribe has been partly blamed for the resurgence of heroin use in the States. Use appears to have occurred across a wide social and economic demographic, so the cost of prescription OP would also account for the switch to heroin.

6% had been using OTC painkillers for more than a year from which the programme extrapolated that around 950,500 people could be dependent on these drugs. In 2009, the National Treatment Agency using data from the National Drug Treatment Monitoring System quoted a figure of 3735 people presenting to treatment services in England with a primary problem defined as one involving a prescription only or OTC medication. A further 28,000 people who were presenting with problems relating to illegal drugs also cited a secondary problem with POM/OTC medication. These figures would also include dependency on tranquillisers, but it is interesting to note that of those presenting to services between 2005-2009 who were not also using illegal drugs, the primary presentation was for prescribed opioid drugs.

In addition, there appears be a growing cohort of users taking these drugs for recreational purposes. In July 2015, the Home Office published the latest findings on drug misuse for England and Wales for 2014/15 among the general population and for the first time, a question was asked on the misuse of prescription-only painkillers. "The survey revealed that in the last year 5.4 per cent of adults aged 16 to 59 had misused a prescription-only painkiller not prescribed to them. Breaking this down by age group, 7.2 per cent of 16 to 24 year olds had misused a prescription-only painkiller in the last year, while 4.9 per cent of 25 to 59 year olds had done so". The survey went on;

- "While the misuse of prescription-only painkillers in the last year declined with age, (8.0% of 16 to 19 year olds compared with 3.0% of 55 to 59 year olds), the decline was shallower than the decline with age seen for illicit drugs. Higher levels of prescription-only painkiller misuse were seen in some older age groups; for example 4.5 per cent of 45 to 54 year olds reported having misused prescription-only painkillers in the last year, compared with 3.2 per cent who reported having used illicit drugs.

- People with a long-standing illness or disability were more likely to have misused prescription-only painkillers and to have used an illicit drug in the last year. Among those with a long-standing illness, 8.5 per cent had misused prescription-only painkillers in the last year (compared with 4.8% without an illness) and 11.9 per cent had taken an illicit drug in the last year (compared with 8.1% without an illness). Cannabis use was a large contributor to these proportions (9.4% of people with a long-standing illness had used cannabis in the last year, compared with 6.3% of those without).
- When compared with illicit drugs, differences were also apparent in certain household factors. For example, misuse of painkillers was similar in both rural and urban areas (5.4% of those in urban areas reported misuse of prescription painkillers, compared with 5.3% in rural areas) whereas the use of illicit drugs is higher in urban areas (9.1% of those in urban areas reported use of illicit drugs, compared with 6.5% in rural areas). This, alongside similar relationships in other personal and household factors, suggests that the misuse of prescription painkillers is distributed more evenly across the general population than the use of illicit drugs. [21]

[21] Home Office (2015). *Drug Misuse: findings from the 2014/15 Crime Survey for England and Wales. Statistical Bulletin 3/15.* pp 5,16.

These findings are not especially surprising and care must be taken not to read too much into one year's figures. However,

- The inclusion of the question at all is another aspect of growing awareness of the issue in official circles.
- It is clear from the prescription data that OP are increasingly in circulation and liable to diversion to those to whom they have not been prescribed.
- There is a risk of increasing overdose in those individuals unaware of the overdose risk.
- There is a lack of awareness that many of the codeine-based drugs being sought also contains large amounts of paracetamol which not only increases the overdose risk, but can permanently damage the liver.

But while it is impossible to calculate the scale of the problem in the UK, there seems little doubt through the limited number of studies which have been conducted and the day to day experience of clinicians, that there are potentially significant numbers of people struggling with a dependency to prescription and OTC painkillers. Dr Cathy Stannard, a pain specialist has been quoted in the *British Journal of Pain* in 2012, "We do not know what the scale of opiate-related harms is, but all of us see patients in this trap in almost every clinic".

Some (mainly Scottish) studies have been conducted over the years to gauge the perceptions of pharmacists in relation to the products they thought had the potential for misuse, the degree to which they thought products were being misused and how suspicions might be alerted. In all cases, the majority of respondents cited codeine-containing products at the top of the list of potentially problematic products and also believed there was an OTC misuse problem in their area.[22]

Who is most at risk of OP dependency?

There would certainly be a view that addiction to OP could happen to anybody – and in theory of course, this is true. But there is UK-based research which indicates a consistent patient profile for those most at risk.

Market research conducted in 2013-2014 among GPs and pain specialists[23] did reveal some consistencies, but also revealed differing perceptions of the cohort at risk and the degree of the problem of opiate analgesic dependency (OAD). In summary:

GPs

[22] Examples include; McBride A.J and Meredith-Smith (1995). *Compound opioid/parcetamol analgesics: misuse and dependence* British Journal of Clinical Practice, 49 (5), 268-269; MacFadyean. L. et al (2001) *Community pharmacists experience of OTC medicine misuse in Scotland.* Journal of the Royal Society for the Promotion of Health 121, 185-192. Matheson et al (2002). *Misuse of OTC medicines from community pharmacies: a population survey of Scottish pharmacies* Pharmaceutical Journal 269, 66-68.

[23] Indivior (2015). *Knowledge, attitudes and beliefs of GP, pain specialists and patients about opioid analgesic dependence*. Presentation to Opioid Painkiller Dependency Alliance.

- OAD patient profile: mostly females – 30s to 50s with chronic back pain, low mood, unemployed, with family and friends dependent on them - and males with poor social support and physical/mental health issues

- Predominant comorbidities - depression, personal history of misuse or abuse of alcohol/drugs and anxiety

- Estimate 3-28% of patients on chronic opioid therapy have OAD

- 86% of GPs completely agree/agree to an extent that OAD is a significant problem amongst non-malignant pain patients

- 83% of GPs completely agree/agree to an extent that OAD is a growing problem amongst these patients

Pain Specialists

- OAD patient profile: patients older than 55 years of age with depression, diabetes, suffered from long term pain/if younger tend to be males with sports injuries /neuropathic pain/musculoskeletal pain

- Predominant comorbidities - depression, personal history of misuse or abuse of alcohol/drugs.

- Estimate 4-10% of their patients on chronic opioid therapy have OAD

- Identify OAD via drug seeking behaviour – increased frequency of GP prescriptions, unwillingness to reduce their dosage/the number of drugs they were taking and/or rigid medication regimes

Professor James Elander and colleagues from Derby University have been engaged in a bank of research to identify potential psychological risk factors in analgesic dependence. Below is a brief overview of some of the work undertaken with relevant publications details[24]:[25]

1. **Survey to identify potential psychological risk factors of analgesic dependence**

Aims: Self-medication with painkillers is widespread and increasing, and evidence about influences on painkiller dependence is needed to inform efforts to prevent and treat problem painkiller use.

Design: Online questionnaire survey.

Participants: People in the general population who had pain and used painkillers in the last month (n=112).

[24] Professor Elander, Personal communication

[25] Other studies include, Good, B and Ford, C (2007) *Dependence on OTC drugs*. BMJ 334, p.17-18; Cooper. R (2013) *'I can't be an addict.I am'. Over the counter medicine abuse: a qualitative study.*BMJ Open 3:e002913. doi10.1136/bmjopen-2013-002913

Conclusions: The people most at risk of developing painkiller dependence are those who use prescription painkillers more frequently, who have a prior history of substance-related problems more generally, and who are less accepting of pain. Based on these findings, a preliminary model is presented with three types of influence on the development of painkiller dependence: a) pain leading to painkiller use, b) risk factors for substance-related problems irrespective of pain, and c) psychological factors related to pain. The model could guide further research among the general population and high risk groups, and acceptance-based interventions could be adapted and evaluated as methods to prevent and treat painkiller dependence.

Publications
Elander, J., Duarte, J., Maratos, F.A. & Gilbert, P. (2014). Predictors of painkiller dependence among people with pain in the general population. *Pain Medicine,* 15 (4), 613-624. DOI: 10.1111/pme.12263
Elander, J., Duarte, J., Maratos, F.A. & Gilbert, P. (2012). *Psychological factors influencing painkiller use and dependence*. Paper presented at the BPS Division of Health Psychology, Liverpool, Sept 5-7, 2012.

2. Study of anxiety in relation to analgesic dependence

Background: Evidence about influences on painkiller dependence is needed to inform initiatives to promote more effective use of painkillers by people with chronic pain.

Methods: Questionnaire survey of 104 people with chronic pain conditions.

Discussion: The findings could help identify people at risk of dependence on pain medication. More research is needed on painkiller dependence because of the potential impact that becoming dependent on painkillers can have for people with chronic painful conditions.

Publications
Page, H. & Elander, J. (2013). Pain anxiety, pain medication concerns, and self-compassion as predictors of painkiller dependence among people with chronic pain (abstract). *Psychology and Health*, 28 (Special Issue, Suppl.), p. 285.
Page, H. & Elander, J. (2013). *Pain anxiety, pain medication concerns, and self-compassion as predictors of painkiller dependence among people with chronic pain*. Poster presented at the European Health Psychology Conference, Bordeaux 16-20th July 2013.
Page, H. & Elander, J. (2013). *Predicting Painkiller Dependence in Chronic Pain: The Effect of Pain-Related Anxiety, Pain Medication Concerns and Self-Compassion*. Poster presented at the Midlands Health Psychology Network Conference, University of Birmingham, 14th February 2013.

3. **Mixed methods study of the role of anxiety in analgesic dependence, with online survey and interviews with selected respondents**

Objectives: To examine forms of anxiety as influences on analgesic dependence, and to explore experiences of pain, anxiety and addiction.

Design: Online questionnaire survey measuring pain anxiety, social interaction anxiety, generalized anxiety, concerns about pain medication and analgesic dependence plus in-depth semi-structured interviews for participants with specific score profiles.

Setting: Analgesic users in the general population. *Participants*: 147 survey respondents, including six interviewees.

Findings: social interaction anxiety predicted analgesic dependence independently of pain intensity, frequency of analgesic use, and risk of analgesic abuse irrespective of pain. However, cognitive pain anxiety and concerns about need for analgesics were the strongest independent predictors of dependence. The interviews showed that participants' anxieties and concerns influenced both the development of dependence and the process of recognition and recovery. These included decision making about using analgesics ("If I'm in a lot of pain my ability to reason about it becomes silly"); the development of habitual use ("I will almost take them like I'm not quite paying attention"); denial and justification for using painkillers ("It won't happen to me, you know, because I'm not one of them"); and reappraisals associated with change and recovery ("I think some of what I am getting from the painkillers is a placebo effect").

Conclusions: Pain anxiety and concerns about analgesics influence self-management decisions both in the development of analgesic addiction and during recovery. These insights can help identify targets for preventative health education and combined treatment interventions for pain and addiction.

Publications
Dys, A., Collins, H., & Elander J. (2015). *Anxiety as a predictor of analgesic dependence: a mixed methods study*. Poster presented at the annual British Psychological Society Conference, Liverpool, 6-8th May, 2015.
Elander, J., Dys, A. & Collins, H. (2014). *Evidence to improve self-management of pain and addiction: A mixed methods study of anxiety and analgesic dependence*. Paper presented at the annual symposium of the Society for the Study of Addictions, York, 6-7th November, 2014.
Dys, A., Collins, H., & Elander J. (2014). *Pain, anxiety, and analgesic dependence*. Poster

What has been the response from medical organisations?

Since the publication of the APPG on Drugs report in 2009, the issues around lack of risk assessment and lack of regular monitoring of OP has slowly risen up the agenda of concerns among the medical profession and government agencies

- In September 2009, the MHRA published new guidelines on the sale and promotion of codeine-containing OTC products[26]which in summary said:

a. Indications

All indications relating to colds, influenza, coughs and sore throats, and references to

[26] MHRA (2009). *Public assessment report: codeine and dyhydrocodeine-containing medicines: minimisig the risk of addiction*

minor painful conditions in product information will be removed. The remaining list of indications will be for the short-term treatment of acute, moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone.

b. Patient Information Leaflets (PIL) and labels

The PIL and medicine labels will state that the products are for short-term use only, for the treatment of acute, moderate pain which is not relieved by paracetamol, ibuprofen and aspirin alone, and that the products can cause addiction or overuse headache if used continuously for more than three days. In particular, the following warning will appear clearly and prominently on the front of the pack: 'Can cause addiction. For three days use only'. The PIL will also carry information about the warning signs of addiction, ie, if the medicine is needed for longer periods and in higher doses than recommended, and if stopping the medicine makes you feel unwell but you feel better when you start taking it again.

c. Pack size

All pack sizes greater than 32 tablets of solid dose codeine or DHC-containing OTC medicines, including effervescent formulations, will no longer be available as pharmacy products (ie, they will only be available on prescription).

d. Advertising

Advertisements will be updated to reflect the new indications and warnings, and will not contain references to painkilling power and strength. Also, all advertisements will include the following statement: 'Can cause addiction. For three days use only'.
The MHRA are currently implementing these measures, and all products with the updated information will be available on pharmacy shelves during 2010. As with all medicines, the MHRA will continue to closely monitor the safety of all codeine and DHC containing products.

- In January 2013, the Royal College of General Practitioners issued an Addiction to Medicines consensus statement "which strongly advocates care in the initiation of any drug that can led to dependence" and followed up with four factsheets "designed to improve the effectiveness and safety of prescribing decisions and the importance of complying with regular medicines reviews where the prescriber assesses the need and risk. The factsheets are also intended to support the identification and management of patients at risk".

  Factsheet 1: Prescription and over-the counter medicines misuse and dependence
  Factsheet 2: Prevention: steps to avoid 'misuse' of and dependence on prescription-only and over-the-counter medicines.
  Factsheet 3: How are patients who are misusing or dependent on prescription-only or over-the-counter medicines identified?
  Factsheet 4: How are patients who misuse and/or become dependent on prescription-only or over-the counter medicines treated?

- In 2014, Public Health England and NHS England issued guidance concerning the prescribing of pregabalin and gabapentin. These drugs have a well-defined role in the management of a number of disabling long-term conditions, including epilepsy and neuropathic pain; and, for pregabalin, generalised anxiety disorder. When used for pain the drugs do not work for everyone but a proportion of patients benefit sufficiently to notice an improvement in quality of life. However, there is growing evidence that these drugs are being misused by cohorts including those attending drug treatment services and offenders. Overall there has been an average 50% rise in numbers of prescriptions for these drugs just in the period 2011-2013.[27]
- The Faculty of Pain Medicine, the British Pain Society and others are putting together a new set of guidance (in the form of a website) which should be released later in 2015.
- The Chronic Pain Policy Coalition, the British Pain Society and Pain UK are all calling for GPs to conduct annual reviews of patients on opioid analgesics.[28]

- In August this year, the Welsh Advisory Panel on Substance Misuse called for evidence on the misuse of prescription only medicines focussing on OP.

There is clearly a need for much more help and guidance for GPs and also pain specialists. The market research cited above revealed that having identified a patient as being addicted to their medication, 67% of the GPs and 75% of the pain specialists surveyed were uncertain what to do with the patient and wished there were good treatment options for the patient even though both groups were open to identify and treat OAD patients by offering good quality of care and were comfortable treating these patients. Other summary findings from the research were that:

- GPs found that having discussions with the patient and incorporating their own intuition and experience was most effective in assessing and establishing whether a patient is developing or has an addiction to their opioid pain medication.

- GPs concur that the prescribing physician should take responsibility for identifying the opioid addiction, those identified patients should be regularly reviewed and monitored for their OAD and patients should be treated in primary care rather than being referred to drug and alcohol treatment services.

- GPs prefer to maintain patients on current opiate treatment but with reduced dosage and increase frequency of patient visits.

- Meanwhile, pain specialists would rather refer patient to a specialist and use opioid rotation to another opioid, an abuse deterrent formulation or a patch.

Apart from all the anecdotal evidence around general lack of awareness of dependency risk and lack of monitoring of OP prescriptions among doctors, two

[27] Public Health England/NHS England (2014). *Advice for prescribers on the risk of misuse of pregabalin and gabapentin.*
[28] Martin Johnson, RCGP lead on chronic member and member of the Opiate Painkiller Dependency Alliance. Personal communication

recent case reports from the *British Medical Journal* highlight the problem. To summarise:

- In one case, the patient was prescribed dihydrocodeine post-operatively which she continued taking progressively over the next four years while failing to mention any problems to her GP for fear of losing her prescription. After further surgery during which time her opioid dependency was identified and the GP informed, still the dependency issues were not addressed and she went on to have spells on illicitly obtained dihydrocodeine and even heroin before she eventually, five years after the original prescription for post-operative pain, was referred to a drug treatment service and began a process of recovery.[29]

- In a second case, the patient was first prescribed OP in 2002, but carried on taking them in escalating doses (especially after the loss of a parent in 2008), from the GP both in and out of hours, from A&E departments, family and friends and also street dealers during which time she would experience physical withdrawal symptoms. It took the arrival of a new GP in 2012, to realise what was going on (by which time the patient was taking 600 dihydrocodeine tablets a week) to build trust with the patient, eventually referring her to a drug treatment service, where like the previous case, she began a course of tapering opiate substitute treatment and was later quoted as saying, "I've got my life back, something I thought would never happen."[30]

What has been the response from drug treatment agencies?

In their 2011 report *Addiction to Medicines,* the National Treatment Agency surveyed the 149 partnerships across England and Wales that were providing substance misuse services. Given the obvious reluctance of patients with POM/OTC problems to come forward to traditional drug treatment service, it was hardly surprising that, "local partnerships reported difficulty in quantifying the level of need within this population". There were very few areas providing specialist services for those who were not otherwise presenting with concurrent illegal drug use problems, rather a "widely held view" that POM/OTC clients were best treated within primary care under shared care arrangements.

It seems that specialist care for this group of patients is still hard to come by with proper assessment tools and national guidance still generally lacking, but two case studies from two English areas suggest ways forward.

Bradford

The long-standing Bridge Project in Bradford has a traditional substance misusing client group, but a couple of years ago, the staff began to see some unusual

[29] Conroy, S and Hill D (2014). *Failure to identify of effectively manage prescription opioid dependence acted as a gateway to heroin use – buprenorhpine/naloxone treatment and recovery in a surgical patient.* BMJ case report 2014 doi: 10.1136/bcr-2014-207458
[30] Hard, B. (2014). *Management of opioid painkiller dependence in primary care: ongoing recovery with buprenorphine/naloxone.* BMJ case report 2014: doin: 10.1136/bcr-2014-207308

presentations of people dependent on OTC medications where the doctor had refused to prescribe any more prescription-only medicines. One client was actually buying codeine phosphate from a street drug dealer. Together with a rise in presentations concerning the new psychoactive drugs (so-called legal highs), Bridge designed a new programme to cater for the needs of some new client groups. Called, 'The Change Programme, it was officially launched in June this year, but has been running as a pilot since 2014.

The profile for the users of the scheme seemed to chime with the studies and surveys mentioned above; often middle-aged women and men in active employment with a physical injury (usually a back problem, going back four years or more) going to pharmacies and buying up as many packs of codeine as they could get. Referrals have come from a number of different sources; signposted from pharmacies, Some had originally gone to NA and found their way to Bridge just trying to get some help. It is also planned that Bridge will work closely with GPs offering clinics and support on a shared care basis; this has proved to be successful with the specialist Benzo service and is currently being negotiated with the local CCGs.

Bridge has two premises; Salem Street for mainstream OTC and associated services and a newer facility called Unity Recovery Centre where they run a service for carers, ~~for~~ volunteers, benzodiazepine clients, abstinent clients etc. The waiting room has more of a feel of a GP surgery rather than a drugs service providing a far more comfortable environment for those with OPD than the normal drug treatment service environment. Bridge also has good connections with local pharmacies who are always asking for leaflets to give out to patients they think might have a problem.

What does the Change Programme Treatment Protocol look like?

1. A structured time-limited psycho-social intervention/behavioural change model. This would normally be over 12 sessions, but for OPD clients could run to 20 sessions.
2. Working with the GP to reduce prescriptions or switch over to an appropriate opiate substitute treatment like buprenorphine/naloxone.
3. With OTC medication, either a reduction plan or a reducing prescription of buprenorphine/naloxone

Alongside having the right physical environment for these new patients (and ultimately that may be a clinic run out of a GP surgery) and having a properly structured care plan, Bridge found that it was important to have comprehensive community buy-in from the Clinical Commissioning Group and GPs.

South Gloucestershire (SG)

South Gloucestershire DAAT have commissioned a specialist benzodiazepine service for the last 10 years using the pooled treatment budget funding to support Battle Against Tranquillisers (BAT), a very small charity offering one-to-one and group sessions with clients and awareness sessions with local professionals. Anecdotally, BAT were also seeing some OTC dependent people. The service clearly delivered effective services and had maintained excellent results against the NTA defined outcomes. The Commissioner was impressed with BAT's local knowledge and understanding, high level outcomes and the high esteem in which they were held by

those using the service. But at the time, it was also a battle for SG to carry on funding this service against a backdrop of criticism from the centre that this was not an appropriate use of budget, at a time when opiate and crack services were prioritised.

Then in 2010, the agenda began to change with the new Drug Strategy and following on from the APPG on Drugs report in 2009, medicines dependency began to come onto the radar. This led the Commissioner to pull together an expert team to compile an OP patient profile drawing on national and international data and studies and whatever limited local data they could find – which showed that SG had some of the highest levels of opiate analgesic prescribing in the region.

And yet again, the profile revealed a very different cohort of problem users and one that presented uncomfortable challenges for services – not the stereotypical heroin/crack user committing crimes to pay for street drugs, but an older cohort which based on initial statistics suggested middle aged users aged 45 plus living in non-priority neighbourhoods obtaining their supplies from doctors and pharmacies. The data suggested that this was prescribed medication not illicit suggesting that the problem could lie in the over prescribing of opiate analgesics

It was also a challenge to GPs, so like in Bradford, it was important to get the GPs who sat on the Joint Commissioning Group to sell the idea to their peers that there was an issue that needed to be addressed in a collegiate manner while making it clear that any new service development was not aimed at 'bashing' GPs about prescribing.

The profiling exercise revealed an array of potential patients to work with, so for the purposes of a pilot study, it was decided to focus on those using Tramadol and those also experiencing low level anxiety and depression. There were a few (American) assessment tools available, but the Commissioner settled on the Opiate Risk Assessment Tool (ORAT) developed by Harvey Walsh, an NHS contractor, which the Commissioner's expert team nevertheless stress tested in terms of data security and other key performance elements.

At the time of writing, the Commissioner is tendering for a service which will put workers in GP surgeries enabling an easy referral pathway for GPs wanting specialist help for any patient with a dependency on medications. The idea further expands the idea that effective shared care yields benefits in terms of improved relationships and more effective collaborative working which maximises the use of primary care and destigmatises accessing substance misuse services.

Patient advocacy

It is often the case that patients themselves have to take up the cudgels to raise awareness of otherwise hidden health issues both at a local and national level and also to establish ways of offering help and advice to those in difficulties. The world of opiate painkiller dependency is no different and the following is a select list of known patient advocacy groups:

Action on Pain
Provides support and advice to people affected by chronic pain as well as trying to assist those have become dependent on opioid based painkillers.

www.action-on-pain.co.uk

DrugFam
Are you affected or someone you know affected by someone else's opioid painkiller dependence?
Office: 01494 442777 | **Helpline**: 0300 888 3853 (7 days a week) 9am – 9.00pm
www.drugfam.co.uk

Opiate Painkiller Dependency Alliance
OPD Alliance brings together pain and addiction professionals in a collaborative approach to raise awareness and understanding of opioid painkiller dependence and to call for appropriate treatment and services across the UK.
http://opdalliance.org

Over-Count Drugs Information Agency
Small non-profit organisation offering support and advice to those affected by dependence on over the counter medications.
http://over-count.weebly.com/

PAIN – Painkiller Addiction Information Network
The first UK charity dedicated to raising awareness of addiction to prescription and over-the-counter opioid painkillers.
http://painkiller-addict.com/

Pain Concern
Providing support to people with pain and those who support them. This includes those dependent on their medication. Call for support, information, or just for a chat.
0300 123 0789 - 10am-4pm weekdays.

Conclusion

It is clear that by every indicator, the use of prescription and OTC painkillers is on the increase. This is accompanied by rising mortality and inaugural data suggesting recreational use of these medicines. And as we are experiencing an ageing population, prescribing for pain is likely to increase further.

Government agencies and the medical profession have begun to engage with the issue, prompting calls for more prescribing guidance for GPs beyond that provided by the British National Formulary and MIMS, at least an annual review of prescribing, evidence-based assessment tools and so on. Evidence suggests that the cohort of those experiencing OPD is very different from the cohort traditionally using drug treatment services and new services need to be developed to cater for their needs. Establishing these services within GP surgeries would be a positive step forward.

At the same time, it would be a mistake for genuine concerns about OPD to become over-heated and certainly this should not develop into an attack on GPs, many of whom do acknowledge this problem. It would not be in the best interests of patients for over-regulation to engender a 'opiophobic' response in doctors.