

EVALUATION OF SUBOXONE FEASIBILITY STUDY IN IRELAND

An independent report for

Department of Health and Children, Ireland
An Roinn Sláinte agus Leanaí

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1. INTRODUCTION

1.1 AIMS, OBJECTIVES AND SCOPE

The aim of this evaluation was:

To review the use of Suboxone in the Irish context.

The evaluation was specific to the use of Suboxone for the treatment of opioid dependence. The evaluation did not consider the use of buprenorphine products for pain relief. The specific objectives of the evaluation were:

- 1) To evaluate how patients were selected for participation in the Suboxone feasibility study and how they progressed through it.
- 2) To examine how the prescribing and dispensing of Suboxone for patients operated in the Irish setting.
- 3) To consider the practical operation of the feasibility study including prescription writing, the operation of the Suboxone database and the role of key agencies.
- 4) To identify the core elements of the regulatory framework needed for the safe and appropriate use of Suboxone in the Irish setting.

Create Consultancy Ltd., an independent agency specializing in substance misuse and health improvement, based in Glasgow, Scotland, tendered for the contract to carry out this evaluation in June 2010 and was successful. The evaluation was carried out between October 2010 and February 2011.

It is important to note that while the Suboxone feasibility study commenced in June 2009, Suboxone had been in use in Ireland for a number of years prior to that date in the clinic setting. As can be seen from the objectives above, the scope of this evaluation was not restricted to those patients who were prescribed Suboxone as part of the study. When the feasibility study started, there was no process in place for formally consenting patients and prescribers who were already receiving or prescribing Suboxone in the clinic setting to take part in the study. In addition, patients who received Suboxone as part of the feasibility study, did not provide written consent at the time of agreeing to receive Suboxone, to have their records reviewed and their details passed onto an independent evaluator for the purposes of the patient survey.

For these reasons, when the evaluation of the feasibility study commenced in October 2010, following ethical approval, it was necessary to seek written informed consent from all patients prior to their involvement. In practice, this meant that not all patients could be contacted for the patient survey and not all patient records were available to be audited as part of this evaluation. Nonetheless, in discussion with the steering group, it was agreed that the above objectives would be considered, where practically possible, in relation to all use of Suboxone in Ireland, whether prescribed prior to the feasibility study or not.

1.2 ABOUT SUBOXONE

Buprenorphine/Naloxone (Suboxone®) is a sublingual tablet indicated for substitution treatment for opioid drug dependence. Suboxone combines a partial opioid agonist (buprenorphine) and an opioid antagonist (naloxone) in a 4:1 (buprenorphine:naloxone) ratio.

Buprenorphine (the primary active compound) reduces patients' opioid cravings and withdrawal symptoms. In addition, buprenorphine may discourage patients' use of nonprescribed opioids by binding to the mu receptor, thereby blocking other opioids' effects¹.

The intention of the naloxone component is to deter intravenous misuse and to help discourage diversion. Naloxone has very limited bioavailability when administered sublingually, as intended. However, in heroin dependent individuals, if Suboxone is crushed and injected, the naloxone is likely to precipitate opioid withdrawal. In the absence of an opioid, the antagonist has no effect.

Buprenorphine's low intrinsic activity causes less euphoria than full opioid agonists, resulting in a lower potential for abuse, but sufficient positive effects to aid in compliance. The low intrinsic activity of buprenorphine also has been shown to produce less physical dependence compared with that of full opioid agonists. Buprenorphine's slow dissociation from the mu receptor prolongs its therapeutic effect and contributes to Suboxone's relatively mild withdrawal profile.¹

Suboxone is generally safe and well tolerated. As with other medications in this class, the most commonly reported side effects for Suboxone include headache, withdrawal syndrome, pain, nausea, insomnia, and sweating.²

Suboxone can reduce respiratory rate. However, because buprenorphine is a partial opioid agonist, when taken alone it exhibits a ceiling dose beyond which no greater effect is observed on physiologic or subjective measures.² This "ceiling effect" on respiratory depression—unlike full opioid agonists with which respiratory depression continues increasing as the dose increases—means Suboxone® by itself is less likely to cause death in the event of an overdose.²

In spite of buprenorphine's favourable safety profile, caution is advised regarding its concomitant use with other sedatives, such as benzodiazepines, due to the additive effects exerted by buprenorphine.³ Inappropriate concomitant use (e.g. higher doses than prescribed, intravenous administration) of psychotropics (especially benzodiazepines) and buprenorphine appears to be one of the risk factors for buprenorphine-related fatalities.^{4 5}

¹ Walsh SL, Eissenberg T. The clinical pharmacology of buprenorphine: extrapolating from the laboratory to the clinic. *Drug Alcohol Depend.* 2003;70(suppl 2):S13-S27.

² Walsh SL, Preston KL, Stitzer ML, Cone EJ, Bigelow GE. Clinical pharmacology of buprenorphine: ceiling effects at high doses. *Clin Pharmacol Ther.* 1994;55:569-580.

³ Buprenex Prescribing Information. Richmond, Va: Reckitt Benckiser Pharmaceuticals, Inc; July 2001.

⁴ Kintz P. Deaths involving buprenorphine: a compendium of French cases. *Forensic Sci Int.* 2001;121:65-69.

⁵ Kintz P. A new series of 13 buprenorphine-related deaths. *Clin Biochem.* 2002;35:513-516

Licensing Conditions

Suboxone was granted a pan-European licence by the European Medicines Evaluation Agency (now the European Medicines Agency) in 2006. It is licensed for

“substitution treatment for opioid drug dependence in adults and adolescents over 15 years of age who have agreed to be treated for addiction, within a framework of medical, social and psychological treatment, by physicians experienced in the treatment of opiate dependence/addiction”.

As is normal in the case of pan-European licensing, no specific guidance is given on what constitutes a framework of ‘medical, social and psychological treatment’ or what level of knowledge or experience need to be met in order to be considered a ‘physician experienced in the treatment of opiate dependence/addiction’. This is to allow flexibility in terms of how these phrases are interpreted by individual Member States in line with their differing health services.

1.3 SUBOXONE IN IRELAND: TIMELINE

Prior to 2006	Buprenorphine (Subutex®) was being prescribed in Ireland for opioid dependence by prescribers in specialist treatment settings. Use was very limited primarily to patients with specific medical need or to some young people.
22nd June 2006	Date of commencement of first patient on Suboxone recorded on the Suboxone database
2006/07	Suboxone pilot proposed by Addiction Services in HSE Dublin Mid-Leinster
7th October 2006	Pan-European Licence for Suboxone announced.
23rd February 2007	Launch of Suboxone in Ireland. Event organized by Schering Plough for senior prescribers, pharmacists and others.
February 2007	First meeting of the Suboxone Expert Group
November 2007	Economic evaluation of Suboxone published by National Centre for Pharmacoeconomics.
April 2009	Final protocol for feasibility study produced.
June 2009	Suboxone feasibility study commenced.
17th June 2009	Date of commencement of first patient on Suboxone initiated in community general practice recorded on the Suboxone database
July 2010	Independent evaluation of Suboxone feasibility study commissioned.
October 2010	Ethical approval granted for independent evaluation.
December 2010	Methadone protocol review report recommends that buprenorphine should be made available in Ireland.
April 2011	Publication of report of independent evaluation of the Suboxone feasibility study.

The protocol for the rollout of the feasibility study is included in Appendix A.

2. METHODS

2.1 METHODS USED IN THE STUDY

This study consisted of a mixed method approach including analysis of quantitative records, clinical records and semi-structured interviews and surveys. The approaches used were designed to capture as far as possible an accurate historical report of what happened as the feasibility study was rolled out and the depth and breadth of opinions, experiences and practices among the staff and patients involved in the feasibility study. The methods used are summarised in the following table.

Table 1: Method	Details	
Stage 1: Planning.	Development of data collection plans, patient information sheet and patient consent forms. Ethical approval obtained.	
Stage 2: Recruitment & Consenting	Provision of consent packs to prescribers and some dispensers. Prescribers/dispensers obtained informed consent from patients where possible.	
Stage 3: Stakeholder Involvement	3a. Semi-structured Interviews with prescribers	n=8 (excluding key informants)
	3b. Semi-structured telephone survey with pharmacists/dispensers	n=13 (excluding key informants)
	3c. Semi-structured survey with patients. Survey was set up online, and completed by patients themselves or by telephone.	n=36
	3d. Patient meetings and submissions	Face to face patient meetings (n=2). Written submissions from individual patients (n=2)
Stage 4: Patient Record Reviews	Review of clinical notes and dispensing records where available for a selection of consented patients.	n=41
Stage 5: Key Informant Interviews	Semi-structured telephone interviews with key informants	n=5 <i>Some were interviewed on more than one occasion.</i>
Stage 6: Analysis	6a. Tallying of quantitative data. 6b. Thematic analysis of qualitative data with transcription as needed. 6c. Review of additional documentation including product licence, economic evaluation, protocols/guidelines in use, patient information and relevant literature.	
Stage 5: Write Up	Final report submitted in March 2011, finalised April 2011.	

2.2 PROCESS & LIMITATIONS OF THE STUDY

There are a number of factors which should be taken into account when reading this report. These are outlined below.

- The findings of this report are based on the fieldwork and methods described above. It cannot be assumed that the views of the participants in interviews or surveys are representative of all similar stakeholders.
- The report is concerned with exploring learning from the use of Suboxone in the Irish context including a range of stakeholders' experiences. The feasibility study was not a clinical trial nor did this evaluation include a formal economic evaluation. This report has sought however to describe how Suboxone was used in Ireland in the feasibility study and to discuss how the findings relate to some of the scenarios discussed in the previous pharmacoeconomic assessment carried out by the National Centre for Pharmacoeconomics.
- The views of those interviewed and surveyed are taken and reported in good faith and are their own, not necessarily those of Create Consultancy Ltd. or the Department of Health and Children of Ireland. Prescriber and key informant interviews were recorded electronically.
- The views of practitioners and patients reported here are only of those who were involved in the study. Doctors and pharmacists who chose not to be involved with Suboxone provision, patients who declined consent for involvement in the evaluation, or patients who were offered, but did not ultimately receive Suboxone treatment, were not included. It is possible that the participants in this evaluation may have been more positively disposed to Suboxone.
- It was difficult to obtain consent from patients who had successfully or unsuccessfully completed Suboxone treatment but who were no longer in regular contact with treatment services. The impact of this on the findings is unknown. However, analysis of the figures for this group would suggest that this would be most likely to lead to a bias in favour of the use of Suboxone in this report. This needs to be taken into account when reading the report.
- Of those patients who did consent to take part, we were unable to conduct the survey with 36 patients. This was due to a variety of reasons including phone numbers not working, no answer to calls, patients not responding to telephone messages or patients not responding to emails.
- We were unable to secure a telephone interview with a prescriber outside of the Dublin area, although we did engage with patients and a pharmacist outside of Dublin.

3. FINDINGS AND DISCUSSION

3.1 SUBOXONE USAGE IN IRELAND

3.1.1 DATA FROM SUBOXONE DATABASE

A total of 139 patients were registered on the Suboxone database held by the DTCB as having received Suboxone between 1st January 2006 and 31st January 2011.

Of these patients, 10 were in treatment with Suboxone on two separate occasions, making 149 treatment episodes over the period for which figures were obtained.

The gender, location and age breakdown of the patients who received Suboxone in this period is included in Table 2 below.

Table 2: Suboxone Treatment Statistics from Suboxone Database

Total Number of Patients	139	Age (+or – 6months) of Patients at Start of each treatment episode.	n=149 treatment episodes
Males	65.5% (n=91)	Under 18	4% (n=6)
Females	34.5% (n=48)	18 – 25 years	21% (n=31)
Total Number of Treatment Episodes	149	26 – 35 years	40% (n=60)
Proportion previously treated with Methadone (as recorded by CTL)	55% (n=76)	36 – 45 years	26% (n=39)
		46 years and over	9% (n=13)
HSE Area	Patients	HSE Area	Patients
ECA	9	NWA	4
MA	2	SEA	3
MWA	1	SWA	46
NA	59	WA	3
NEA	10	No Fixed Abode.	2

Table 3 on the next page provides a breakdown of where patients were treated. It includes details of those patients who may have changed prescriber or location of prescribing or dispensing in the one treatment episode.

Table 3: Prescribing and Dispensing Settings from Suboxone Database for Treatment Episodes

Totals for all or part of Treatment episode:		
Prescribing Setting: DTCB=50; Clinic=61; GP=53.		
Dispensing Setting: DTCB=51; Clinic=45; Community Pharmacy (CP)=65; Hospital Pharmacy=3		
Details of Specific Prescribing/Dispensing Combinations		
Prescribing Setting / Dispensing Setting	Full treatment episodes	Full or Part Treatment Episodes.
DTCB / DTCB	46	49
Clinic* / Clinic	44	49
GP / CP	42	52
Clinic / CP	3	12
GP / Clinic	1	1
DTCB / CP		1
Transfers between settings i.e. part of treatment episode prescribed and dispensed in one combination and part(s) in another.		
Clinic/Clinic to Clinic/CP		1
Clinic/Clinic to Clinic/CP back to Clinic/Clinic		1
Clinic/CP to Clinic/Clinic		1
Clinic/CP to GP/CP		6
GP/CP to DTCB		1
GP/CP to Clinic/Clinic back to GP/CP		1
DTCB to GP/CP		1
DTCB with 1 day dispensed in CP.		1
<i>*includes 5 in ACCEPT clinic, 2 of which were dispensed in DTCB and 3 in Waterford Regional Hospital.</i>		

Table 4 below provides an indication of the number of prescribers and dispensing locations involved in providing Suboxone and the numbers of Suboxone patients who were managed by/in each.

Table 4: Analysis of Individual Prescribers and Dispensing Locations

Prescribers	Number of Individual Prescribers	Range of Patient numbers managed.	Dispensers	Number of Locations	Range of Patient Numbers Managed.
DTCB/Clinic	11	2-18	Community Pharmacies	39	1-7
GPs	7	1-25 patients	DTCB	1	45 total
<i>3 of the 7 GPs managed 49 patients between them. The other four managed 1 patient each. 2 of the GPs are also included in the 11 clinic prescribers. The vast majority of community pharmacies only managed 1 patient.</i>			HSE Clinics	9	1-15
			Hospital Pharmacies	1	3 total

3.1.2 SELECTION OF PATIENTS AND REASON FOR PRESCRIPTION

The Suboxone database figures show that of the 149 separate treatment episodes, 27 (18%) were originally registered for detox, the remainder being registered for maintenance treatment. Of those who were originally registered for detox, 10 are still in treatment with Suboxone, 8 of whom were commenced prior to June 2009.⁶

Reason for Suboxone Prescription as Recorded during Patient Record Reviews

Other data that can inform our understanding of the reasons for prescription were gathered in this evaluation through the patient record reviews, prescriber interviews and patient survey. Table 5 indicates the reasons for prescription recorded in the 41 patient records which were reviewed.

Table 5: Selection of Patients/Reason for Prescription noted in Clinical Record or Reported by Prescriber for a Patient	41 Records were Reviewed ⁷
Patient had low level of heroin dependence <i>having either never injected, had a short history of use, had rarely injected, or had only injected a long time prior to treatment.</i>	16
Patient requested it, or didn't want methadone.	10
Detox requested not maintenance	6
Previous failed methadone treatment noted, or particular difficulties coming off methadone are noted in the record.	5
Stable: <i>notes include mention of how stable the patient is, in some cases stable on methadone, in other cases meaning 'socially stable', even if not in treatment.</i>	5
Medical need: <i>Prolonged QT interval was the medical need in these four cases.</i>	4
Codeine dependent / oxycodone dependent	4 / 1
Previous buprenorphine treatment e.g. in UK or self treatment noted.	3
Unclear <i>if any of the above apply</i>	2

⁶ It seems likely that different clinicians use different criteria for deciding when to indicate that a treatment episode is for detox or maintenance. It does not seem that a change in the treatment programme for an individual patient (e.g. from detox to maintenance) would necessarily be communicated to the Suboxone database.

⁷ This table should be viewed bearing in mind the following factors: the reason for prescription was recorded for an individual patient if it was noted in their clinical record; where possible, particularly in cases where the reason was unclear, and the prescriber was available, the prescriber was also asked the reason for prescription and this was recorded; more than one reason may have been recorded in relation to each patient file; there may have been other reasons/factors not recorded in the clinical records and/or not mentioned by the prescriber.

Approximately half of the patient records which were reviewed indicated that the patient had previously been treated with methadone. In addition to this, a small number of patients who had never been maintained on methadone had had detox treatment previously. Most patients had been heroin users, though about a quarter had never injected the drug. There was a small cohort of codeine users (n=4) whose records were also reviewed.

As noted in Table 2 above, of those patients (n=139) who received Suboxone between 1st Jan 06 and 31st Jan 11, 55% (or 76 patients) had been treated with methadone on at least one occasion prior to receiving Suboxone.

Reasons for Prescribing Suboxone reported by Prescribers

In interviews, doctors described the kind of patients for whom they would consider prescribing Suboxone. Their descriptions focused on similar groups and criteria:

1. Those who wanted to detox fairly quickly or who had been successful in achieving periods of abstinence in the past.
2. Those with a fairly short history of use, particularly those who had never or v. rarely injected heroin.
3. Those who were relatively stable socially, domestically, particularly if in education or employment. Stability was seen more as a prerequisite for consideration for Suboxone treatment, rather than that all stable patients should be offered Suboxone.
4. Those who were requesting it, out of a desire for an alternative to methadone. This group tended to include those who had been on methadone previously and found it hard to come off it in the past. In the main however, this group consisted of people who had heard positive reports about Suboxone (generally on the 'grapevine').
5. Those who had reduced their methadone dose to, say 20mg, and were finding it difficult to reduce further.
6. Those who were dependent on codeine rather than heroin.
7. Those who had a medical need including heart or respiratory problems that meant that methadone was contra-indicated.

Table 6: Main drug of dependence (where listed)		41 Records
Heroin		34
<i>of which: heroin (smoked but not injected)</i>		10
Codeine		4
Subutex from UK,		1
Oxycodone,		1
Also mentioned:		
Benzodiazepines		2 cases
Alcohol		2 cases
Cocaine		2 cases

Prescribers reported generally avoiding prescribing Suboxone to drug users who were more chaotic or who were poly-drug or benzodiazepine users or who had a history of non-compliance.

Reasons for Being Prescribed Suboxone reported by Patients

Both patients who had previously been on methadone and those who hadn't indicated that they were prescribed Suboxone as it was felt after discussion with their doctor that it was the best option for them (79% of 33 patients).

Patients who had previously been on methadone (n=22) were most likely to say that they had been prescribed Suboxone because they had previous side effects from methadone (45%), methadone didn't work for them (41%), they wanted to detox (41%) or they requested it (41%).

The most common reasons for having been prescribed Suboxone among patients who had never previously been treated with methadone (n=11) were:

- I wanted to detox (e.g. to be substance free) rather than to stay on treatment (e.g. maintenance) – 55%
- I wanted to be more alert than I would be on methadone – 46%
- I thought Suboxone would suit me because I felt I was less likely to top-up while on it than with methadone (e.g. with heroin or other unprescribed opioids) - 36%
- I didn't want methadone because I have heard bad things about methadone - 36%
- I didn't want methadone because I have heard methadone is very hard to come off/detox from - 46%
- I didn't want methadone because I feel methadone is not for people like me - 36%
- Suboxone was recommended to me - 36%

3.2 OUTCOMES AND EXPERIENCES OF SUBOXONE

3.2.1 SUBOXONE DATABASE FIGURES

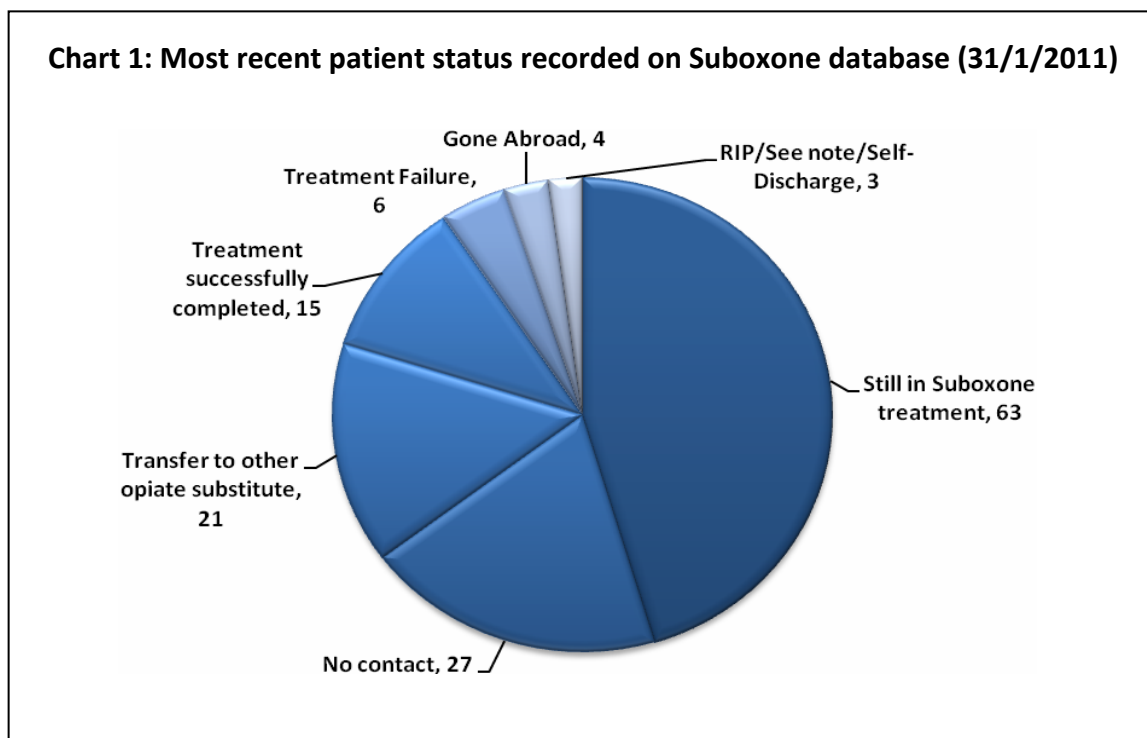
The Suboxone database records an exit reason at the end of each treatment episode and the reasons recorded for the Suboxone feasibility study are shown in Table 7 and Chart 1 below.

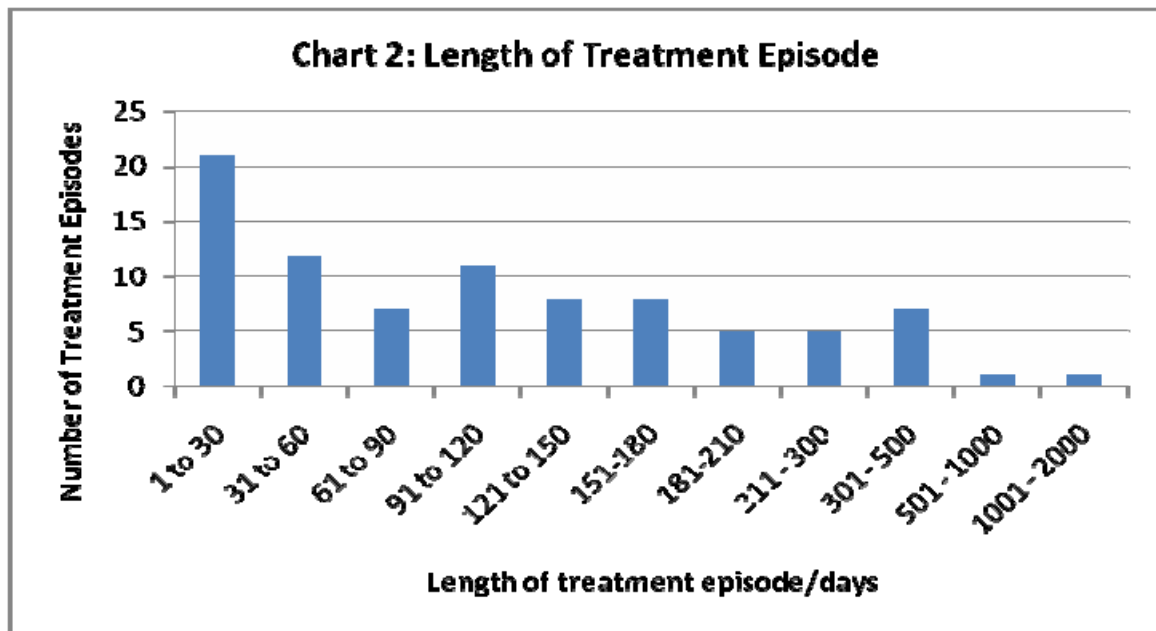
Table 7: Treatment Outcomes as recorded on Suboxone Database	Outcomes per Treatment Episode Total n=149	Outcomes for Individual Patients Total n=139
Still in Suboxone treatment on 31st Jan 2011	63 (42%)	63 (45%)
Exits from treatment (or from treatment episode)	86 (58%)	76 (55%)
Reason Recorded for Exit:	<i>Reasons for exit as % of those who exited:</i>	
No contact	34% (n=29)	36% (n=27)
Transfer to other opioid substitute	27% (n=23)	28% (n=21)
Treatment successfully completed	22% (n=19)	20% (n=15)
Treatment Failure	8% (n=7)	8% (n=6)
Gone Abroad e.g. UK	6% (n=5)	5% (n=4)
'RIP ⁸ '; 'See Note'; Self-Discharge	3% (n=1 of each).	3% (n=1 of each)

⁸ The death of this patient was unrelated to treatment with Suboxone.

Key points of interest are that:

- The figures indicate that on the 31st January 2011, 11% or 15 of the 139 patients who had started on Suboxone were recorded as having successfully completed treatment with Suboxone. This included 6 of the 27 patients who were originally registered with the Suboxone database for detox treatment and 9 who were registered for maintenance. Of those who were no longer on Suboxone treatment (n=76) as at 31st Jan 11, 33 patients were registered in treatment with methadone on that date. This included 20 who had had methadone treatment prior to being treated with Suboxone and 13 who had not had methadone treatment prior to being treated with Suboxone. The exit reasons recorded for Suboxone indicate that 21 patients transferred directly to methadone treatment.
- Of the 86 completed treatment episodes, the length of time in treatment with Suboxone ranged from 1 day to 1,573 days with the median being 94 days, and the mean being 138 days. The numbers of episodes of different durations are shown in Chart 2 on the next page.





3.2.2 PATIENT OUTCOMES AND EXPERIENCES

Behind the hard figures on retention in treatment and exits from treatment, patients, mainly who were still being treated with Suboxone, provided very positive reports of the benefits of Suboxone for them. Their final comments on the survey provide a good sense of the range of views that were given, but as can be seen from the full range (see Appendix B), users who consented to take part in the survey were almost overwhelmingly positive.

Among the benefits reported by patients were feeling like themselves again, reduced cravings, not thinking about heroin, having a clear head and recovering a range of aspects of normal living. A couple of patients spoke about the difficulties of having to be in withdrawal at the start of treatment and how this might be a barrier for some individuals. Many spoke about Suboxone as being for people who really want to come off opioids, whereas it was seen as normal to use heroin on top of a methadone prescription, especially at the start.

"I just think it's the best thing that's ever happened to me and if there's people out there who are determined to stop using they should be put on this drug. It's just changed my life for the better. I couldn't get out of bed for depression - now I'm nearly 25 weeks clean! It's an amazing drug. And the good thing is I know I can't smoke when I am on it because of the negative.. I was on methadone for 3 years and was still using and using, it didn't work. It kills all the cravings - it's great. I have to praise it that much because it's changed my life and the lives of my family and children - I am there for them now."

"Anyone that wants to, will get off heroin 120%, your life just comes back. It's unbelievable how sharp your brain gets. It's incredible; you're just back to yourself. Absolutely amazing."

"Personally it has been a godsend. For 3 years I was hopelessly addicted to Nurofen Plus. I should be dead by now, however because of Suboxone I am still alive."

"I think if you get Suboxone you still have to really want to be clean; it doesn't hypnotise you or anything. But I think they should get rid of methadone - nobody ever really gets clean using methadone."

"I genuinely am a supporter of it. I would imagine, it's not my scene but I would imagine it's probably safer than methadone. I think the drowsiness of methadone is almost self-perpetuating, people like to add to it, maybe they're people that want to do that anyway, but Suboxone doesn't even enter into that territory of topping up.

Other findings from the patient survey not reported elsewhere in this report are described below. A full report of the survey findings can be found in Appendix B.

- Heroin was the most common opioid misused by patients (83%) prior to treatment with Suboxone followed by codeine (11%). Others selected 'prescribed methadone', but it is unclear what substance they used prior to their methadone prescription, and it is likely that some of those who selected heroin were also being treated with methadone immediately prior to treatment with Suboxone.
- Just under half of patients (44%) first heard about Suboxone through a doctor, with smaller numbers hearing about it through addiction counsellors (14%) and other drug users (11%).
- Of the 36 respondents, 85% (n=30) were still being treated with Suboxone, 9% (n=4) had switched to treatment with methadone, and 6% (n=2) had detoxed from Suboxone and were no longer taking any opioids.
- The majority of patients felt that treatment with Suboxone had improved the quality of their lives (88.9%) and had made their health better (58.8%).
- 31.4% of patients felt that there was a downside to treatment with Suboxone. These downsides included negative or upsetting side effects from treatment with Suboxone, problems with the way it is taken or prescribed, the need to go into withdrawals before treatment, and that you are still addicted to a drug and as such there may be difficulties 'detoxing' from Suboxone.
- 69% (n=25) of patients had previously been treated with methadone for opioid dependence.
- Of these 25 patients, a large majority reported that Suboxone was more effective at preventing withdrawals (80%) and controlling cravings (84%) than methadone. 96% said that they were less likely to use other opioids to top up while on Suboxone than on methadone. Of the 16 patients who had tried to reduce their dose or come off Suboxone, 94% (n=15) reported that they found it easier than with methadone. One patient found it the same and no-one found it more difficult.

Two patients submitted letters/written testimonies of their experiences with Suboxone. These were both very positive. One described how he had always used heroin and continued to do so daily for the first four weeks of treatment with Suboxone, until one Saturday when he found that he couldn't get any heroin and so only had Suboxone that day. He described how he had expected to have been up all that Saturday night, but was surprised that he slept well that night and the next night, and didn't experience any strong withdrawals (due to the Suboxone treatment). That was 14 months prior to him writing the testimony and he claimed not to have taken any heroin since.

"I can function daily, do my college course and virtually do what I want."

“I have done lots of detoxes but I could not get off (heroin) no matter what. I think I’m on Suboxone around a year now and I’m doing really good. I came off heroin no problem. Suboxone is very good.”

It is important to recognise that the views of the patients who were not retained in or who did not successfully complete treatment are missing from the survey as they could not be contacted or consented to take part. Intuitively however, their views would be likely to be less positive. It is worth noting nonetheless, that the considered comments of users in this survey reflect attitudes about use of opioids to ‘top up’ while in treatment with methadone that are similar to those reported in the UK SUMMIT trial⁹. The SUMMIT findings, as reported by <http://findings.org.uk> suggested that patients who choose buprenorphine and methadone treatment may want different things from their treatment:

“Methadone-choosers were more wedded to continuing to experience opiate-type effects and more likely to see treatment as a way to control their opiate use while still occasionally ‘enjoying’ heroin or using it to help them cope. They valued methadone’s stronger opiate-type effects and its ability to prevent withdrawal symptoms. In contrast buprenorphine-choosers more often valued its ability to prevent them feeling opiate-type effects and to pave the way to ending (illicit) opiate use altogether. They seemed more likely to be in treatment for ‘cure’ rather than ‘control’ purposes.”

3.2.3 PRESCRIBER AND DISPENSER VIEWS

Prescriber and dispenser views about the success of Suboxone were much more mixed than those of the surveyed patients and for many were based on experience with only a small number of patients. Pharmacists and dispensers reported mixed experiences in terms of how it had worked for patients, which largely depended on the individual patients they had dispensed to.

Prescribers also reported mixed views in the telephone interviews. Those prescribers who had a lot of patients felt that it had in general worked well and felt that they were gaining in experience of using it in terms of who it was most likely to work for. These quotes are from three different prescribers:

“Those who do well on it are fine with it – its good overall. It is just another option.”

“I was probably promoting it myself also...I needed to develop more robust criteria for putting them on Suboxone for myself. Some people weren’t suitable and failed.”

“I see methadone remaining the dominant treatment but first timers may well choose or benefit from Suboxone.”

They reported examples of where Suboxone hadn’t worked for patients and their reports echoed the sentiments expressed by users. They noted that some patients didn’t like the fact that Suboxone did not give them a ‘stoned’ feeling, whereas this lack of a ‘stoned’ feeling was felt by other patients to be a clear advantage of Suboxone. For those being treated in the young people’s programme, a level of wariness was reported about being ‘fobbed off’ with treatments other than methadone and this contributed to some patients wanting methadone. Other prescribers also mentioned that some

⁹ http://findings.org.uk/count/downloads/download.php?file=Pinto_H_3.txt

users wanted methadone due to the familiarity, the sense that they have tried it and they know it works in relieving withdrawal.

In discussing the experiences of individual patients as part of the record reviews for this evaluation, prescribers reported similar findings. They noted that some patients did not feel that being on Suboxone 'counts' as being opioid dependent. They also reported that patients who they did not initially feel were suitable for Suboxone but who had strongly requested it either surprised them with how well they were doing or had, as they expected, not done very well on it and had switched back to methadone or dropped out of treatment.

3.3 DISCUSSION OF SUITABILITY OF PATIENT GROUPS

There is currently no published evidence that demonstrates enhanced efficacy of Suboxone maintenance for any particular treatment cohorts though there is some evidence that it may be a better agent for detoxification from opioids¹⁰. The UK National Institute for Clinical Effectiveness has recommended that buprenorphine be used for maintenance therapy only where there are clinical reasons related to the person's history of opioid dependence, their commitment to a particular long-term management strategy and an estimate of the risks and benefits of each treatment. Where both methadone and buprenorphine are equally suitable, NICE recommend that methadone should be prescribed as first choice.

Of the groups who prescribers describe as being suitable for Suboxone in the feasibility study, it is worth considering which fit the NICE criteria. It is worth noting that there may be a clinical rationale for the provision of Suboxone but that does not necessarily mean that such use will be effective or the best option and further research is necessary to judge the effectiveness of Suboxone for different groups. In addition, rational prescribing does not necessarily equate with cost-effective prescribing, this is discussed in Section 3.4.4.

- 1. Those who wanted to detox fairly quickly** (perhaps including those who had been successful in achieving periods of abstinence in the past).

There is a general perception that buprenorphine is easier to detox from than methadone and this was supported by a recent enhanced meta-analysis synthesising the results from 20 separate clinical trials. This concluded, though with a small degree of uncertainty, that buprenorphine was more effective than methadone (and other non-opioid agents) at promoting completion of a detoxification regime¹¹. This supports the case for buprenorphine as first line treatment for detox regimes albeit with a couple of cautionary notes. The Suboxone database figures available show that in practice there is often a very grey area between detox and maintenance with many detox patients quickly being re-registered for maintenance, or on doses that are reduced over several months or longer. The NTORS study in the UK reported that slow reduction programmes that did not follow a pre-determined dose reduction regime often turned into maintenance programmes but with lower

¹⁰ Meader N. (2010). A comparison of methadone, buprenorphine and alpha2 adrenergic agonists for opioid detoxification: a mixed treatment comparison meta-analysis. *Drug and Alcohol Dependence*, 108, 110–114.

¹¹ Meader N. (2010). A comparison of methadone, buprenorphine and alpha2 adrenergic agonists for opioid detoxification: a mixed treatment comparison meta-analysis. *Drug and Alcohol Dependence*, 108, 110–114.

initial and ongoing doses. These were associated with poorer outcomes, particularly for highly dependent individuals, than regimes that set out to provide maintenance from the start¹².

As with any opioid, detoxing may not be the most difficult part for an individual, the more difficult element of recovery being to stay abstinent after the detox has been completed. In addition, there is a risk of overdose following detox, perhaps more so where detox is rapid or carried out outside of a community setting, due to loss of tolerance. It is worth noting that the Royal College of General Practitioners guidelines on the use of buprenorphine¹³ state that

“When comparing detoxification and maintenance treatment with methadone, outcomes are considerably better with long-term maintenance treatment. There is some evidence to suggest that this is also true with buprenorphine...Detoxification can be attempted with patients who wish to detoxify from all opioids. There is a high relapse rate to heroin use unless detoxification is combined with psychosocial interventions. As such, detoxification should not normally be seen as a stand-alone treatment.”

If Suboxone is being used for detoxification, it would seem wise to ensure that this is only done in combination with a programme of psychosocial intervention.

As noted above, 11% or 15 of the 139 patients who had started on Suboxone were recorded as having successfully completed treatment with Suboxone including 6 of the 27 patients who were originally registered with the CTL for detox treatment. It is not known whether these patients have remained abstinent since exiting treatment. It is also not known how these figures compare with methadone which may be useful, notwithstanding the differences between the two groups. The group of patients selected to receive Suboxone included more stable, less dependent individuals, often with a shorter history of opioid use and a perceived greater desire to be drug free and so one might reasonably expect a higher success rate than with a methadone cohort.

2. Those with a fairly short history of use, particularly those who had never or v. rarely injected heroin.

As can be seen from the audit of patient records, a relatively high proportion of those who received Suboxone fell into this category. Prescribers felt that Suboxone was more appropriate for these patients due to a sense that it would be counterproductive for many of these patients to become dependent on methadone. It was felt that putting them on methadone amounted to ‘increasing their dependence’ and that it would be difficult for them to come off it.

It may well be that Suboxone offers a treatment option which patients will find more easy to detox from, however for some patients who are relatively treatment naïve, retention in treatment may be more important than ease of detox and methadone has been found to be slightly superior in that

¹² Gossop M., et al., (2000). Patterns of improvement after methadone treatment: 1 year follow-up results from the National Treatment Outcome Research Study (NTORS). *Drug and Alcohol Dependence*, 60, 275–286; Gossop M., et al., (2001). Outcomes after methadone maintenance and methadone reduction treatments: two-year follow-up results from the National Treatment Outcome Research Study. *Drug and Alcohol Dependence*, 62, 255–264.

¹³ Royal College of General Practitioners, (2004). Guidance for the use of buprenorphine for the treatment of opioid dependence in primary care.

regard¹⁴. It could be argued that if an appropriately low dose of methadone is used, it should not increase their dependence, but this can also then affect retention. One reason why dependence may increase with the use of methadone is the culture of ongoing heroin use during initiation which is not the case with Suboxone. Further experience and research into the effectiveness of Suboxone with this group of patients is necessary to guide future prescribing.

Current thinking and policy in addiction treatment and funding is changing, particularly in the UK, so that retention in treatment is becoming less valued compared to in the past, and achievement of abstinence is becoming a more explicit goal of treatment in line with the wider 'recovery' movement. This shift in the politics of treatment will also likely influence decisions about whether buprenorphine or methadone are the most appropriate medication for different individuals.

3. Those who were relatively stable socially, domestically, particularly if in education or employment.

Stability was seen more as a prerequisite for consideration for Suboxone treatment, rather than that all stable patients should be offered Suboxone. It could be argued that the reduced sedation experienced by those being treated with Suboxone may make it beneficial as a first line treatment for some patients who are in education or employment. This would fit with the NICE criteria relating to risks and benefits but may not be welcomed by all patients.

4. Those who were requesting it, out of a desire for an alternative to methadone. This group tended to include those who had been on methadone previously and had relapsed as well as those who found it hard to come off methadone in the past. In the main however, this group consisted of people who had heard positive reports about Suboxone (generally on the 'grapevine').

In this case, the reasons behind the request need to be looked at. Some prescribers suspected that the requests came from a sense that being on Suboxone was somehow a 'better place' to be than being on methadone. Others may have felt that as a Suboxone patient, they were less vulnerable to the charge of being 'still an addict', that it didn't 'count' as an opioid or as put by one pharmacist that it was 'posh methadone'. Similar perceptions were also reported recently in relation to buprenorphine in the SUMMIT trial¹⁵. In these cases, it may be difficult to argue that there is any clinical reason for providing Suboxone without other justification.

However, if the request is based more clearly on previous failed treatment with methadone, previous side effects or a genuine desire to become opioid-free, it may reflect an informed weighing of risks and benefits of each treatment by the patient, and that would seem to fit the NICE criteria. In addition, the SUMMIT trial found that there were patients who would not enter treatment if methadone was their only maintenance choice. Suboxone offers a valuable alternative in these cases, though true refusal of methadone may not be easy to judge unless clinicians are prepared to 'call a patient's bluff', which would be difficult ethically. If patients have a strong desire for

¹⁴ Mattick RP, Kimber J, Breen C, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database of Systematic Reviews 2008, Issue 2.

¹⁵ Pinto, H., Maskery, V., Swift L., et al. (2010). The SUMMIT Trial: A field comparison of buprenorphine versus methadone maintenance treatment. *Journal of Substance Abuse Treatment*, 39, 340-352.

buprenorphine, this may be justified or changed by an informed and careful analysis of the risks and benefits of each drug with their clinician.

If patients have previously tried and failed to recover with methadone maintenance or detox and they wish to become substance-free, then it may make sense to offer Suboxone.

5. Those who had reduced their methadone dose to, say 20mg, and were finding it difficult to reduce further.

In the UK, the national clinical guidelines on drug misuse and dependence¹⁶ suggest that patients who have been maintained on one opioid substitute should remain on that opioid for detoxification. It could be argued that those who are already stable on methadone may not gain any benefit from moving to Suboxone and it risks destabilising them. However, where patients have already tried to reduce their methadone dose further and failed, it would be within the UK National criteria to try Suboxone as second line therapy, if the patient wants it.

6. Those who were dependent on codeine rather than heroin.

There is no published data on the use of Suboxone for detoxification or maintenance in these circumstances. Other forms of detoxification can be considered, particularly with lower codeine doses, but Suboxone may have a role to play in treating some patients, particularly where detoxification is the goal rather than maintenance. This group of patients seem to have been a relatively small proportion of those who received Suboxone in the feasibility study but as they were almost all treated in community settings, the numbers may increase significantly should Suboxone be more widely available for GPs to use.

7. Those who had a medical need including heart or respiratory problems that meant that methadone was contra-indicated.

In these cases, there is a straightforward argument for the availability of Suboxone where the alternative would be a potentially dangerous treatment (e.g. methadone) or no treatment at all. These patients would certainly merit being offered Suboxone based on the UK NICE guidelines, all other things being equal. This would also include patients on medication that interacts with methadone.

Groups Not Considered Suitable for Suboxone

Prescribers reported generally avoiding prescribing Suboxone to drug users who were more chaotic or who were poly-drug or benzodiazepine users or who had a history of non-compliance. This seems sensible.

In practice this was not always adhered to, with some patients who had been non-compliant on methadone having been prescribed Suboxone. Some of these patients did very well, and some less well.

¹⁶ Department of Health (England) and the devolved administrations (2007). Drug Misuse and Dependence: UK Guidelines on Clinical Management. London: Department of Health (England), the Scottish Government, Welsh Assembly Government and Northern Ireland Executive. http://www.nta.nhs.uk/uploads/clinical_guidelines_2007.pdf

3.4 PRESCRIBING AND DISPENSING IN PRACTICE

3.4.1 ASSESSMENT CRITERIA

The audit tool which was provided to us (based on a tool from the National Institute for Clinical Excellence) includes an item relating to the percentage of patients who have had an assessment that included:

- The person's history of opioid dependence
- The person's commitment to a particular long term management strategy
- An estimate of the risks and benefits of each treatment made by the responsible clinician in consultation with the patient.

In addition, the scope of this evaluation included an item relating to the setting of short and long term treatment goals. We attempted to audit the number of patients for whom assessment included these items via the review of patient records.

In all cases a drug history was taken and was recorded in varying levels of detail in the patient paper or electronic record. It was not possible to audit the extent to which patient goals and the risks and benefits of each treatment were discussed as these were rarely recorded in patient records. We could find five instances where some mention of patient goals (e.g. detox or maintenance) was recorded and one instance where the notes specifically recorded that a detailed discussion of Suboxone was carried out.

In general prescribers reported that they would not record details of patient's treatment goals or of the risks and benefits of each treatment in patient records. They felt that patient goals and discussion or risks and benefits would always happen at initiation of treatment. It is likely that the level of detail and depth of this discussion would vary from patient to patient and prescriber to prescriber.

3.4.2 DOSAGES AND DOSING REGIMES

Maintenance doses in use varied widely for different patients from 2mg daily up to 26mg daily. As records were reviewed at different times and dates, and the range of doses in use was changing week to week as some patients increased or reduced their dose, it does not make sense to report an average dose. We did not get a sense from prescribers that there was a standard dose, dosing was highly patient specific as would be expected given the wide range of patients recruited to the feasibility study.

A variety of initiation regimes were in use – with doctors varying their regimes for different patients and also some trends across doctors.

- 4mg in the morning, followed by 4mg in the afternoon on day 1, 12mg on day 2, 16mg on day 3, 20mg on day 4. Stabilising dose within 3-4 days.
- 4mg in the morning with another 2-4mg on same day, stabilising within 5 days.
- 6mg in the morning, followed by 6mg in the afternoon on day 1.
- 2mg on day 1 and 2-6mg a few hours later

More than one prescriber noted that their practice in initiating patients had changed since they first started prescribing Suboxone in that they were now less cautious about rapidly increasing the dose. Given the variety of regimes used, it would make sense for clinicians both in the community and clinic setting to have more contact with each other to share experiences and expertise gained through this feasibility study. Experienced clinicians would benefit from comparing their practice with that of others and less experienced clinicians could more rapidly gain a level of expertise and wisdom gained from practice based on the experiences of others.

Only one prescribing clinic made extensive use of double or triple dosing regimes to enable dispensing to be carried out less than daily without incurring the need for takeaway doses. Double doses were used only very occasionally or not at all by other prescribers. Where double dosing was used, the doses provided were up to 56mg. It is important to note that Suboxone (buprenorphine/naloxone) is licensed only for provision of doses up to 24mg/6mg in any one day, although Subutex (buprenorphine only) is licensed for daily doses of up to 32mg of buprenorphine.

An extract from the licence for Suboxone relating to less than daily dosing describes this:

“Less than daily dosing: After a satisfactory stabilisation has been achieved the frequency of Suboxone dosing may be decreased to dosing every other day at twice the individually titrated daily dose. For example, a patient stabilised to receive a daily dose of 8 mg may be given 16 mg on alternate days, with no dose on the intervening days. However, the dose given on any one day should not exceed 24 mg. In some patients, after a satisfactory stabilisation has been achieved, the frequency of Suboxone dosing may be decreased to 3 times a week (for example on Monday, Wednesday and Friday). The dose on Monday and Wednesday should be twice the individually titrated daily dose, and the dose on Friday should be three times the individually titrated daily dose, with no dose on the intervening days. However, the dose given on any one day should not exceed 24 mg. Patients requiring a titrated daily dose > 8 mg/day may not find this regimen adequate.”

We received three different documents, produced for clinic settings, outlining policy or guidelines in relation to the prescription of Suboxone. Two of these made no reference at all to the possibility of less than daily dosing. This also underlines the need for clinicians to share their experiences with Suboxone.

3.4.3 SUPERVISION LEVELS

We attempted to audit the extent to which patients received daily supervision dispensing of Suboxone, at least 6 days per week, for a minimum of three months from the commencement of treatment. We found the following:

- Of the 41 files reviewed, we reviewed details of dispensing history for 26 patients.
- Of the 26, 8 were supervised at least 6 days a week for three months.
- 15 were supervised less than 6 days per week though this included:
 - A small number of patients who received double doses but still no more than one takeaway per week.

- A small number of patients who received takeaways for Easter or Christmas but other than that were supervised daily for at least 6 days per week.
- In 3 cases, the dispensing history obtained was inconclusive or the patient did not actually stay on Suboxone for three consecutive months.

We were unable to judge the extent to which this group included patients who had previously been stable on methadone, and had been receiving regular take away doses of methadone with no apparent problems.

3.4.4 SUPERVISION PROCEDURES

We asked pharmacists and dispensers to describe their procedures for supervising the dispensing of Suboxone and also requested copies of any official guidelines or policy on this. The supervised dispensing protocol for Suboxone provided to us by the HSE Addiction Pharmacists is included in the box below.

Supervision Protocol: HSE Addiction Pharmacists' Guidelines

- Check that the patient does not have chewing gum or another similar product in his or her mouth to which the tablets might adhere. Ask them to remove.
- Ensure patients takes a glass of water
- Place complete dose on a 5ml plastic spoon or in a measure.
- Give to patient with instruction to place under the tongue
- Dissolution and absorption is variable and may take from 5- 10 minutes. During this period the pharmacist or an experienced technician **must watch** to ensure that the tablets are not removed from the mouth, as street diversion of buprenorphine products has been described internationally. The usual time required is 2-5 minutes
- Discard plastic spoon or measure.
- The use of plastic disposable tumblers is encouraged
- The prescriber may request that the pharmacist may be asked to look in the mouth to ensure that the tablets have dissolved. This may not be a necessary requirement.
- Be discreet, friendly and ask how they are.
- If patient misses any dose please inform the prescriber.
- If patient misses consecutive 3 days dosing, it is necessary that they be reassessed by prescriber

In practice however, the level of supervision was very varied. Table 8 on the next page indicates the responses to the dispenser survey on this issue.

Table 8: Supervised Dispensing Protocols as described by Pharmacists/Dispensers

Clients are asked to take a drink of water prior to dispensing.	Always: 3 Sometimes: 1 Optional: up to client: 7
Clients are asked to take a drink of water after dispensing.	Always: 4 Sometimes: 1 Optional: up to client: 6
Clients are asked to remove gum/sweets before dispensing.	Always: All (if arisen)
Clients' mouths are inspected visually to check for dissolution of the tablet.	Always: 5 Mostly: 1 Sometimes: 3 (esp. in first few weeks) Rarely/never: 2

Pharmacists and dispensers were also asked to describe what actually happens once the patient has put the tablet under their tongue – what actually constitutes supervision of dissolution in their practice. The responses given illustrate a whole range of practices ranging from total, constant supervision (e.g. eyeballing the patient for the whole time the tablet is dissolving) to relaxed supervision involving glancing at the patient periodically. This continuum is reflected in some of the descriptions given:

“In the first two weeks, we would sit beside them, after that we would observe them periodically.”

“We would not be staring at them, we would do other things. Sometimes we might talk with them, some patients can mumble while they’re taking it.”

“It dissolves quite quickly. Once they have taken it they go into another room opposite the hatch but are still visible. They are still being supervised (though others are also being dispensed). People are very stable.”

“One of us [pharmacists] is watching them the whole time. You can’t do anything else.”

“You are pretty much staring and interacting with them the whole time.”

“They get the Suboxone and I follow them with my eyes to where they sit on a chair at the back of the dispensary and then I keep an eye on them while doing other things. You have to do other things.”

From the descriptions given, we were able to classify the supervision protocols in use as either ‘constant’ or ‘periodic’ in 10 cases. 6 of these described periodic supervision (where the patient was not being watched constantly, as the pharmacist continued with dispensing or was doing other things) and 4 described constant supervision (where they were watching the patient constantly and generally not doing anything else). The differences did not relate to the dispensing location, both levels of supervision were found in clinic and community pharmacies.

The level of supervision in practice has significant implications for the ease with which Suboxone may be diverted, particularly should it be more widely used in future. It would be helpful if guidelines were uniform across all pharmacy and dispensing settings and if they explicitly outlined

what is expected in terms of inspection of each patient's mouth and the specific supervision process and precautions expected.

It was not possible to accurately audit the average time taken for Suboxone to dissolve as this was reported to vary greatly from patient to patient, even for similar doses. In general, larger doses took longer to dissolve but again this was not uniform. It seems that four or five minutes may be sufficient for a large proportion of patients but there were also reports of some patients for whom it was taking 20 minutes or even up to 45 minutes for the Suboxone to dissolve. This was despite reported efforts by the pharmacist/dispenser to explore why it may be taking so exceptionally long in these cases. The time taken will clearly have implications for what level of supervision is possible in practice.

3.5 OPERATIONAL ISSUES

3.5.1 PRESCRIBING

As noted above we received three different protocols or guideline documents for the use of Suboxone. This represents a duplication of effort across public services and could be confusing for clinicians who practise in more than one setting, and results in inconsistent approaches to treatment. We feel that one guideline on the use of Suboxone in Ireland should be produced by the relevant clinical stakeholders (GPs, consultants, pharmacists) in partnership with each other. This should be disseminated to and be sufficiently flexible to apply to all settings in which Suboxone is prescribed in Ireland.

The current position in Ireland is that only consultants in addiction treatment clinics or Level II GPs can initiate methadone prescription. This ensures that only consultants and medical practitioners with a higher level of training in the provision of methadone can start a patient on the drug. For this study, a small number of Level II GPs were identified as being interested and suitable for prescribing Suboxone and they were given the chance to participate in the feasibility study. Most had previously been to conferences and training abroad in relation to Suboxone, as had many of the consultants involved. There was no formal training or competency-based assessment of clinician's expertise required prior to prescribing Suboxone. In the main, this informal system appears to have worked reasonably well for the feasibility study, with interested clinicians taking responsibility for their own expertise, in some cases accessing informal peer support. Doctors interviewed for the study were happy with the level of training they had accessed.

If Suboxone is to be rolled out subsequent to this feasibility study, we would argue that more formal arrangements would be wise. For community based General Practitioners, Suboxone training should be built into the Level 1 and Level 2 opioid addiction training run by the Irish College of General Practitioners. The audit system for methadone prescribing that forms part of the Level 1 and 2 training process is a valuable addition and ought to be extended to include audit of Suboxone prescribing. Consultants and general practitioners in addiction treatment clinics should also consider how an adequate level of expertise of Suboxone can be assured prior to anyone prescribing it.

There is also a need to consider what audit processes can be put in place for prescribing in clinic settings as it cannot be assumed that prescribers have sufficient expertise and experience, especially where they may be prescribing Suboxone only occasionally. In both community and clinic settings, part of the process of ensuring the expertise of prescribers who use the drug only occasionally or

who are inexperienced in its use, needs to allow for sharing of good practice and experiences between more and less experienced doctors.

Checks and balances in relation to prescriber expertise are also important where doctors (e.g. registrars) who are not consultants/Level 1/2 GPs are carrying out the prescribing in practice, albeit supervised by the consultant or lead GP for that clinic. It was apparent from this evaluation that the doctor named on the Suboxone database as the prescriber for a patient, was not always the doctor who was managing the day to day prescribing decisions and adjustments in dose for the patient. One clinic-based survey respondent reported that the pharmacy staff supported and advised the registrars on prescribing Suboxone as they appeared to him to be unfamiliar with it. It was difficult to get a clear picture of how well this prescribing was supervised in practice but it is clear from some interviews that there are some doctors who have taken full responsibility for prescribing Suboxone for patients but who are not named as their doctors on the Suboxone database.

We are not suggesting that there was necessarily any problem resulting from prescribing in these cases, or with the expertise of the doctors involved, but there ought to be a process in place whereby it is clear who is sufficiently experienced and skilled to prescribe Suboxone, with clarity on the role and supervision of less experienced doctors who deal with the patients in clinic settings. The division of roles and responsibilities is very clear in community settings for Level 1 and 2 GPs, but appears from this evaluation to be less clear cut in clinic settings. Greater clarity would provide a better opportunity for good clinical governance.

3.5.2 DISPENSING

As noted above, we received a copy of a guideline document for pharmacists on dispensing Suboxone that was produced by the HSE Addiction Pharmacists. This was dated June 2009 and provides a useful introduction to Suboxone dispensing for this group. It is not known if it was provided to dispensers and pharmacists in all settings e.g. across all addiction clinics and DTCB. Another set of guidance is provided as part of a HSE Suboxone policy document which we received. As with the prescribing guidelines above, it would be helpful if one overall guideline on the use of Suboxone in Ireland was produced jointly by GPs, consultants and pharmacists that would then apply to all dispensing settings to avoid inconsistency and duplication of effort.

For the feasibility study, pharmacists received support and training prior to dispensing Suboxone from a variety of sources. Most did their own reading/study based on company materials, materials provided by the HSE addiction pharmacist or by their own online research. All the community pharmacies also had an opportunity to discuss the dispensing of Suboxone with the HSE Addiction pharmacist, either in person (the chief pharmacist came to the pharmacy) or over the telephone, however this was while they were on duty in their pharmacies. Some of the clinic based pharmacists attended in house meetings or sessions about Suboxone.

The 12 pharmacists/dispensers who answered the relevant survey question rated their satisfaction with the training as follows:

- 6 Adequate/More than Adequate. I felt confident and knowledgeable about dispensing Suboxone before starting to dispense it.
- 3 Okay. Any concerns I had about dispensing Suboxone prior to starting to dispense it were minor or I was prepared to address them myself.

- 3 Inadequate. I would have welcomed a higher level of support or training prior to first dispensing Suboxone.

The respondents who were unhappy with the level of support provided commented as follows:

“This is a major area. The client could have initially had a very bad reaction. I didn’t know what to do. I was concerned as to what might happen or what I should do if he had fallen down etc. I wasn’t confident about how to respond if he did have a bad reaction.”

“I would have liked more information, maybe more about practicalities. About physically supervising the dose, can they actually drink water while taking it? A few things. I would still welcome training on it.”

“Training is no longer necessary but it was dire at the time. We had to look everything up ourselves.”

It would be wise to ensure that only pharmacies who are experienced in dispensing methadone should be permitted to supervise the dispensing of Suboxone. Training should be provided in relation to Suboxone, prior to the pharmacy being asked to dispense the drug. Ideally, this would be part of formalised training for pharmacists on the dispensing, supervision and counselling in addiction treatment services and the supply of treatments for opioid dependence, incorporating both methadone and buprenorphine products. This could be provided by means of online or distance learning through existing mechanisms for continuing professional development or by one to one support from the HSE addiction pharmacists. If the latter, it is important that such training is carried out at a dedicated time, not when the pharmacist is actually working in the pharmacy. Regardless of the means of training, the HSE addiction pharmacists should decide what knowledge and skills are required by pharmacists dispensing Suboxone (and other treatments for opioid dependence), and agree how that knowledge/skill will be covered by whatever means the training is provided.

Some key informants felt that it would be better to spread Suboxone patients across a wider number of pharmacies. We are concerned that this may make it more difficult for pharmacists, support staff and regular locums etc. to become accustomed to Suboxone dispensing and for expertise to develop. In short, it may result in expertise being spread thinly. It also increases the likelihood of problems with stocking, e.g. if a pharmacy has only one patient who then switches off the drug and the pharmacy is then left with stock they can’t use. However this concern could be addressed if a system for transfer/return/refund for this stock could be established (see below).

In future, it would make sense to use the expertise of the pharmacists who are dispensing Suboxone regularly in the treatment clinics to support the pharmacists in community pharmacies who may only be dispensing it occasionally. As noted for prescribers, it would be wise for more opportunities to be made available for clinicians including pharmacists to get together and share experiences in relation to Suboxone (and for the treatment of opioid dependence in general if such opportunities are not already available). This would avoid individuals having to come up with solutions to problems that others have already solved. Some of this sharing could perhaps be facilitated by an online discussion group e.g. using Google groups which could be used to disseminate information and for clinicians to ask questions.

We feel that a Suboxone Interest Group or Network (possibly as part of an opioid dependence treatment network) should be set up to provide a forum for sharing experiences, disseminating

information and accessing peer support around the use of the drug in Ireland. Bearing in mind how busy professionals are, it might be that this group would meet infrequently e.g. for an annual event (perhaps part conference, part meeting) but would be active online, or there could options for having more frequent short network meetings e.g. quarterly. The value, acceptability and feasibility of this kind of network should be further explored.

3.5.3 PRESCRIPTION FORMS & DISPENSING RECORDS

There was some confusion initially about what forms should be used for prescribing Suboxone. It is noted that the feasibility study protocol states that:

“Prescriptions for Buprenorphine/Naloxone (Suboxone) should not be generated on a GMS script but on a non-GMS (private) prescription of the registered medical practitioner.”

This requirement changed over the course of the study and later guidelines for pharmacists show that prescriptions should have been made and claimed for on GMS prescription forms.

Pharmacists reported multiple problems with how prescriptions for Suboxone were written, particularly where prescriptions did not conform to the requirements of the Misuse of Drugs Act. This did not seem to be specific to Suboxone (some said that it was no worse than with methadone prescriptions) but was thought to be worsened by the absence of a specific Suboxone prescription form. The two different strengths of Suboxone available, the possibility of double dosing and/or takeaway dosing and the requirement to combine the strengths to achieve many of the daily dosing regimes adds to the potential for confusion.

Some pharmacists developed their own dispensing record sheets, which they felt were necessary to accurately and clearly record what had been dispensed when. It would be better if this was done centrally and a uniform document was used by all pharmacies. In addition, for community pharmacies there is a need for providers of dispensing software to ensure that the systems can be adapted to accommodate a Suboxone dispensing scheme. At the moment it appears that only one of these systems allows pharmacists to set up a new scheme themselves.

We would suggest that the existing methadone prescription form either be adapted to work for any opioid or that a specific Suboxone form be developed as well as a suitable paper and electronic record system for pharmacists to use. Both would need to comply with the Misuse of Drugs Act requirements for prescription writing and record-keeping.

3.5.4 STOCKING/SUPPLY ISSUES

There have been problems with the supply of Suboxone 2mg tablets on more than one occasion. These appear to have been related to administrative errors in relation to when import licences have been applied for, though it was beyond the remit of this evaluation to explore exactly how the shortages have occurred. In practice, these shortages have caused multiple problems for pharmacists, dispensers and patients.

When the 2mg tablets have been unavailable, pharmacists have coped as follows:

- By transferring patients from community pharmacy to clinic dispensing. This is only an option for patients who are being prescribed in clinics.

- By obtaining stock from a clinic, however this is strictly speaking illegal supply under the Misuse of Drugs Act.
- By splitting 8mg tablets, in some cases into quarters. This is off-licence provision.

We feel that in future more than one wholesaler should be allowed to import and stock Suboxone to reduce the likelihood of shortages due to administrative error (assuming that it is unlikely that two companies would make an error at the same time).

Pharmacists need clear guidelines on the processes and procedures they should undertake with a moral and legal framework in the event of shortages. Such guidance should aim to set out clear parameters for instances where the most ethical option involves supply between pharmacies/clinics that is contrary to the Misuse of Drugs Act or off-licence. This guidance should be discussed with and cleared by the Pharmaceutical Society of Ireland.

Some pharmacies have been left with stocks of Suboxone that they can no longer use as none of their patients have continued with the drug. One pharmacy reported that they ordered a bigger stock owing to the previous shortages and were now left with €300 of stock which they no longer need and cannot return. It would be helpful for the future recruitment of pharmacies, especially if they may only have 1 or 2 patients, if a mechanism was agreed with the company/wholesalers/clinics for refund or return of unused stock in these circumstances, or if the PSI could provide guidance on how such stock may be transferred to where it is needed without risk of reprimand.

While it was beyond our remit to review the use of buprenorphine only products for opioid dependence, it is clear that there are some circumstances where the lack of availability of such products in Ireland caused problems for prescribers. This arose in particular in relation to female patients being treated with Suboxone who become, or plan to become pregnant. It would be wise for the Suboxone Expert Group to consider the circumstances in which buprenorphine-only products should be made available for treatment of opioid dependence in Ireland. Consideration should include the issue of what safeguards would be necessary to prevent diversion of buprenorphine as it is clear from discussions with patients that buprenorphine/Subutex is recognised 'on the street' as having more potential for illicit use than Suboxone.

3.5.5 PATIENT INFORMATION

Patients reported receiving information about Suboxone both verbally and in written form from both prescribers and pharmacists/dispensers. The level of detail of discussions that were had with patients seemed to vary, particularly in relation to whether or not prescribers disclosed all of the risks of treatment. Providing patients with understandable and balanced information on risks is recognized as a difficult task in relation to any medical procedure or treatment option and Suboxone treatment is no different in this regard.

Table 9: What information did you receive before taking Suboxone?

Answer Options	Yes	No	Response Count
Benefits associated with Suboxone (e.g. alertness)	10	0	10
How Suboxone works e.g. risk of withdrawals if using other opiates.	15	1	16
How Suboxone is taken e.g. under the tongue/not to be swallowed.	11	1	12
Level of supervision required (time taken to dissolve under tongue etc.)	6	1	7
The need to wait until experiencing withdrawals before using Suboxone	6	2	8
Risks associated with Suboxone for liver	3	5	8
Risks of Suboxone in pregnancy (women only)	1	4	5
Didn't receive any information	1	2	3
Don't remember	2	1	3
		answered question	22
		skipped question	11

Some of the comments from patients in relation to the information received provide greater depth to this question.

"I was given a leaflet - but they only had one leaflet and I was lucky to get it. I don't think that that's enough. There could have been more information given. The doctor gave me a bit of info but I don't think the doctors even know that much about it because it's new."

"It was a very thorough discussion"

"It's hard to remember what information I was given as I was still using drugs at the time, but I was given a little booklet about it."

"I'm disappointed that I wasn't told about the liver risks. Mind you I doubt that I would have declined to take Suboxone even if I had been told about this. But still, I think I should have been told about this aspect of the drug."

"I know some people got a sheet, but I didn't get anything, wasn't really told anything."

"Everything, leaflet, asked a million and one questions."

"The doctor told me all the clinical stuff, but not really about how I would feel on it."

As part of the evaluation we asked prescribers, pharmacists and dispensers what they provided to Suboxone patients when first discussing or dispensing the drug. There was a general similarity in the aspects that were discussed verbally with patients, but a lot of variability in what written information is provided. As illustrated by the above quotes, patients can easily forget what they have been told, particularly as they may be intoxicated at the time when they are having some of these conversations. Accessible information written specifically for patients is therefore very

important. Where possible, we sought examples of the written information provided to patients and found that it consisted of the following:

- Treatment cards – small credit card sized cards designed to be carried at all times to let medical services know that the carrier is being treated with Suboxone. These are not designed to provide patients with information.
- Suboxone: A Patient’s Guide to Treatment. A comprehensive booklet produced by Schering Plough to provide information to patients.
- Suboxone – what you need to know. A single-side A4 sheet with some basic information on Suboxone produced by Schering Plough.
- Notes on buprenorphine (Suboxone) for patients and families. Two pages of A4 produced for patients attending the young people’s service at DTCCB. This appears to have been used for other patients in DTCCB also.
- Patient information leaflets provided in the Suboxone packaging or downloaded from www.medicines.ie were used in some community pharmacies.
- Some services also required patients to sign a treatment contract prior to receiving Suboxone but this was not consistently required, in that sometimes it would only be asked of new patients and the contracts may not have been adapted specifically to work for Suboxone treatment, where they were originally written for methadone.

As with prescribing and dispensing guidelines, it would be beneficial if some consensus was developed across services as to what information patients need in deciding whether or not to receive treatment with Suboxone and prior to first taking it. Of course this issue may not be restricted to provision of information on Suboxone, but in view of the newness of the drug in Irish opioid treatment, key stakeholders should work with the company and with patient groups to decide what information is appropriate and develop a consistent approach to its provision, regardless of setting.

3.5.6 REMUNERATION

Prescribers interviewed for the evaluation generally felt that while managing Suboxone patients was slightly more onerous at the beginning of treatment, this was only for a few days at most and that overall it was not any more time consuming than managing methadone patients.

Only a small number of GPs were interviewed for this evaluation and not all of them prescribed Suboxone in their own community practices, but the impression we have been given is that it seems likely that the level of patient care fee and urinalysis fees currently paid for methadone patients would also suffice for Suboxone. The cost of regular liver function tests may need to be considered.

The length of time taken to supervise provision of Suboxone depends on the method of supervision used by pharmacists. If patients are to be continuously supervised over the full time that the Suboxone takes to dissolve, as is recommended in both of the dispensing guidelines we received, then it is clear that the dispensing and supervision of Suboxone takes longer than for methadone. This may be mitigated by more infrequent dispensing or a higher level of take away doses if Suboxone patients are more stable, but since double dosing was rarely used in the feasibility study, it is difficult to comment on this. Clear and specific guidance will be needed, regarding what

supervision should entail and how it is to be carried out by pharmacists, in order to inform consideration of an appropriate fee.

Some community pharmacists were pragmatic about the difficulties for the HSE of paying increased fees in the current financial climate. However, importantly, one pharmacist from a pharmacy chain commented that as things currently stand they would be unlikely to take on more Suboxone patients because methadone patients take much less time to manage for the same fee.

3.5.7 OPERATION OF CAP ON NUMBERS IN PRACTICE

The original protocol for the feasibility study outlined that 60 patients attending specialist clinics and 40 patients attending Level 2 General Practitioners would be selected for participation in the study. The study commenced at the end of June 2009. A decision was taken in May 2009 to reduce this maximum figure to 40 patients in clinics and 40 in the community.

In the clinic setting, as noted above, patients were already being prescribed and dispensed Suboxone since 2006. Prescribing was led by individual consultants in the DTCB or guided by protocols agreed in local clinics. In these cases, the provision of Suboxone was funded through the existing pharmacy budgets for those clinics. These arrangements did not change after June 2009 and there was no specific process by which those patients or prescribers were asked to become or became part of the feasibility study.

Discussion with consultants would suggest that the commencement of the feasibility study appears to have had little or no impact on how Suboxone was prescribed in the clinic setting, except that some clinics were able to prescribe it to patients who could then have it dispensed through community pharmacies which had not previously been possible. Importantly, the cap on patient numbers was not felt by most consultants to have limited the patients to whom they could prescribe Suboxone. This was also felt to be the case by some clinic-based GPs, one of whom felt that there was a lot of interest when Suboxone first became available but that there was no longer any pent-up demand for it.

There was little sense that a waiting list existed specifically for Suboxone in clinics due to the cap on numbers, although some patients reported having asked repeatedly for Suboxone over a period of a number of months before they were prescribed it. These patients reported that they were not prepared to accept methadone treatment instead. It is unclear the extent to which this was because their doctor was unconvinced of their suitability for treatment or whether a place was unavailable.

In the community setting, despite efforts made by the relevant members of the Suboxone Expert Group, some GPs experienced difficulties with understanding the how the cap on numbers was working or found it cumbersome. Many of the issues arose from confusion or misunderstanding about the process for getting a place on the study for a new patient and the availability of places at different stages of the study. These issues are explained below but it is firstly useful to outline the basic mechanism of the cap:

After the study had commenced, GPs wishing to put a patient on Suboxone notified the Department of Health & Children and/or the HSE in various ways of their intention to start the patient. Having verified that the cap was not exceeded, approval was issued by the Department for the patient's name to be added to the Suboxone database and the prescriber was informed that the patient could commence Suboxone therapy.

There were a number of areas of difficulty or confusion however including:

- In speaking with individuals, it is clear that the ways in which GPs requested a place on the study varied across the different HSE areas with a number of individuals having different roles.
- In early 2011, most of the general practitioners operating who were interviewed reported currently having a small number¹⁷ of patients whom they felt were suitable for Suboxone and/or who were requesting Suboxone, who currently couldn't get it. One prescriber specifically referred to patients who were on low doses of methadone, were finding it difficult to reduce further and wanted to switch to Suboxone. It is unclear however, if these GPs had requested places on the study for these patients or if such places were available.
- In 2009 and early 2010, the delay in commencement of the feasibility study and some of the supply issues that arose after that also meant that some patients in the community with whom Suboxone treatment had been discussed could no longer wait and were commenced on methadone.
- One community GP reported reluctance to prescribe Suboxone out of a fear that it would be withdrawn at a later date and patients who had started on it would no longer be able to get it. While this was not the case, as it was always the policy that anyone who was included in the feasibility study would be kept on Suboxone after the end of the study as needed, this was not clearly understood by this GP.
- At some point, some prescribers, particularly in the community, reported that they were told that they could no longer initiate any new patients on Suboxone, and this is supported by a note in the minutes of a meeting of the Suboxone Expert Group from May 2010. This situation changed again by July 2010 as the numbers being prescribed in the community fell but it is not clear what prescribers were told in relation to initiating new patients at that later stage. There appears to have been some confusion about whether or not, or when the feasibility study had ended. It was also unclear if towards the end of the feasibility study, new patients could still take up a place vacated by another patient who had come off Suboxone.

Many of these issues could have been helped or avoided had the processes and lines of communication for the operation of the cap on numbers been more clearly documented. Specifically, it would have been useful to have documented the specific mechanisms by which and to whom GPs made their application to start a new patient, the decision-making process or basis for including or excluding a patient from the feasibility study, the mechanisms for communication of such decisions and any changes in process or availability of places over time.

Ideally these processes would have been outlined in the study protocol (Appendix A) which should have been updated as needed over the course of the study to ensure that the process was practical, transparent and equitable. The arrangements in place were somewhat ad-hoc.

¹⁷ It is difficult to get a sense of how many patients they were talking about, in some cases one or two, in others perhaps five or more.

3.6 FUTURE USE OF SUBOXONE IN IRELAND

3.6.1 CAPACITY

The information gathered in this evaluation suggests that doctor, dispensing and pharmacy capacity is unlikely to limit the number of patients who could receive Suboxone in the near future in Ireland. Prescribers interviewed for the evaluation generally felt that while managing Suboxone patients was slightly more onerous at the beginning of treatment, this was only for a few days at most and that overall it was not any more time consuming than managing methadone patients.

While pharmacists and dispensers were concerned about the time needed to supervise Suboxone consumption, most still felt that they could physically cope with significantly higher numbers of Suboxone patients than they were currently caring for. On being asked to indicate the maximum numbers of Suboxone patients that they could manage in future, the figures given were: 3-4 (2 pharmacies); 9-10 (1 pharmacy); 10-14 (1 pharmacy); more than 19 (1 pharmacy) and a final community pharmacy did not want to take on any more patients. Obviously these figures would depend on whether patients were being dispensed to daily or less often.

In some cases, particularly in HSE dispensing clinics, pharmacists felt that it might be necessary to consider the physical facilities available if any significant increase in numbers was considered. For example, they expressed a need to open up an additional dispensing hatch. Another pharmacist suggested that if numbers increased they would perhaps have to consider having specific dispensing times for Suboxone for example by extending current dispensing times. In the community, one suggested that if numbers were to increase significantly, they would also need to ask patients to come at specific time periods. None of these factors were felt to be insurmountable. Clinic staff also felt that if numbers increased significantly, extra staff would likely be needed to cope.

3.6.2 LEVEL OF NEED AND DEMAND

Decisions on the future provision of Suboxone in Ireland are likely to depend in part on the level of need and demand anticipated. As discussed in Section 3.3, there are a wide range of groups for whom Suboxone may offer a suitable and beneficial treatment, and there is little research evidence to suggest that one group is more likely to benefit than another. We asked prescribers and patients their views on the level of demand and need for Suboxone and found a mixed picture.

Some patients reported knowing lots of people who want it as shown in Table 10 but many of the comments suggested that many users are unaware of it currently. If their awareness was to increase, demand may also rise.

Table 10: Patient Survey Question: In your experience is there a demand for Suboxone treatment among other opiate users who currently cannot get it prescribed to them?

Answer Options	Response Percent	Response Count
Yes, I am aware of a few people who want it but can't get it (e.g. 1-5 people)	25.0%	8
Yes, I am aware of quite a few people who want it but can't get it (more than 5)	18.8%	6
No, I am not aware of anyone not being able to get it.	21.9%	7
Don't know	34.4%	11
	<i>answered question</i>	32
	<i>skipped question</i>	1

These are some of the patient comments about the level of demand for Suboxone:

"Anyone I know has been able to get on it - trying to get all the young people onto it. But you have to want to get clean."

"I don't think people know too much about it."

"Some people wouldn't want it because there's a blocker in it."

"Not that much of a demand, some people just love their methadone. A lot of people don't know about it. Even at my clinic people see me taking it, putting the tablet under my tongue and they are like "What the fook is that?" So maybe if people were more aware of it there might be more of a demand."

"A few people want it but have been told that they are unsuitable and are reluctant to accept this."

Some prescribers reported having a small number of patients to whom they wanted to provide it but currently couldn't. On the other hand, some prescribers felt that there was a greater level of demand when it was first launched but that that had since calmed down. Others felt that the majority of opioid users would not want Suboxone as they did not intend to be opioid free.

We have spoken with colleagues in the Glasgow Addiction Service where Suboxone can be initiated only in clinic settings, but where there is no restriction on who can receive it. They had a cap on numbers initially as they were concerned about being flooded with patients, but this has not happened and they are prescribing only to a few hundred patients. They are considering changing their system to allow Suboxone to be initiated in the community. They reported a general sense that once it is explained to patients how it works and that they need to be in withdrawal before they go on it, many don't then want it.

The different groups who were identified by prescribers as suitable for Suboxone are quite broad so there are potentially quite large numbers of patients who would fall into these categories. It is difficult to predict how many of them will want it. One other aspect that is different from the Glasgow experience is that there may be a higher level of codeine dependence in Ireland. As this group may be less likely to find methadone or clinic based treatment acceptable, there may be a

group of patients who are as yet untreated and unidentified, who may start to come forward if Suboxone treatment was made available. The size of this group would need to be estimated, as well as the numbers of heroin users for whom Suboxone may be suitable in any predictions of future need for Suboxone in Ireland.

3.6.3 POTENTIAL FOR DIVERSION

We asked prescribers, dispensers and patients about the extent to which they felt Suboxone was being diverted to the illicit drug market in Ireland, how available they felt it was, and whether there was a demand for illicit Suboxone.

In general, there was a sense that there is very little or no diversion of Suboxone currently from that provided via the feasibility study. We felt that this was probably true, given the low level of use and the tight controls placed on it and the relatively stable patients being put on it.

In the survey, 72% (n=26) of patients said that in their experience Suboxone was not available on the black market or the street in Ireland, with comments suggesting this may be because of a lack of awareness of the drug or because of the blocking effects of the naloxone component.

One patient reported that Suboxone was 'definitely' available on the internet from America and prescribers suggested that Subutex was coming in from Northern Ireland or from the UK to the illicit Irish market. Just a few patients reported either buying it in Ireland (in one case from an English origin) or being aware of others who had used a tablet illicitly.

Some people felt that there was a low potential for diversion because of the naloxone but most felt that it would be diverted if it were more widely used. In particular the potential for diversion arises from the difficulties of continuously supervising patients who are consuming it in pharmacies but also from the long duration of action of Suboxone. Perhaps more so than with methadone, users who have take home doses of Suboxone may choose to skip those doses (even if they are not using illicit opioids) and could then stockpile or sell extra Suboxone.

Most commentators were pragmatic that there is always the potential for diversion of Suboxone. From our investigations, it may be misused in more than one way:

- Unprescribed sublingual (under the tongue) use for relief of withdrawal symptoms in between opioid use for dependent individuals.
- By crushing and insufflation (snorting), to get a high (it will be possible to get a high in this way for recreational users (non-dependent) or for those already on Suboxone though in the latter case it may be only slightly greater than the effect of taking it sublingually).
- By crushing and injection to produce an opioid agonist "high" if injected by non-dependent persons.
- By crushing and injection by dependent persons who are unaware of the effects of the naloxone component. This is likely to precipitate withdrawal.

While the risk of accidental overdose appears lower with Suboxone than with methadone, the potential risks in terms of vein damage and blocking if the particular sublingual formulation of the tablet is injected make the potential for such damage quite serious.

While we believe that the inclusion of naloxone makes injection of buprenorphine less likely, history tells us that there are few substances which will not be in some way abused. It would be unwise to assume otherwise and precautions are essential, particularly if use is increased. The setting of adequate guidelines and training relating to the provision of take away doses and for supervision of consumption by pharmacists are important elements in minimising the risks of this, coupled with continuous patient education.

3.6.4 COSTS

In this section, we have considered the findings of the cost effectiveness analysis that was carried out by the National Centre for Pharmacoeconomics¹⁸ (NCPE) based on what we have found in this evaluation. We requested some further information from the NCPE to support this discussion but had not received a response by the time of finalising the report.

The NCPE pharmacoeconomic evaluation of Suboxone reported that:

- *From the evidence available Suboxone and buprenorphine cannot be considered cost-effective for patients attending HSE clinics in the Irish setting unless opiate abstinence rates are at least 10% higher with Suboxone than with methadone (e.g. mirroring an unpublished U.S. trial).*
- *Also cost effective compared with methadone if patients are switched to three times weekly dosing after 8 weeks stabilisation.*
- *Becomes cost-saving if patients are switched to three times weekly dosing after 8 weeks and then transferred to community setting after 28 weeks.*
- *Thrice weekly dosing may be a suitable option for some patients based on clinical assessment of stability and likely abstinence.*
- *Suboxone initiated in the community cannot be considered cost-effective (compared with methadone) under any scenario investigated.*
- *The cost effectiveness profile may improve as the evidence base underpinning the use of buprenorphine and Suboxone develops.*

The study also found that:

“Although an undesirable patient care outcome, poorer retention rates improve cost-effectiveness, due to savings on Suboxone treatment costs” (p7)

“Another analysis investigated the cost-effectiveness of Suboxone as compared with no treatment e.g. in patients who are intolerant or unsuitable for methadone. The ICER (incremental cost-effectiveness ratio) remained not cost-effective in both the clinic and community settings due to the high cost of the drug plus care (€1,041,922 and €165,904). However, for such patients without other options, factors other than cost-effectiveness should be considered.”

¹⁸ National Centre for Pharmacoeconomics (2007). Economic evaluation of the use of Suboxone for opiate addiction.

Absolute cost of Suboxone is dependent on:

- Numbers of patients to whom it is prescribed
- Doses prescribed
- Dosing regimes (which are restricted by licence to a degree)
- Supervision regimes
- Length of treatment

The information provided above about what happened in the feasibility study should help to inform predictions of future cost based on these factors.

There are a few additional key points that are relevant to evaluating the cost of Suboxone:

- The ability to reduce costs by using thrice weekly dosing regimes as noted in the economic evaluation may be limited by the licence restrictions on maximum dose.
- Current guidelines do not support a reduction in supervision to less than daily after only 8 weeks, though a case for this could more clearly be made for patients who were transferred directly from methadone who had previously been stable in treatment for some time.
- The findings that Suboxone treatment is not cost effective compared with no treatment goes against current thinking in terms of the value of treatment as a harm reduction strategy.
- Opioid addiction, and consequent crime and disorder, impacts adversely on society as well as on the individuals involved. Therefore the treatment of opioid dependence, unlike the treatment of many diseases or conditions, has the potential to benefit not just the individual and their family, but also society as a whole. Consideration of the costs and benefits of the provision of Suboxone, whether economic or otherwise, needs to take into account these and other broader benefits.
- The low cost of methadone makes it particularly difficult for any alternative treatment to be considered cost-effective in comparison without using broader criteria or taking a longer-term view. A study in Spain was recently highlighted to the evaluation team¹⁹ and it would be worth searching the literature for other similar papers and fully analysing their findings.
- In a cost-effectiveness analysis of opioid treatment, the costs and savings due to reduced policing, criminal justice services, social protection and so on when a patient is effectively treated should be considered. This requires a different methodology than that which is used for cost-effectiveness analysis on other drugs. These wider societal costs appear not to have been costed into the NCPE report.
- In short, provision of Suboxone to patients for whom there is a clear rationale and reasonable likelihood that they may benefit from it, even if it is more expensive than methadone, may have economic and other benefits for society as a whole that ought to be taken account of in making decisions about the future use of the drug.

¹⁹ Martínez-Raga J, González Saiz F, Pascual C, Casado MA and Sabater Torres FJ (2010). Suboxone (buprenorphine/naloxone) as an agonist opioid treatment in Spain: a budgetary impact analysis. *European Addiction Research*;16(1):31-42.

3.6.5 MECHANISMS FOR REGULATING PROVISION

Part of the purpose of this evaluation is to identify the regulatory framework necessary for the safe and *appropriate* use of Suboxone in the Irish setting. In an ideal world, Suboxone would be available to anyone who could potentially benefit from it, providing the potential benefits outweigh any risks to them. In reality however, funding one drug for one patient means that another service for another individual cannot be provided and there is therefore, a need to consider where funding has the potential to provide maximum benefit.

One consideration in assessing the appropriateness of use is whether the cost of Suboxone treatment is justifiable, compared with other alternatives such as methadone treatment or other forms of detoxification. If it is assumed that there are some patient groups where Suboxone can be justified as first or second line treatment, then there will be a need to monitor and contain the cost of Suboxone.

For this reason, we have discussed possible mechanisms for monitoring or controlling or reducing the cost of Suboxone usage in Ireland with key stakeholders as part of this evaluation. The need to consider how this could be achieved was also identified by the steering group for this evaluation as an important outcome for the evaluation. The goals for such regulatory controls should be to:

- Ensure the safe use of Suboxone by minimising diversion without overly compromising patient care and ease of engagement with treatment.
- Ensure that, where possible, and clinically appropriate, Suboxone is used in the most cost-effective way possible.
- Ensure that there are ongoing mechanisms for gaining experience in the use of Suboxone in Ireland that allow for shared expertise and consensus to develop on how it should be used and with whom.

The possible mechanisms which we discussed with prescribers and key informants are discussed below. There was little clear consensus among these interviewees as to which mechanism was most appropriate.

Continuation with a cap on patient numbers who can be prescribed it.

Some respondents were concerned that this would lead to a waiting list for Suboxone and they were keen to avoid having a waiting list. Others felt that a cap would be one way of ensuring that any guidelines on who should receive Suboxone would be more tightly controlled. This may be simply because clinicians know that they have to report their usage to someone else, which in itself is likely to promote reflection on practice and on which patients really need the drug.

We see some advantages to the idea of a cap, as opposed to restricting Suboxone to certain groups, in that it leaves decisions about who can receive Suboxone to clinical judgement about the needs of individuals and patient choice rather than to pre-determined criteria. However, the main flaw with the cap system is that it does not relate directly to cost and so a certain number of patients does not equate to a certain cost due to individual differences in dosage etc. We also observed some practical difficulties with the operation of a cap that are discussed on page 33 above.

Allocation of a fixed budget cap (rather than cap on patient numbers) for Suboxone.

If a budgetary cap, rather than a cap on numbers was used, this would facilitate budgetary planning in terms of a specific figure for cost but may be difficult to operate in practice as it would require continual monitoring of the budget for this drug and the ability to get up to date figures on provision, dispensing and supervision. It also requires consideration of whether the allocated budget should consist of the difference in cost between Suboxone treatment and that of methadone or whether all Suboxone treatment cost should be budgeted for. It would be more difficult with this system to inform clinicians as to how many places are still available for them to initiate patients on the drug.

Restriction of prescribing to certain groups of prescribers, patients or other restrictions.

This was favoured by some interviewees but the difficulty in enforcing any such restrictions was noted.

- We would favour having strict criteria for which patients should be considered for Suboxone treatment. This should be informed by the discussion above and give particular consideration to:
 - Whether and when Suboxone can be justified as first choice treatment of methadone-naive patients who have low tolerance, a history of smoking only or a short history of use, or whether low-dose methadone may be equally suitable.
 - Whether Suboxone can be justified as first choice treatment for codeine dependence or whether there are alternatives such as detox with non-opioids and psychosocial treatment that may be equally suitable.
 - How prescribers should take into account the motivation of the patient for detox or maintenance and guidance on the management of situations where detox turns into maintenance, if a desire for detox was the reason for the use of Suboxone in the first instance.
 - Whether Suboxone should be first choice treatment for patients who are in education or working (particularly considering the benefits to society of maintaining them in education or employment).
 - Whether Suboxone is appropriate for use as second line treatment for people on low dose methadone who want to reduce further but have tried and failed to do so.
 - Which medical needs and conditions justify the use of Suboxone as first choice treatment.
 - In which cases Suboxone should not be prescribed, or should not be first-line treatment. This may include provision based on patient request without other justifiable reason.
- In order to facilitate ongoing provision of Suboxone to the most appropriate groups in the short to medium term, we would suggest that the Suboxone Expert Group discuss and agree interim criteria which would be subject to review, for example in 2 years. During these two years, we feel there is a need for prescribers and other national stakeholders to come

together as a group to consider and discuss the criteria in more detail. This process would ideally be facilitated by an independent chairperson who could manage the discussion.

- Over the same time period, there is a piece of work to be done to support this which is to review the literature on the use of Suboxone or alternatives to Suboxone in each of the potential patient groups so that decisions on suitable groups are informed by the latest evidence of effectiveness, even where studies are limited in number. Such a review should be carried out by an individual or group with no vested interest in the use of Suboxone, rather than by prescribers themselves.
- Such criteria will have limited effect unless they are monitored and it is recognised this poses problems if only done in retrospect, i.e. if a patient has been put on Suboxone that does not fall into the right criteria, it would be difficult to take them off the drug. Nonetheless, if prescribers are required to report a reason for each patient to whom they prescribe Suboxone (perhaps to the Suboxone database, though we recognise some difficulties with this), then it would be easier to audit and to monitor trends/anomalies in relation to the identified criteria across different prescribers.
- It was pointed out to us that a mechanism for audit of prescribing already exists in the community for methadone and that this could be adapted to audit Suboxone usage. It would be necessary for a similar mechanism to exist for clinics, whether internally or externally managed, but with external reporting.
- We favour the idea that prescribing of Suboxone should be restricted to doctors who are experienced in the treatment of addiction. In this case, clear criteria should be established for both the clinic and community setting as to who can initiate and who can continue Suboxone treatment, taking into account the current systems in operation in each setting.
 - It was suggested by one prescriber that in the community setting, it may make sense for initiation to be restricted to only those Level 2 GPs who have a higher level of expertise in the treatment of addiction. We believe that not all current Level 2 Gps should automatically be able to initiate Suboxone, but would favour a competency based approach. For example, any Level 2 GP who goes through a suitable training process, including supervised or shadowed practice, should then be able to initiate treatment, providing they do so within a certain time frame from when they complete their training. This kind of training process should also be included as standard in the training for all Level 2 GPs in future.
 - Consideration should be given to the training requirements of clinicians operating in clinic settings before they are permitted to initiate Suboxone treatment.

“Consider restricting it to those who are more likely to succeed, in view of the expense...They ought to look to establish broad criteria on those suitable. Audited, supervised guidelines...there is an audit process for the methadone protocol. It could be incorporated into that. There is no audit system for the treatment centres.”

Prescriber, in telephone interview.

Engagement with company on price, projected level of need and shared-risk if projection is exceeded.

The final mechanism for controlling the cost of Suboxone to the taxpayer involves a process of engagement with the pharmaceutical company. This entails negotiation on the price, an agreement on the projected level of need for the drug and associated budget cost, and negotiation of shared-risk arrangements. The latter means negotiating with the company so that if the allocated budget is reached in a given year, the company would share the additional cost or would pay for any drug over and above this allocation.

This process is eminently important for the management of the cost of Suboxone in Ireland.

4.0 OVERALL CONCLUSIONS & RECOMMENDATIONS

- 4.1 Suboxone has been used in this feasibility study with a wide range of patient groups, for whom it has the potential to be beneficial and it appears to offer a number of advantages over methadone.
- 4.2 Prescribing of Suboxone in the feasibility study has largely been rational and in line with the audit criteria of the UK National Institute for Clinical Excellence.
- 4.3 Suboxone has been and can be safely provided in Ireland, though some operational issues need to be addressed.
- 4.4 Provision of Suboxone to patients for whom there is a clear rationale and reasonable likelihood that they may benefit from it, even if it is more expensive than methadone, may have economic and other benefits for society as a whole that ought to be taken account of in making decisions about the future use of the drug.

Recommendations	Who should act?
<p>1. The Suboxone Expert Group discuss and agree interim criteria for who should be eligible for Suboxone treatment which would be subject to review, for example in 2 years. During these two years, prescribers and other national stakeholders should come together as a group to consider and discuss the criteria in greater detail. This process would ideally be facilitated by an independent chairperson and supported by an independent literature review.</p>	<p>Suboxone Expert Group. Prescribers from all settings, Primary Care Reimbursement Service (PCRS), HSE, patient groups.</p>
<p>2. If Suboxone prescribing is restricted to certain groups/subjected to certain criteria in future, audit and reporting processes should be established to add weight to the criteria and enable any prescribing patterns that are unusual or fall outside the criteria to be identified and explored.</p>	<p>Prescribers and national stakeholders.</p>

<p>3. National guidelines on the use of Suboxone across all prescribing and dispensing settings should be developed including:</p> <ul style="list-style-type: none"> - Prescribing notes including guidelines/restrictions/criteria on use in certain groups. - Options for initiation regimes and guidance on choosing one. - Guidance on minimum supervision levels (i.e. days per week) in first three months of treatment (for different groups as needed). - Guidance on double dosing. - Detoxification regimes. - Guidance on management of situations where Suboxone was used for its detox potential but where the patient is not coping with the agreed regime. - Guidance on dispensing and protocols for supervision of dispensing (with specific guidance on what constitutes supervision in relation to Suboxone). 	<p>A collaborative working group including prescribers and dispensers from both clinic and community settings.</p>
<p>4. Standard patient information resources should be used across all settings. If an existing resource cannot fulfil this role, a new resource should be developed and agreed on.</p>	<p>Opioid Protocol Implementation Committee in collaboration with patient groups and where appropriate, made available by the pharmaceutical company.</p>
<p>5. Prescriptions for Suboxone should be designed for clarity and avoidance of ambiguity. This will entail the production of a specific prescription form for Suboxone or adaptation of the methadone prescription form to allow either drug to be prescribed on it.</p>	<p>Representatives of community prescribers and dispensers along with national stakeholders as needed e.g. PCRS/HSE</p>
<p>6. The system for remuneration of Suboxone in future should be incorporated into remuneration systems for opioid treatment services and should be clearly communicated to prescribers and dispensers (including any future prescribers and dispensers)</p>	<p>PCRS with support from the GP co-ordinators and Addiction pharmacists.</p>

<p>7. Clarification of the ethical and legal position of pharmacists and clinics in relation to the various options for coping with stock shortages should be provided. Professional guidance should be prepared in relation to the appropriate management of such situations</p>	<p>Addiction pharmacists in collaboration with the Pharmaceutical Society of Ireland (PSI).</p>
<p>8. Arrangements should be made for the appropriate management of Suboxone stock which may be left in pharmacies where they no longer have any patients on the drug.</p>	<p>Addiction pharmacists in collaboration with wholesaler and pharmaceutical company and PSI as needed (e.g. to authorise stock transfer).</p>
<p>9. Suboxone should be made available through more than one wholesaler to reduce the likelihood of stock shortages.</p>	<p>Department of Health and Children (DOHC).</p>
<p>10. Suboxone initiation and prescribing should be restricted to those with suitable expertise and training. A clear and robust system of training, support, clinical supervision and audit needs to be put in place in all settings. Ideally this would form part of integrated training in the overall management of opioid dependence.</p>	<p>Irish College of General Practitioners (ICGP), Senior clinicians in HSE clinics/DTCB as part of a collaborative approach to training with the PSI and the Irish Centre for Continuing Pharmaceutical Education (ICCPE).</p>
<p>11. Suboxone dispensing should be restricted to those with suitable expertise and training. A clear and robust system of training, support, supervision and audit of care needs to be put in place in all settings. Ideally this would form part of integrated training, support, supervision and audit in relation to the overall management of opioid dependence.</p>	<p>Addiction pharmacists in conjunction with ICCPE, the PSI or a provider of online learning as part of a collaborative approach to training with ICGP.</p>

<p>12. There is a need for a mechanism for prescribers (and to a lesser extent pharmacists/dispensers) to share and discuss their experiences with Suboxone (and in the management of opioid dependence in general including methadone). The value and feasibility of a multidisciplinary interest group should be considered. All those prescribing or dispensing Suboxone should automatically become members and the group should be used to provide peer support and shared learning between more experienced practitioners specifically, but not limited to:</p> <ul style="list-style-type: none"> - Identifying issues arising at an early stage e.g. diversion trends, - Developing experience of which groups are most suitable for Suboxone - Reporting issues or problems to the Opioid Protocol Implementation Committee. <p>The group could operate online if more feasible than meeting physically but some facilitation would be needed in either case.</p>	<p>Opioid Protocol Implementation Committee in collaboration with interested prescribers and dispensers.</p>
<p>13. Engagement should take place with the pharmaceutical company marketing Suboxone in order to consider price, budget projections and shared-risk arrangements for any future use of Suboxone.</p>	<p>HSE, PCRS and pharmaceutical company</p>
<p>14. Any future consideration of the cost-effectiveness of Suboxone should take into account the full range of potential benefits from successful treatment of opioid dependence including reduced social costs.</p>	<p>HSE/PCRS/Health Information and Quality Authority/DOHC</p>

Appendix A: Protocol for feasibility study for use of Buprenorphine/Naloxone (Suboxone) as an alternative treatment to Methadone for opiate dependency

April 2009

The Expert Group set up by the Department of Health and Children to examine the use of Buprenorphine/Naloxone (Suboxone) recommended the introduction, in the short term and as a feasibility study, of the prescribing and dispensing of Buprenorphine/Naloxone (Suboxone) in specialist addiction clinics with pharmacies and supervised dispensing on site and in a selected number of community settings (Level II GPs and community pharmacists).

The protocol for the feasibility study is as follows:

General

1. The study will run for one year and prescribing/dispensing at the study sites will be evaluated, commencing after 8 months of the study and being completed after 12 months, before a decision is made on the possible extension of prescribing/dispensing to the entire community.
2. Four specialist addiction clinics with a pharmacy and supervised dispensing on site will be included in the study and the number of clinics may be expanded after 3-4 months, if necessary. The sites to be selected include Trinity Court and one clinic in each of the former SWAHB, NAHB and ECAHB areas.
3. The ICGP will identify suitable Level II GP practices to participate in the study and those practices, in conjunction with the Liaison/Chief Pharmacists will identify suitable community pharmacies to provide supervised dispensing. In accordance with this protocol for a Suboxone feasibility study, the Liaison/Chief Pharmacists will have a role in the development of protocols, practices and training of pharmacists working with the addiction services.
4. This protocol will apply equally to study sites in addiction clinics and in community settings, to ensure that there are no operational or clinical variations across sites.
5. Buprenorphine/Naloxone (Suboxone) will be free of charge to the clients involved in the study.
6. The running of the study will be overseen by the Expert Group.
7. The evaluation of the study will be conducted independently, according to agreed evaluation criteria and using a recognised audit tool.

Selection of clients and registration with DTCB

8. Buprenorphine/Naloxone (Suboxone) is indicated for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and young adults over 15 years of age who have agreed to be treated for addiction.
9. 60 clients attending specialist clinics and 40 clients attending Level II GPs will be selected for participation in the study.
10. Clients who wish to be included in the study must consent to treatment and to having their record held by the Drug Treatment Centre Board (DTCB).
11. The DTCB shall maintain a database of clients participating in the study which shall contain information notified to it under paragraph 15.
12. Only the DTCB may amend an entry in or delete an entry from the Buprenorphine/Naloxone (Suboxone) database.
13. Where a notification is made to the DTCB, the DTCB shall inform the registered medical practitioner as to whether the person is/has previously been included in the Methadone Central Treatment List.

Prescribing of Buprenorphine/Naloxone (Suboxone)

14. Only physicians experienced in the management of opiate dependence/addiction (Level II ICGP Qualification or Consultant Psychiatrist) may prescribe Buprenorphine/Naloxone (Suboxone).

The Royal College of General Practitioners' ***'Guidance for the use of Buprenorphine for the treatment of opioid dependence in Primary Care'*** for the initiation and maintenance of clients on Buprenorphine/Naloxone (Suboxone) will be used in GP settings. The RCGP guidance document is available at

http://www.rcgp.org.uk/PDF/drug_buprenorphine.pdf.

The specialist addiction clinics will use a combination of RCGP, NHS/NTA, NICE and SAMHSA guidelines.

15. Where a registered medical practitioner intends to prescribe Buprenorphine/Naloxone (Suboxone) for the first time to a person who has presented to the registered medical practitioner for treatment, the registered medical practitioner shall not issue a prescription for Buprenorphine/Naloxone (Suboxone) until he or she notifies the DTCB of the name, address and date of birth of the person and the person has consented to be part of the pilot study.

16. A registered medical practitioner shall not issue a prescription for Buprenorphine/Naloxone (Suboxone) unless it complies with the controlled drugs regulations i.e. Misuse of Drugs Regulations 1988. The PH number of the client must be on the prescription.
17. Prescriptions for Buprenorphine/Naloxone (Suboxone) should not be generated on a GMS script but on a non-GMS (private) prescription of the registered medical practitioner.

Dispensing of Buprenorphine/Naloxone (Suboxone)

18. Pharmacists shall not supply Buprenorphine/Naloxone (Suboxone) other than when the prescription complies with the controlled drugs regulations in full.
19. Pharmacists should not supply Buprenorphine/Naloxone (Suboxone) other than to a person participating in the feasibility study, who has been referred by a registered medical practitioner and who, at the first dispensing, presents photo identification, and at subsequent dispensings, either presents photo identification or is known to the pharmacist.
20. Dispensing shall be supervised for at least the first 3 months. Stable patients switching from methadone may not need to be supervised for such a period.
21. A pharmacist shall forward to the PCRS -

In respect of each supply of Buprenorphine/Naloxone (Suboxone) –

A copy of the prescription on which the supply of Buprenorphine/Naloxone (Suboxone) was made,

and

in respect of the prescription, a statement which confirms the identity of the person to whom the prescription was issued, if the information given on the prescription form is inadequate, illegible or misleading,

and

Particulars of each supply of Buprenorphine/Naloxone (Suboxone) made to registered medical practitioners pursuant to a requisition, not later than 14 days after the last day of the calendar month in which the supply of Buprenorphine/Naloxone (Suboxone) made on that prescription was completed or when no further supply may be made on that prescription.

The original of the prescription must be held at the pharmacy.

NOTE: For the purposes of Article 19.2 of the Misuse of Drugs Regulations (preservations of prescription), the duplicate copy of the prescription, made by the practitioner at the time of writing the original, shall be treated as if it were the keeping of the original document.

22. The Minister shall cause to be maintained by the PCRS a record in electronic form of all prescriptions. The PCRS may amend an entry or delete an entry from the said record.
23. Each prescription shall be preserved for a period of two years from the date of receipt of that prescription.
24. A person shall not supply Buprenorphine/Naloxone (Suboxone) to a registered medical practitioner unless that person is conducting a retail pharmacy business and the supply is made by or under the supervision of a registered pharmacist.
25. For the purposes of this study, the sole supplier, United Drug, shall not supply Buprenorphine/Naloxone (Suboxone) to a person conducting a retail pharmacy business unless the pharmacist is participating in the study. Confirmation of the pharmacist's participation in the study can be obtained by contacting Mary O' Reilly, Department of Health and Children, Phone (01) 6354093.

Prescription of Buprenorphine only

26. There may be instances where a client who is on Buprenorphine/Naloxone (Suboxone) becomes pregnant and has to be switched to Buprenorphine only as Buprenorphine/Naloxone (Suboxone) does not have a licence for use in pregnancy. There may also be cases of clients who are currently on methadone who, for urgent medical reasons, require a switch to Buprenorphine. Arrangements for the provision of Buprenorphine will be made, if and when, necessary.

NOTES:

- It is intended in this study that the medicinal products used will be appropriately authorised by the Irish Medicines Board.
- While this study is not a Clinical trial, the IMB will be informed of it.
- In this document, in every reference to **Suboxone** the following proprietary medicinal product is intended:
 - - °Suboxone▼2 mg/0.5 mg sublingual tablets
 - °Suboxone▼ 8 mg/2 mg sublingual tablets

2mg tablets

Each tablet contains 2 mg buprenorphine (as buprenorphine hydrochloride) and 0.5 mg naloxone (as naloxone hydrochloride dihydrate).

8mg tablets

Each tablet contains 8 mg buprenorphine (as buprenorphine hydrochloride) and 2 mg naloxone (as naloxone hydrochloride dihydrate).

It should be noted that for the purposes of this study, the Misuse Of Drugs Regulations 1988(as amended) will apply in full including prescription writing requirements, safe custody and Article 16 requirements relating to keeping of a controlled drugs register.

Appendix B: Full Results of Patient Survey

These results have been presented in the order that they appeared in the study, with statistics followed by a representative sample of the additional comments made by respondents. Overall 33 patients participated in the survey, 20 males and 13 females.

1. PRIOR TO FIRST BEING PRESCRIBED SUBOXONE IN IRELAND, HAD YOU PREVIOUSLY BEEN TREATED WITH MEDICATION FOR OPIATE DEPENDENCE?

Answer Options	Response Percent	Response Count
Yes, methadone treatment	69.4%	25
Yes, detox (community or residential)	27.8%	10
Yes, subutex/suboxone in UK/elsewhere	8.3%	3
No, I had not previously been treated with medication for opiate dependence.	16.7%	6
Other	11.1%	4
<i>answered question</i>		36

Additional information on “Other” responses:

“Self administered temgesic once upon a time. lofexidine in the past also.”

“I was given codeine tablet's, in March 2009, to help me get over my dependence. I was in St. Jame's hospital in Dublin. Because I had being taken so much Nurofen Plus, it had depleted the hemoglobin in my blood, and as such was at a very low level. I was given several pints of blood. To take care of the codeine addiction they gave me codeine in tablet form. Soon after leaving hospital I recommenced taking Nurofen Plus. This was meant as a detox.”

“I also tried self medicating using street purchased methadone.”

“I briefly received Methadone treatment in 1992 in the US.”

Additional comments:

“5 naltrexone implants previously. 2 in Portugal, 3 in Latvia, detox and a chip. All terrible, didn't work. It's a magic tablet.”

“When I got addicted I only went for help once, but I did take methadone before for a while, and I wasn't on heroin at that time.”

“15 years on methadone”

“Yes...as many probably have done it as me. Anyway, I used to take 90mg daily of Methadone and on top of that I would also need 40mg of valium a day. When finally they give a place [at the clinic] I already detoxed myself off methadone and I was already on 24mg of Suboxone. [My doctor] was very understanding and soon she detoxed me off benzos so that she could start my detox from the suboxone! I would tell to anyone that wants start this journey to be sure that this is what they want because it take at lots of strength...but you know what, its all well worth it!”

“I needed a knee replacement - so was a rapid thing”

“Had Subutex on black market a few years ago from UK as a stop gap.”

2. WHAT OPIATE DID YOU MAINLY MISUSE IMMEDIATELY PRIOR TO BEING TREATED WITH SUBOXONE?

Answer Options	Response Percent	Response Count
Prescribed methadone	5.6%	2
Street methadone	0.0%	0
Heroin	83.3%	30
Codeine e.g. Solpadeine other...	11.1%	4
Buprenorphine e.g. Subutex/Suboxone	0.0%	0
Other	0.0%	0
<i>answered question</i>		36

3. HAVE YOU PREVIOUSLY BEEN PRESCRIBED METHADONE?

Answer Options	Response Percent	Response Count
Yes	69.4%	25
No	30.6%	11

4. HOW DID YOU FIRST HEAR ABOUT SUBOXONE?

Answer Options	Response Percent	Response Count
Addiction counsellor	13.9%	5
Doctor	44.4%	16
Pharmacist	0.0%	0
Other drug users	11.1%	4
Media reports	5.6%	2
My own research	8.3%	3
From another support service or organisation e.g. the community drugs team	5.6%	2
I was previously treated with Suboxone or Subutex in the UK	0.0%	0
Other	11.1%	4
<i>answered question</i>		36

Additional information on “Other” responses:

“I went to a clinic and went on Suboxone for 2 weeks, then came off. Years later I went onto methadone, and then was put back onto Suboxone”

“My ex partner heard about it on the internet”

“I was admitted [for dental treatment] in mid - January 2008, in order to have my two bottom wisdom teeth out When the operation was finished, the doctor said that there may still be some pain i.e. throbbing of the gum sockets. He said that if this was the case that I should take Panadol and if this did not work that I should try Nurofen Plus. When I got home I tried the Nurofen Plus first off. I took three and noticed that I felt a euphoric feeling which I enjoyed. That was the start of my addiction.”

“Someone on the street told me about it.”

Additional Comments:

“I was clear for 10 years but went back on it and the doctor recommended it.”

“I was asked if I wanted methadone or Suboxone”

“I was weaning off methadone and my doctor suggested it.”

“When I went to the clinic to get clean the doctor told me about it and said it was an alternative to methadone. And I had heard people mention it as a new alternative.”

“He [the doctor] was brilliant”

“I knew about temgesic and naltrexone, in Europe. Checking myself.”

“I saw it on a documentary on television, then I searched the internet for it. I was fed up with methadone and looking for something else. I then spoke to a community key worker.”

“I was looking at going to a clinic and read about Suboxone on the internet”

“My doctor hadn’t heard of it, but the drug counselor told me about Suboxone.”

“I bought 40 2ml Suboxone tablets from someone, but didn’t know how much to take, so I just held on to them. I didn’t want to go on methadone as it almost got a hold of me before.”

“Long term friend and user who was being treated with Suboxone”

“Heard about it from someone in England years ago.”

“I had heard about Subutex off other drug users, not Suboxone.”

5. IF YOU HAVE PREVIOUSLY BEEN PRESCRIBED METHADONE, WHY WERE YOU PRESCRIBED SUBOXONE?

Answer Options	Response Percent	Response Count
Following discussion of my circumstances, it was felt by me and my doctor that it was the best option for me.	72.0%	18
I requested it.	36.0%	9
I wanted to detox (e.g. to be substance free) rather than to stay on treatment (e.g. maintenance)	44.0%	11

I wanted to be more alert than I would be on methadone	36.0%	9
I thought Suboxone would suit me because I felt I was less likely to top-up while on it than with methadone (e.g. with heroin or other unprescribed opiates)	28.0%	7
I wanted a tablet not a liquid as more discreet in pharmacy	8.0%	2
I had previous side effects from methadone	44.0%	11
Methadone didn't work for me.	40.0%	10
I didn't want to go back on methadone because it is too hard to detox off.	20.0%	5
I felt there is a stigma with methadone	12.0%	3
Suboxone was recommended to me.	32.0%	8
I was already on Suboxone outside of Ireland.	0.0%	0
Other	32.0%	8
<i>answered question</i>		25

Additional information on "Other" responses:

"Taking the medication every second day was also a factor. I thought Suboxone would break me out of the habit. I wanted to come off the Phy quickly so my doctor recommended Suboxone as I wanted to stay on maintenance or else I would go straight back on the gear."

"Wanted to go on Lofexidine but couldn't because I suffered from depression"

"More discreet for travel. Mental clarity would have been a big issue for me, less toxic on the system. I'm just more mentally vital on it. Main reason along with travel - can't carry liquids, they have to go in the hold - stressful."

"Because of my liver, and you didn't have to take it at a certain time."

"Partner and doctor."

"The doctor said as i hadn't been on heroin for very long the Suboxone might be a good option."

"I am a fighter, you know what i mean, so the doctor thought the Suboxone would be good for me. I had seen someone at the hatch and noticed they weren't taking the green liquid so i asked him what it was and he said Suboxone. Didn't like the taste of methadone, and what it did to me - you'd still think I was on heroin. Started on 4ml of Suboxone then went up to 6ml then 8ml"

"In hospital with heart condition (hereditary) - methadone was damaging heart and sub would be a safer because I was on a high dose of methadone. So it wasn't really a choice, it was for health reasons."

Additional information on Recommendations:

"Naltrexone chips and home detox didn't work for me. Suboxone was recommended by a friend."

"Worker in drop in centre recommended it so spoke to doctor who thought it would suit."

"Clinic recommended it."

"By the counselor"

Additional comments on why the respondent was prescribed Suboxone:

“Had to fight for it for 4 months. Was told I wouldn't get it, but I wasn't willing to take methadone as it just didn't work for me, so just kept on asking, kept pushing for it. I was told that it wasn't available, that it was only a pilot, no more spaces.”

“I found methadone made me worse”

“Because of irregular heartbeat from methadone, and I have children and I don't want them going down the same road”

“I'd done a methadone detox before and did not want to do it again.”

“I heard that it was better than methadone, someone on the street told me”

“Had almost weaned off methadone and wanted to be totally clean and Suboxone would be better for the final kick. Felt that doctors were looking for people to go Suboxone.”

“I had read that it had a higher success rate.”

“I was willing to take anything I was so bad.”

6. IF YOU HAVE NOT PREVIOUSLY BEEN PRESCRIBED METHADONE, WHY WERE YOU FIRST PRESCRIBED SUBOXONE (RATHER THAN METHADONE) IN IRELAND?

Answer Options	Response Percent	Response Count
Following discussion of my circumstances, it was felt by me and my doctor that it was the best option for me.	90.9%	10
I requested Suboxone.	9.1%	1
I wanted to detox (e.g. to be substance free) rather than to stay on treatment (e.g. maintenance)	54.5%	6
I wanted to be more alert than I would be on methadone	54.5%	6
I thought Suboxone would suit me because I felt I was less likely to top-up while on it than with methadone (e.g. with heroin or other unprescribed opiates)	36.4%	4
I wanted a tablet not a liquid as more discreet in pharmacy	18.2%	2
I was already on Suboxone outside of Ireland.	0.0%	0
For medical reasons e.g. I couldn't take methadone	0.0%	0
I didn't want methadone because I have heard bad things about methadone	36.4%	4
I didn't want methadone because I feel methadone is for harder drug users	9.1%	1
I didn't want methadone because I have heard methadone is very hard to come off/detox from	45.5%	5
I didn't want methadone because I feel methadone is not for people like me	36.4%	4

I didn't want methadone because I feel there is a stigma with methadone	18.2%	2
I didn't want methadone because I wanted a tablet not a liquid as more discreet in pharmacy	18.2%	2
Suboxone was recommended to me. Please explain below by whom and why?	45.5%	5
Other	9.1%	1
<i>answered question</i>		11

Additional information on "Other" responses:

"They started reducing my methadone by 10mg a week and when finally I reached 30mg that's when they switched me to Suboxone! I have to say it was hard and painful but I'd my mind set from the start to complete the Suboxone ... Today I'm down to 6mg - which is great because I started with 24mg!"

Additional Comments:

"My local addiction support key worker and counsellor advised me to look into Suboxone because I had almost got substance free on my own by self medicating using street purchased methadone. They felt I would be a good candidate for this reason."

"The doctor had worked with it before and thought it was the best"

"Suboxone was recommended to me because the doctor felt I was not taking enough heroine to justify methadone"

"I didn't want to get addicted to something else. I had worked with a guy who was on it [Methadone] for a couple of years and, excuse the French, he still looked like shit even though he was off the heroin."

"I was working in an environment with heavy machinery and so it was important that I was alert."

7. WHAT INFORMATION DID YOU RECEIVE BEFORE TAKING SUBOXONE?

Answer Options	Yes	No	Response Count
Benefits associated with Suboxone (e.g. alertness)	12	0	12
How Suboxone works e.g. risk of withdrawals if using other opiates.	17	1	18
How Suboxone is taken e.g. under the tongue/not to be swallowed.	14	1	15
Level of supervision required (time taken to dissolve under tongue etc.)	9	1	10
The need to wait until experiencing withdrawals before using Suboxone	9	2	11
Risks associated with Suboxone for liver	3	6	9

Risks of Suboxone in pregnancy (women only)	1	4	5
Didn't receive any information	1	2	3
Don't remember	2	1	3
<i>answered question</i>			25

8. HOW DID YOU RECEIVE THIS INFORMATION?

Answer Options	Response Percent	Response Count
Written information from doctor/pharmacy	71.4%	25
Discussion with doctor/pharmacy	80.0%	28
No information received	11.4%	4
Don't remember	5.7%	2
<i>answered question</i>		35

Additional Comments:

"A couple of pages/printout to take home"

"Got a leaflet with the Suboxone box"

"It was a very thorough discussion"

"It's hard to remember what information I was given as I was still using drugs at the time, but I was given a little booklet about it."

"everything, leaflet, asked a million and one questions"

"Didn't receive a lot of information in the hospital as I was being treated by two consultants, a cardiologists and one for something else and they didn't know much about it - it was all new to them. When I went to the clinic I was given a booklet."

"I know I received a lot of information and the doctor spoke to me quite a bit, but I was in a terrible state and can't really remember."

"I found out information on the internet myself"

"Was given a few wee pamphlets and did my own research on the internet, but I felt that the doctors didn't know that much about Suboxone either."

"They only had one leaflet and I was lucky to get it. I don't think there's enough. There could have been more information given. The doctor gave me a bit of info, but I don't think the doctors even know that much about it because it's new."

"I think I was one of the first in the country to go on it so there wasn't a lot of information. The doctor told me all the clinical stuff, but not really about how I would feel on it. He pointed me to a website as well and I found out stuff there."

"I know some people got a sheet, but I didn't get anything, wasn't really told anything"

"Told to always carry the card."

“Knew it was basically the same as Subutex, but with an added ingredient Nalaxone.”

“Was told all about the risks of drinking alcohol - that it can kill you.”

“I was unaware about the liver. I will ask about this in due course.”

“I'm disappointed that I wasn't told about the liver risks. Mind you I doubt that I would have declined to take Suboxone even if I had been told about this. But still, I think I should have been told about this aspect of the drug. Can I get information about this please?”

9. ARE YOU STILL BEING TREATED WITH SUBOXONE?

Answer Options	Response Percent	Response Count
Yes	84.8%	30
No because I have detoxed off it and am no longer taking any opiates (prescribed or otherwise)	6.1%	2 *
No because I have relapsed and am no longer receiving drug treatment	0.0%	0
No because I have switched to methadone.	9.1%	4 **
No because Suboxone didn't work for me	0.0%	0
<i>answered question</i>		36

* Specific comments made by these respondents will appear in *italics* throughout this appendix.

** Specific comments made by these respondents will appear in **bold** throughout this appendix.

Additional Comments:

“I was on 24mls, and had gotten down to 2mls every third day, but that was because I had gotten caught out by the head shop's and was addicted to ivory wave, MDVP I think the drug was. I didn't think I'd get a problem from something I bought over a counter. Lesson learned. Now I'm on 4mls of Suboxone everyday and have been for around 4 months.”

“I was awake for 4 days straight, and I wasn't sick for heroin but I was sweating really badly and crying for four days and I felt that I couldn't go through it anymore.”

“It was very effective - cut down eventually came off it with no problems at all”

“I tried to go cold turkey just after Christmas. This was a bad idea. I was in pain all over and I could not sleep well. I spoke to [my doctor] again and we agreed that I should recommence taking the Suboxone, and then when I am ready I will wean down slowly. I therefore began on a light dosage, 4mg, thus going up to 24mg.”

“Didn't like how suboxone made me feel especially after drinking alcohol.”

10. HOW DO YOU FEEL THAT YOUR TREATMENT WITH SUBOXONE HAS AFFECTED THE QUALITY OF YOUR LIFE?

Answer Options	Response Percent	Response Count
Made it better	88.9%	32
No change	5.6%	2
Made it worse	5.6%	2
<i>answered question</i>		36

Additional Comments:

"I'm happy now i'm not just existing anymore."

"Suboxone saved my life. It's made me a member of life again...if it wasn't for Suboxone I'd say I'd be dead by now."

"Never felt as well in my life, I am new person - I have a whole new life"

"I could not control the Codeine cravings, and as such I was in and out of hospital. I knew that the eventual outcome would be death, therefore I chose life. I had no confidence whilst I was on drugs. I was merely existing and not living."

"Made a better quality of life. One thing is that I don't need to go to clinic every day anymore."

"Suboxone is allowing me to take my time with my recovery but at the same time it's allowing me to work and be a good father."

"I want my life back. And now I am a different person - I'm like the person I used to be before I took drugs. And when my wrong friends come round I can walk away, I just say how you doing boys and then keep walking."

"Made it better doesn't even come close to describing it."

"I know an awful lot of people who are on Phy and they go around stoned looking still, and that's why you want to come off the gear at the end of the day. The Suboxone doesn't affect you at all - no effects."

"Definitely improved. Still tied to something but better than being tied to methadone."

"The effect of it is far gentler on the system, working 2 hours after I took methadone, I could become over animated, if stimuli and if not stimuli I became drowsy. There is a slight pick up with Suboxone but it is far more ephemeral or vague, and no drowsiness with Suboxone. Palour and appearance better with Suboxone. People noted I appeared and sounded more sane".

"A million times better. You can function normally, you're not drowsy or anything, all your emotions are back, on methadone they're blocked, but you get all your emotions back again."

"When I was on methadone I would sleep all day, get up for dinner and go back to bed and I wouldn't spend any time with my children."

"I don't feel as though there are side effects like there is with methadone, don't feel feel drowsy like I did with methadone"

"I got into a bad habit, and it was a fairly painless recovery"

"Worse for a few days though I was told it would get better if I had stayed on it."

“About 20 minutes after taking Suboxone I'd get a burst of energy throughout the day, it was quite distressing, I couldn't think straight, my mind was racing. I couldn't relax, I was talking and walking. I couldn't take it in the evening because i wouldn't be able to settle. So in that way it affected my life in a bad way. I know that some users like that effect though.”

11. HOW DO YOU FEEL THAT YOUR TREATMENT WITH SUBOXONE HAS IMPACTED ON YOUR HEALTH?

Answer Options	Response Percent	Response Count
Made health better	58.8%	20
No change	38.2%	13
Made health worse	2.9%	1
<i>answered question</i>		34

Additional Comments:

“My lung's are no longer like tar pits ... I keep active enough, go for a walk everyday, train my son's football team. Without Suboxone I'd still be sitting alone in my bedroom, setting my hair on fire, or the bed. It's saved my bacon.”

“I haven't been to a doctor in months. Before I was getting headaches and was hungry all the time.”

“I don't feel pain on my liver!”

“Now that not smoking heroin at all, asthma is much better.”

“I feel a bit healthier - before I got pains in stomach and legs, never better. I feel like I could run a mile and I am 42!”

“I wasn't well when I went on it, but with Suboxone there have been no side effects”

“I just feel more relaxed, walking a lot more since started on it, but didn't do much when on methadone. Got a clear head and now much more active.”

“Appetite is back. I'm looking a lot healthier than I have in a long time as well.”

“More active - I'm like anybody else who takes nothing.”

“Much better. I am eating much better and as such I am putting back on weight. I have more confidence and my general outlook on life and my quality of life has greatly improved exponentially. My blood count is also back to normal.”

“Used to get really light headed without the Suboxone, but that's really the only thing.””

“My health has worsened due to other circumstances not related to Suboxone or drug use”

“Apart from the mental way it affected me [bursts of energy throughout the day, mind racing] I don't think so.”

“Difficult to say as not sure of long term effects. I feel better in myself, but can't say that I feel brilliant.”

“Was always pretty healthy anyway. I wouldn't have been typical heroin addict, was working, had to be presentable, both injecting and smoking.”

12. DO YOU FEEL THERE IS ANY DOWNSIDE TO TREATMENT WITH SUBOXONE?

Answer Options	Response Percent	Response Count
Yes	31.4%	11
No	68.6%	24
<i>answered question</i>		35

Additional Comments:

"I went to the dentist and I could feel all the pain, not sure if this was to do with Suboxone. Got a larger dose of the injection the next time"

"I get pain in my back and stomach but not sure if that's through the treatment for HIV or Suboxone."

"Well...the thing is that during this medication it's impossible to go in the toilet...and day by day is getting worse!"

"Apart from slight drowsiness in the beginning you can live your life unobstructed."

"Sometimes sleeplessness"

"Apart from the manky taste in your mouth not really."

"As above [bursts of energy throughout the day, mind racing] - major downside."

"Made me depressed."

"No more so than with any other addiction - you're still reliant on something"

"Other than the fact that you're addicted to a drug."

"I was under the impression that Suboxone was easier to come off than methadone. I was on 12mg, have been on it for 11 months, wanted to cut down and so went to 8 and I found the jump was not as easy as it thought it was going to be. Now I am worried that it will be tough coming off of it altogether."

"Not for me, but you'd need to be strong to stay off drugs once you come off Suboxone and not start using again."

"I suppose there is a slight psychological dependence and a feeling of security taken from the drug. I imagine it will be a bit of a challenge to stop taking it. I'd like to take my time doing this when the time is right. I'd like to do it gradually. Perhaps taking it miligram by miligram month by month."

"Not really. Only negative, need to take at the same time, and if you don't, you get very fatigued."

"The only down side for me is, I live 23 miles from the clinic, and I handed in the extra tablet's I had, so if it snow's or if anything goes wrong, and it has done, I have no Suboxone and it's a constant worry. I'm kind of living in an episode of Jerry Springer at the moment and it's an added stress I could do without. I don't want to go to dealers to try build up a supply again, I don't even want to talk to anybody like that. after almost 2 year's going to the clinic, they should trust me enough to overcome this."

"The only downside is the length of time it takes for supervision at the pharmacy. With methadone you drink it then you go. With Suboxone you have to wait for it to dissolve, then they check under

your tongue. It felt degrading. But the benefits outweigh that so I wouldn't not choose Suboxone because of it."

"I have been on Suboxone 3 years but I've always had to go to the clinic, I'm not on a prescription so I can get it in the pharmacy. I think that should be more available and the health board need to look in on that a bit more. Having to go to the clinic every day is a downside."

"I mean you have to go into the chemist everyday which is a drag, but the bonuses you get it's worth it."

"You really have to commit, and people need to know how severe the withdrawal is, it nearly pushed me off it. You have to be determined to be on it. But you have to look at the bigger picture if it's worth it in the long run. If people did know about the withdrawal they might not take it. If I'd known I wouldn't have taken it."

"I think looking back I just didn't give it long enough but I knew I wouldn't feel sick on methadone."

"It is very difficult to stabilize at the beginning, the first three or four days in particular"

"If you don't really want to come off the heroin and are put on it, it will make you sick."

"I think people don't try it because you can't use anything else with it."

"Absolutely not!"

"Not so far, don't know about when I stop taking it but definitely not so far."

"If anything it made me better."

"I think it's all good."

"Any experiences I've had have just been positive."

13. IF YOU HAVE PREVIOUSLY BEEN PRESCRIBED METHADONE, WAS SUBOXONE WAS MORE EFFECTIVE (THAN METHADONE) IN PREVENTING WITHDRAWALS FOR YOU?

Answer Options	Response Percent	Response Count
More Effective	80.0%	20
Less Effective	12.0%	3
Same	8.0%	2
<i>answered question</i>		25

Additional Comments:

"I went straight into withdrawal when I first took Suboxone, it was a lot worse than going cold turkey."

"The first few days are really hard but overall [Suboxone is] more effective."

"When I first went on Suboxone I was in withdrawals but after they found a good dose it held me and I stopped taking heroin after 2 and a half weeks."

“It is hard to compare the two because with Suboxone you have to go through withdrawals but then once you are on it you are ok, but with Methadone you start on a low dose but you're still taking the drugs on top until you get to the higher dose.”

“I had no withdrawals at all.”

“It holds you longer.”

“Some people say Suboxone has no withdrawals, but I know that's not true.”

“Went through withdrawals for a day and a half before i went on Suboxone. For the first week in Suboxone I was getting these pains in my legs, but i wasn't dying sick you know - I just kept saying to myself that this was my body getting back to normal. Suboxone was way better than methadone at presenting withdrawals. On Suboxone I wasn't falling asleep, you have your wits about you.”

“There's a big difference between the two of them, although I was stable on methadone when I went on Suboxone”

14. IF YOU HAVE PREVIOUSLY BEEN PRESCRIBED METHADONE, WAS SUBOXONE WAS MORE EFFECTIVE (THAN METHADONE) AT CONTROLLING YOUR CRAVINGS?

Answer Options	Response Percent	Response Count
More Effective	84.0%	21
Less Effective	4.0%	1
Same	12.0%	3
<i>answered question</i>		25

Additional comments:

“Since I've been on it I don't really have any cravings.”

“You don't get cravings on Suboxone and your head is clearer. Before I went on drugs, that's the way I feel now. I had no energy on Methadone. I lost weight when I went on Suboxone because I had more energy.”

“I can't really answer that one because I was already stable on the Methadone, I wasn't taking any heroin.”

15. IF YOU HAVE PREVIOUSLY BEEN PRESCRIBED METHADONE, WERE YOU LESS LIKELY TO USE OTHER OPIATES (TOP UP) WHILE ON SUBOXONE (THAN ON METHADONE)?

Answer Options	Response Percent	Response Count
Yes, Less likely to top up.	96.0%	24
No, More likely to top up.	4.0%	1
No difference.	0.0%	0
<i>answered question</i>		25

Additional Comments:

“With Methadone you can still smoke heroin but with the tablets you can't, so it makes you think about it a bit more.”

“You get told that you have a higher chance of ODIing if you take anything with it, so it stops you doing it.”

“You can't use heroin on it because it makes you feel really sick. Though I know some people smoke hash.”

“That's the beauty of it, you don't get the same kick out of heroin or methadone. It's like a safety net and it makes you feel more normal.”

“I knew I couldn't take anything else or it would interact with the medication so that helped a lot. I felt a bit of sickness when I was going on it because the methadone has to be out of your system, and I think mine wasn't properly out of my system which is why I felt the sickness. So now I know that I would feel 10 times sicker if I took anything now, so that helps.”

“I was less likely to top up because of the blocker, though a high dose of meth would do the same thing. But by the time I was going onto Suboxone I had really lost the appetite for drugs.”

“A different place in my life so less likely to top up.”

“100% less likely to top up”

“Haven't used anything on top of Suboxone since started in Jan 2010.”

16. IF YOU HAVE PREVIOUSLY BEEN PRESCRIBED METHADONE, DID YOU FIND IT EASIER TO REDUCE YOUR SUBOXONE DOSE/COME OFF SUBOXONE, THAN METHADONE?

Answer Options	Response Percent	Response Count
Yes, it was easier.	60.0%	15
No it was more difficult.	0.0%	0
It was the same	4.0%	1
Doesn't apply to me.	36.0%	9
<i>answered question</i>		25

Additional Comments:

“A hell of a lot easier coming off Suboxone than methadone”

“I have been reducing and it is easier to lower, less withdrawal”

“Much much easier - I am detoxing off it at the moment down to 8 from 26”

“You get quite sick coming off it”

“I was on Heroin for about 2 months and then was only on Phy for a short time until the Suboxone came in so it's hard for me really to compare the two. I did try to detox off the Suboxone as I was getting married but it didn't work, I came off it too quick. So I've been on 24mg since. I do plan to try to detox again but this time more slowly.”

“Went on Suboxone and doctor suggested a higher dose, but I wanted to stop on 8 ... At one point I went down to 1/2 of 2mls, and my friends came round, but I was able to walk away. I know I was able to walk away on 2mls, but I went back on a higher dose to be safe.”

“They never left me on Suboxone - I was stopped after a week.”

“I haven't done a full detox from methadone but I know just reducing the dose was pretty hard. I understand that it's easier with Suboxone.”

“I never reduced my methadone dose so it's hard to say if it was easier – I just stopped taking it and switched to Suboxone.”

17. OVERALL PLEASE RATE YOUR EXPERIENCE OF USING SUBOXONE:

Answer Options	Response Percent	Response Count
Very good	84.8%	29
Good	12.1%	5
Neither good nor poor	0.0%	1
Poor	0.0%	0
Very Poor	3.0%	1
<i>answered question</i>		36

Additional Comments:

“Excellent, would recommend them to anybody.”

“It helped me a lot.”

“Excellent really”

“Excellent - more than very good. The best thing I have ever done - it has been amazing for me.”

“1: I am healthier. 2: I have better confidence. 3: I have my appetite back. 4: More optimistic outlook on life. 5: My mother is happier and relieved that I am clean, which makes me happier. 6: I sleep much better at night, with no nightmares. 7: I can initiate my goals in life, IE starting college next September.

8: I have more money in my pocket. 9: I am a better father. 10: I am alive, and all the stronger for it.”

“Don't have the cravings, its not in your head like you're thinking about it, you can't mess on it, you can drive, you can go to work and you're not “goofing”. It's very good.”

“Its capacity to act as an opiate blocker, it seems to be effective at a level that's far less tangible to your system than methadone. If one was to go out and buy heroin...it seems to block the hit off the heroin at a lower dose than with methadone.”

“Excellent - I can't find a word for it - I was suicidal before, I'm a different person now - everyone says it! Nobody can believe it. I dad tried to come off so many times before and couldn't do it.”

“199/200%...the best drug I have been on.”

“Suboxone helped me stay clean from heroin.”

"It saved my life. It also helped when I was coming off the MDVP. I didn't really hang around with heroin users I just stayed to myself, so when I came off the heroin and onto Suboxone I didn't know what to expect, I hadn't talked to other people who used it and it was my first time without heroin for 4 year's. Some advice would help, like what to do when your habit rather than your addiction is testing you, and how long that will last. I'd say if less determined people knew these things, they might not fall off the wagon as quick. These were things I had to find out for myself."

"They can't start you on it till you've gone a day into your sickness, which is hard. That might be a reason why other people don't use it - they won't go a whole day sick."

"I just couldn't face another night of no sleep."

"Apart from the effects I would rate it very good, it's just a shame I got those side effects or I would still be on it."

18. IN YOUR EXPERIENCE IS SUBOXONE AVAILABLE ON THE BLACK MARKET/STREET IN IRELAND?

Answer Options	Response Percent	Response Count
Yes	8.3%	3
No	72.2%	26
Don't know	19.4%	7
<i>answered question</i>		36

Additional Comments:

"Most haven't heard of it, not as available as Phy on the street."

"Somebody rang me once and they had a tablet of it and wanted to know what the story was with it."

"I'd doubt it - very few people know of it."

"Not many doctors know about it in Ireland."

"If more people go on it, it will become available because they won't take it."

"It's all methadone - I have never come across anyone trying to sell me Suboxone. I think it's because there is a blocker in it, so nobody really wants it."

"I don't know why it would be - why would other drug users want to use it. It's not like methadone, you can't get stoned on it, as far as I know,"

"Before I went for treatment, I bought some Suboxone, but the person had brought them back from England I've never heard of them being sold here."

"I wouldn't waste my tablet on someone else."

"Never seen it, know it is in other countries like England where they have the Subutex but never in Ireland."

"I can't answer that question. That is an area of life I keep well clear of, but I would not be surprised if it was available on the street/black market."

"Not that I am aware of, I would be fairly sure that it isn't."

19. IN YOUR EXPERIENCE IS THERE A DEMAND FOR SUBOXONE TREATMENT AMONG OTHER OPIATE USERS WHO CURRENTLY CANNOT GET IT PRESCRIBED TO THEM?

Answer Options	Response Percent	Response Count
Yes, I am aware of a few people who want it but can't get it (e.g. 1-5 people)	25.7%	9
Yes, I am aware of quite a few people who want it but can't get it (more than 5)	17.2%	6
No, I am not aware of anyone not being able to get it.	25.7%	9
Don't know	31.4%	11
<i>answered question</i>		35

Additional Comments:

"I don't think people know too much about it."

"Not that much of a demand, some people just love their methadone. A lot of people don't know about it. Even at my clinic people see me taking it, putting the tablet under my tongue and they are like "What the fook is that?" So maybe if people were more aware of it there might be more of a demand."

"It's not well know - anyone I have said it have never heard of it. It's not getting advertised in the clinics. I've spoken to a couple of people and recommended it and they've then gone and got it and have come back to me and said it was great and they were glad they had spoken to me."

"A lot of people have approached me in the clinic and asked about the Suboxone. They want to know how much a table of Suboxone is equivalent in methadone and I try to explain that it doesn't work like that. I tell them to ask the doctor. They wouldn't have heard much about it though."

"Anyone I know has been able to get on it - trying to get all the young people onto it. But you have to want to get clean."

"I think doctors are unwilling to change treatment once you are on methadone, but I think if somebody wanted it they could get it."

"I was the first [in the clinic] who went onto Suboxone, but then I think everyone else came off the methadone and went on Suboxone, so they could all get it."

"There seems to be a lot more people going on it in the last year. I think it depends on what you want. If you want to be substance free and be clean then it's much better than methadone."

"They see the difference in me now and would love to be able to give it a try."

"They asked the doctor, they noticed how good I looked but they were on high doses of methadone."

"Some people who have been told they are unsuitable have difficulty accepting this, idealizing it and imagining that they would be more successful if they had it rather than facing their failures with detox or methadone."

“One person I know has asked doctor but can't get it. ... Available on the internet from America - Suboxone definitely not just Subutex.”

“I hear loads asking to go on it. They don't know the right way of going about it.”

“A few people want it but have been told that they are unsuitable and are reluctant to accept this.”

“Not something that I would really know.”

“Some people wouldn't want it because there's a blocker in it.”

20. ANY ADDITIONAL COMMENTS OR SUGGESTIONS ABOUT THE FUTURE USE OF SUBOXONE IN IRELAND?

“If I was able to give it up anyone can. If you want to come off heroin, there is no better thing to take, for me it's a magic tablet and it does work, anyone that wants to will get off heroin 120%, your life just comes back, it's unbelievable, how sharp your brain gets. It's incredible, you're just back to yourself. Absolutely amazing.”

“Yes, take everyone off the other stuff and put them on it. up to me when I decide to stop. Compared to what I see from long term methadone users, Suboxone seems to be better.”

“I'd recommend them to anybody, I think they're much better than Phy, you can get stoned on Phy but you can't get stoned on these, you can smoke heroin on the Phy but you can't on these. Don't get anything out of it, it's not worth the money, smoking the gear, with Phy you still get a better whack than if you're taking Suboxone.”

“I just think it's the best thing that's ever happened to me and if there's people out there who are determined to stop using they should be put on this drug, it's just changed my life for the better. I couldn't get out of bed for depression - now I'm nearly 25 weeks clean! It's an amazing drug. And the good thing is I know I can't smoke when I am on it because of the negative. I was on methadone for 3 years and was still using and using, it didn't work. It kills all the cravings - it's great. I have to praise it that much because it's changed my life and the lives of my family and children - I am there for them now.”

“I genuinely am a supporter of it. I would imagine, it's not my scene but I would imagine it's probably safer than methadone. I think the drowsiness of methadone is almost self-perpetuating, people like to add to it, maybe they're people that want to do that anyway, but Suboxone doesn't even enter into that territory of topping up. So in that sense I think it's safer, easier on the system. Not governing your perceptions to the same extent.”

“To be honest, I'm nearly 36, I was using heroin for 9 years, I'd taken methadone on the street, but it didn't work. You just really feel normal. I'd really recommend it; I think it's absolutely brilliant. I hope I'm still saying that when I come off it. I had used heroin about 14 hours before but I went straight into withdrawal. It was worth it though because I never thought I'd see the day that I'd be like this again. I just hope it does come in for other people to get a chance to do it because we were very lucky to get it.”

“Need to try to make people more aware of it, and if they could do anything about making it so you don't have to have a day of sickness then a lot of other people would try it I think.”

“Just that it's a really difficult thing to do in the first few days. The withdrawal is so severe that if people knew about it then it might put them off using it, but then again everyone's different, but it's probably something that people need to know. Nobody knew much about Suboxone - I got one wee sheet with some basic information on it. And sometimes the info was mixed e.g. the doc said wait 12 hrs before taking, but the sheet said to wait longer.”

“Yes, it needs to be made widely available in now. It’s a joke that if it snows and I can’t get to Dublin, I can’t get it anywhere else. [My clinic] is brilliant, nobody ever looked at me like a scumbag, if it happened once, I’d never have gone back, but they are amazing, but there needs to be places other than there that stock Suboxone. How long does it need to be on trial? Surely it’s proven far better than methadone? There is a ridiculous amount of school goers on heroin and Suboxone is the ideal thing to treat them with. It’s not the next step to being a bum like methadone is. You could nip them in the bud without introducing a different buzz that methadone would give.”

“I think if you get Suboxone you still have to really want to be clean, it doesn't hypnotise you or anything. But I think they should get rid of methadone - nobody ever really gets clean using methadone.”

“I think a lot more people should be on Suboxone and not methadone.”

“I just wish it was more available. I was lucky to get on the pilot as I could never have afforded it myself. The follow up you get is great, seeing the consultant regularly and being treated like a person, not like dirt. The whole thing is really very good and I cannot rate it highly enough.”

“I just think it should be more widely available. The quality of life on Suboxone compared to methadone, well there's really no comparison.”

“I think it is very good.”

“I'd like to talk to you again once I had tried to come off it completely. It is a good drug in the sense that you don't get withdrawal and if it works for people but they had trouble coming off it completely then I guess they could just stay on it. But I guess they maybe don't know what the long term effects of that would be. It's always a worry and is a concern for me with it being a new drug.”

“A lot of people want to get on it and were told they couldn't get it. I think it’s brilliant. They should put that on and take the methadone off because people are just stuck in limbo with the methadone, but at least with the Suboxone they know that in a couple of months or in a year, their life is back to normal. With the methadone, it’s just another top up drug.”

“It was excellent. My doctor was brilliant - there for me any time I needed help. I'd hope that Suboxone was allowed to be used in Ireland, I mean I don't know, am I just one of the lucky ones? It was just excellent from day one right through to the end, and I came off it with no problems at all.”

“Personally it has been a God send. For three years I was hopelessly addicted to Nurofen Plus. I should be dead by now, however because of Suboxone I am still alive. From my own experience it should be made on a large scale basis for opiate addicts. It helped me so why not others. I am aware that there is over 12,000 people in the greater Dublin area addicted to opiate medication. A lot of these addicts will never admit that they are addicts as they are legally available over the counter (Nurofen Plus/Solpadeine). Suboxone can only help if local G.P.'s responsibly can prescribe it to these people.”

“I think it should be more widely available. I mean I know there is a cost issue, but it's just a much cleaner drug than methadone, the withdrawals are definitely not as bad. It takes ages for methadone to come out of your system. When I went on Suboxone I had to be clean of methadone, but after 10 days there was still methadone in my system which caused sort of a delayed withdrawal. So yeah, I think Suboxone should be made more available.”

“I think it should become more available.”

“I just think more addicts need to be made aware of it, it's like this wonder drug, and is definitely a lot better than methadone. In my experience, if I didn't get those side effects I would still be on it.”

“They need to get it more highlighted.”

"I think everyone in Ireland should be on it and should be told about it. It is a way out better than methadone. You never want to take any other drugs as you get nothing out of them. I am a fighter - I know if I slipped I would go and see the doctor that day, because I want my life back. The brown methadone makes your teeth fall out, the green stuff makes your jaw slack, but Suboxone makes you feel great."

"Just that I think that it's brilliant. There's more benefits than on methadone. Personally I think I have been on it too long a time, but that was my choice. If I was to do it again I'd go on it for a short time and then detox off it."

"There should be more people on it. Methadone should be wiped out. Suboxone is a much safer drug than methadone. [told story about friend who had died taking methadone]"

"I can only speak for meself. Suboxone compared to methadone, when you take methadone, it doesn't, kind of pacify your mind; you're constantly still thinking of drugs, you take methadone because there's nothing else. Suboxone you don't even think about heroin. You build up, and you get better over time, which is something that I never got with the methadone."

"It should be used more than methadone. I don't think people realise about it. There are people that want to change but doctors aren't giving people much of an option. They should be giving all the options and letting the patient choose what they want."

"Early intervention with Suboxone rather than later methadone prescription when addiction is more advanced would probably be more successful than the current system, when possible."

"I think Suboxone is a very good form of treatment if taken correctly and more strict supervision whilst taken the tablet. Just didn't suit me so didn't complete the course."

"It's a good medication if the individual is keen to get clean from addiction."