The NTA’s 2006 National Prescribing Audit
An assessment of prescribing practices for opioid substitution treatment in England, 2004–05

National Treatment Agency for Substance Misuse

April 2007
The National Treatment Agency for Substance Misuse

The National Treatment Agency for Substance Misuse (NTA) is a special health authority within the NHS, established by Government in 2001, to improve the availability, capacity and effectiveness of treatment for drug misuse in England.

Treatment can reduce the harm caused by drug misuse to individuals’ well-being, to public health and to community safety. The Home Office estimates that there are approximately 250,000–300,000 problematic drug misusers in England who require treatment.

The overall purpose of the NTA is to:

- Double the number of people in effective, well-managed treatment between 1998 and 2008
- Increase the percentage of those successfully completing or appropriately continuing treatment year-on-year.

Reader information

**Document purpose**

This audit aims to produce a systematic analysis of prescribing for management of illicit drug use in a treatment context and to examine implementation of clinical guidelines. It will also inform the NTA and Healthcare Commission improvement reviews.

**Title**


**Lead authors**

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**Publication date**

April 2007.

**Target audience**

Primarily providers and commissioners of drug treatment services in England.

**Circulation list**

Managers and commissioners of treatment services, co-ordinators and chairs of local partnerships (e.g. drug action teams and crime and disorder reduction partnerships), service user and carer groups. Commissioners of pharmaceutical enhanced services, local pharmaceutical committees, regional government department leads on drugs, central government department leads on drugs.

**Description**

An England-wide survey of prescribing for the management of illicit drug use in a treatment context.

**Cross reference**


**Timing**

Ongoing.

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**Gateway/ROCR approval**

The NTA is a self-regulating agency in relation to Department of Health Gateway.
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1 Executive summary

The Department of Health (DH) Clinical Guidelines in Drug Misuse and Dependence: Guidelines for Clinical Management (1999), referred to as the Clinical Guidelines, and Models of Care (NTA, 2006) provide the basis for drug treatment based on evidence for effectiveness and provide guidance on prescribing to drug users. These documents have provided a framework for the development of local treatment systems in partnership areas to meet the requirements of the Drugs Strategy. As part of the review of this process, the National Treatment Agency (NTA) and the Healthcare Commission (HCC) identified community prescribing as one of two areas for the 2005/06 Improvement Reviews of drug treatment. This report has been commissioned to inform this improvement review by auditing the prescribing practices undertaken in community services in England.

The absence of a single, central database meant that the method selected for the audit combined secondary analysis of DH data on prescriptions with a national survey of specialist community treatment services in England, supplemented by an exploratory analysis of a primary care database to assess activity in this area. The primary source of data is the national survey, initially piloted on 23 services within 15 partnership areas and then circulated to 373 specialist drug services.

1.1 Findings

1.1.1 National survey

The questionnaire was completed and returned by 242 specialist community drug prescribing services, providing a response rate of 66 per cent nationally (though this varied across the nine Government regions from 52 per cent in the South East to 80 per cent in the West Midlands).

The services that responded had an average caseload of 213, of which 158 on average were prescribed drugs as part of their treatment (74.2 per cent). Participating services prescribed methadone to an average of 133 clients, two-thirds of whom were receiving maintenance prescriptions averaging a daily methadone maintenance dose of 56.7mg. There was much less regional variation here, with the highest regional mean methadone maintenance dose of 59mg and the lowest of 52mg. The vast majority of methadone prescriptions (96.9 per cent) were in oral formulation, with 1.6 per cent of methadone maintenance clients being prescribed methadone ampoules and 1.7 per cent methadone tablets. Although nearly all services (92.5 per cent) had some methadone clients supervised in the first 12 weeks of treatment (as recommended by the Clinical Guidelines), 13.4 per cent of participating specialist services had between none and 20 per cent of clients supervised in this period. Supervised consumption, for both methadone and buprenorphine, was much less common after the initial 12-week period. Of those clients receiving methadone on a reduction basis, just under a quarter had been receiving their prescription for more than one year.

A slightly lower proportion of services participating in the survey prescribed buprenorphine (88 per cent) to some of their clients than prescribed methadone (95.5 per cent). Of those services involved in buprenorphine prescribing, 88.4 per cent of clients received maintenance prescriptions with a mean dose of 3.9mg. In total, 28.8 per cent of services did not have any clients receiving buprenorphine on supervised consumption, while 41 per cent of services had all of their buprenorphine clients receiving their prescriptions under supervision. The majority of services involved in the survey (71.7 per cent) also reported that at least some clients received benzodiazepine prescriptions, with diazepam most commonly prescribed at a mean dose of 22.5mg. However, a wide range of benzodiazepines were prescribed, including both temazepam and nitrazepam.

Participating services generally reported widespread use of written policies and protocols, with 90 per cent having written adverse incident policies, 92.5 per cent having written prescribing policies and 99 per cent having written complaint procedures. However, written policies on prescribing reviews were less frequent (82 per cent) as were formularies.

1.1.2 National prescribing practices

Prescription cost analysis (PCA) data was used to assess national level changes in total prescribing in England over a ten-year window for methadone and over a three-year window for buprenorphine (reflecting its recent availability). The total number of methadone prescriptions has increased from 970,900 in 1995 to 1,810,500 in 2004 (an increase of 86.5 per cent), with an increased use of methadone specifically for the treatment of substance dependence (from 81.1 per cent in 1995 to 95.1 per cent in 2004). Similarly, in the same period, the proportion of methadone prescribed in oral liquid form has increased from 81.5 per cent in 1995 to 95.2 per cent in 2004. The recent availability of buprenorphine has not resulted in reductions in methadone prescribing, with a combined analysis indicating that, nationally, the number of prescriptions for buprenorphine or methadone has increased from 46.5 prescriptions per 1,000 members of the population in 2001 to 78.9 prescriptions per 1,000 people in 2004.
1.2 Overview and conclusions

The overall finding is one of increased treatment coverage for substitute prescribing with a virtual doubling of methadone prescribing in the last ten years, supplemented by the increased availability of buprenorphine in the last three years of available data, resulting in improved clinician and patient choice. The national survey provided evidence of a mean dose only slightly below the window suggested in the Clinical Guidelines, although there were marked variations in dosing at service level. Greater concerns about under-dosing arise in relation to the mean buprenorphine maintenance dose of 8.9mg, and around the inconsistencies in supervision arrangements and the prescription of benzodiazepines to opiate addicts. Limitations in research evidence may partially explain some of this local variability, but the weaknesses in data availability suggest that much further work is needed both locally and nationally to address some of the key issues identified and that more robust data collecting systems are needed to support this process.

2 Introduction

The “British system” (Strang and Gossop, 2005) for the management of drug problems has a unique history dominated by the autonomy of clinicians and the centrality of their prescribing practices. In recent years this autonomy has been eroded by a number of legislative changes and policy initiatives, culminating in a national strategy that emphasises clinical consistency in this area. The current report has utilised a range of data sources and research strategies to assess consistency in substitute prescribing across England. Nonetheless, it is worth a brief consideration of the policy framework in which the audit is set and against which the results must be judged.

The policy basis for prescribing and dispensing substitute opioids is dominated by the Department of Health’s Clinical Guidelines (DH, 1999), supplemented by the proxy national service framework for drug misuse – Models of Care (NTA, 2006). The Clinical Guidelines and Models of Care both provide the basis for treatment based on evidence for effectiveness.

The guidelines summarise what is known about “what works” in substitute prescribing, focusing on two main domains – evidence of impact on adverse health and social outcomes, and around prescribing that is safe for both the individual drug user and the community. These clinical guidelines outline a number of overall aims for prescribing substitutes. They are to:

- Assist the patient to remain healthy until they can achieve a drug-free life
- Reduce the use of illicit or non-prescribed drugs by the individual
- Deal with problems related to drug misuse
- Reduce the dangers associated with drug misuse, particularly the risk of HIV, hepatitis B and C and other blood-borne infections acquired from injecting and sharing injecting paraphernalia.

This is based on a significant evidence base asserting the benefits of methadone and, more recently, buprenorphine (NTA, 2004). Nonetheless, there has been limited research attention paid to substitute prescribing levels and practices at a national level, with much of the evidence deriving from two postal surveys of community pharmacies (conducted in 1995 and 1997) reported by Strang and Sheridan (2001). The more recent of the surveys showed that the mean NHS dose of methadone prescribed was 47.2mg with 86.2 per cent of these prescriptions dispensed in the form of oral mixture. There was a marked variation by formulation – oral doses tended to be much lower with 71.2 per cent of all prescriptions for a daily dose of 50mg or under, while this was the case for 58.4 per cent of methadone tablets dispensed and 52.6 per cent of the methadone ampoules dispensed. The mean dose had risen between 1995 and 1997. These surveys did not
differentiate between methadone maintenance and methadone reduction regimes – which may provide a lower overall methadone dose and makes comparison with this report problematic. Nevertheless, the Strang and Sheridan findings remain below the recommended levels for methadone maintenance (of 60–120mg) set out in Models of Care and in the Clinical Guidelines.

In a more recent analysis of this dataset for the NTA, Strang and Hunt (2007) reported that the mean methadone daily dose was 36.9mg in primary care settings, based on data collected in 2001. Again, this varied by formulation with lowest doses being prescribed in oral form (the mean being 36.5mg), compared to 41.3mg for methadone tablets and 44.6mg for ampoules. However, the mean doses reported tend to be higher in specialist treatment services. Dunn, (2003) reported on a survey of 169 patients on long-term methadone in one specialist drug service and found that the mean dose of methadone for maintenance was 65.8mg – consisting of mean doses of mixture 57.4mg, tablets 81.5mg and ampoules 113mg. The author also reported that “the proportion of urines positive for non-prescribed opiates was inversely correlated with methadone dose”.

National Drug Treatment Monitoring System (NDTMS) figures provide a general picture of overall prescribing patterns and report a continued year-on-year increase in numbers of individuals in contact with drug treatment services. In 2000/01, 118,500 individuals were receiving structured drug treatment, rising by 28 per cent to 128,200 in 2001–02, continuing to increase to 140,900 in 2002–03 (a 41 per cent increase). The figures for 2003–04 were 154,0001 (a 54 per cent increase from the previous year). The majority of these individuals reported heroin as the main drug of misuse and, in 2003–04, over half (63 per cent)2 were recorded as receiving prescribing treatment, either through GP prescribing (nine per cent) or specialist prescribing (54 per cent).

With regard to the growth of buprenorphine prescribing, De Wet et al., (2005) described disproportionate increases in the prescription of buprenorphine between 2001 and 2003 using the PACT/PCA data source described, with the authors reporting an increase in buprenorphine prescribing to 23 per cent of all opiate prescriptions by 2003.

Although outcome studies have demonstrated important benefits for substitute therapies in the UK and overseas, the literature on national prescribing patterns is more limited. Strang and Sheridan, (2003a, 2003b) examined methadone prescription patterns between 1980 and 2002 to track injectable prescriptions as a proportion of all methadone prescriptions distributed in this period. They reported that in 1980, one-third of all prescriptions were injectable, but by 2002 this had dropped to just five per cent of all the methadone prescribed for any reason. They also reported that the proportion of methadone tablet and ampoule prescriptions remained fairly stable in the period between 1990 and 1995, but began to decrease in 1996 and this decrease could be evidenced year-on-year until 2001.

Despite recommendations from the Clinical Guidelines and in Models of Care that methadone prescribing should be predominantly in an oral formulation, with some room for prescribing ampoules in exceptional cases, research findings show that there is significant prescribing of both tablets and ampoules. However, recent studies would suggest that the proportion of tablets and ampoules dispensed is decreasing.

Telfer and Barnard (2001)2 attempted to assess how well treatment services measured up to the standards set in the Clinical Guidelines. They conducted a survey of 178 specialist treatment agencies, eliciting 99 responses, and found that 63.6 per cent of services (63 services) had supervised consumption on-site. Twenty-three per cent of responding services started all clients on supervised consumption and 17 had supervised consumption for the first three months (but not necessarily to all clients).

There is markedly less evidence about the effectiveness of buprenorphine prescribing in the UK. In the US, Ling et al., (1998) reported that a study cohort prescribed 16mg had better treatment retention and less heroin use than lower dose groups in the study. Similarly, Montoya et al., (2004) found that a group prescribed 16mg daily of buprenorphine showed greater reductions in heroin and cocaine use than those prescribed 8mg of buprenorphine. In the GP survey conducted by Strang and Hunt (2007), the mean dose of buprenorphine was 5.8mg (with a range of 0.4mg to 16mg). However, there is less evidence available on dispensing and prescribing regimes for buprenorphine from the UK. This has been addressed to some extent by a review of buprenorphine and methadone by the National Institute for Health and Clinical Excellence (NICE), which was published early in 2007.4

2.1 The purpose of the audit
The data outlined here represents part of a joint review of prescribing currently being undertaken between the Healthcare Commission (HCC) and the NTA. Community prescribing is one of two initial themes for improvement reviews undertaken as part of the ongoing standards and inspection programme of work jointly managed by the HCC and the NTA.

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1 This figure is an estimate from a bridging exercise, as NDTMS recorded 125,545 individuals in contact with structured treatment, but this figure is not comparable with previous national figures produced by NDTMS because of differences in data collection and analysis methodologies.

2 All subsequent NDTMS figures quoted refer to number of episodes as opposed to number of people.


HCC improvement reviews are in line with the Department of Health Standards for Better Health, (2004). The focus of the current work is to look at drug treatment systems with respect to care planning and prescribing. The aim of the work is to produce an “independent assessment of the quality of the drug treatment services in each drug action team area and to use the system to facilitate improvements in key aspects of these services”.

The overall aim of this report is to produce a systematic analysis of all prescribing directly related to the management of illicit drug use in a treatment context. This will contribute to the joint work with the HCC and will also inform the development of clinical guidance and policy within the NTA.

2.2 Design and questionnaire development

A draft questionnaire was developed and then circulated to key informants within the NTA and discussed in workshops with participating drug action teams (DATs). There was a rigorous pilot process. The draft version of the questionnaire was circulated to 15 DATs who forwarded it to services in their area.

The questionnaire was point prevalence – in other words, each service was asked to provide a snapshot of prescribing practice on the day of survey completion. Twenty-three questionnaires were completed and returned between 10 October and 7 December 2004.

3 Results of the national survey

The results section reports on substitute prescribing levels and practices at a national level, building on (and including) the pilot work described previously. It provides information on Tier 3 prescribing services, firstly addressing issues of methadone supervision, dispensing and dose levels and then repeats this for buprenorphine prescribing practices. The next analysis examines benzodiazepine prescribing in combination with methadone and buprenorphine. Additional information on shared care, service procedures and the prescription of other drugs is also presented before the results are discussed and implications derived.

Analysis of the pilot data provided information that was used to make a number of amendments to the questionnaire, identifying questions services felt were ambiguous and needed clarification and adding extra questions to gain more information. The questionnaire was a point prevalence one – each service was asked to provide a snapshot of their prescribing practice on the day of survey completion. The study received ethical approval both from the Review of Central Returns Steering Committee (ROCR) and Gateway (14 January 2005, ROCR/04/029).

3.1 Procedure

Two waves of questionnaires were sent out to a named service manager in each service. The first wave was mailed on 25 March 2005. The services were given the option of completing either the paper copy of the questionnaire mailed to them or an online version. A second wave of questionnaires was mailed out to all non-responding services on 10 May 2005. Again, the services that had not returned their questionnaires were telephoned to encourage them to complete them. Additionally, NTA regional managers were also asked to contact non-responding services in their area to encourage them to participate.

Of the 447 services originally identified in the database, 74 did not fulfil the criteria of being both Tier 3 and prescribing services. Therefore, out of 373 services, questionnaires were returned by 242 services, giving an overall response rate of 66 per cent.

A total of 242 (66 per cent) specialist drug treatment prescribing services in England returned completed questionnaires from a possible sample of 365 specialist drug services identified from a range of sources. They were able to provide information on 51,482 clients and, of these, 38,335 clients in 236 Tier 3 services were prescribed opioid substitution drugs as part of their drug treatment package.

5 The 15 DATS involved volunteered as part of the standards and inspection process.
6 Thirty-two services did not provide information on the total number of clients in treatment, therefore the total number of clients in treatment reported here includes the average number of clients in treatment (213) as a default for these 32 services.
7 Thirty-nine services did not provide information on the total number of clients prescribed drugs, therefore the total number of clients in treatment reported here includes the average number of clients prescribed drugs (158) as a default for these 39 services.
In all, 231 services prescribed methadone to 30,901 clients, (80.6 per cent of all clients in the sample who were receiving substitute opioids). In the study sample, 23,087 clients (74.7 per cent) on a methadone prescription were prescribed methadone on a maintenance basis and 7,148 (23.1 per cent) on a reduction basis9,10 (basis not known for the remaining 2.2 per cent).

Slightly fewer services (213, 88 per cent of the services in the study) prescribed buprenorphine either instead of, or as well as, methadone and on average to fewer clients per service. A total of 6,692 clients11 were currently being prescribed buprenorphine, 3,995 (59.7 per cent) on a maintenance basis and 2,594 (38.8 per cent) on a reduction basis from the services who completed the survey.

3.2 Service information

Questionnaires were received from a variety of types of drug service, the majority being statutory drugs services, which accounted for 71.7 per cent of all questionnaires returned. Non-statutory drugs services represented just 12.4 per cent of responses, and 8.6 per cent from criminal justice agencies. Other services (7.3 per cent) included young persons’ services and homeless services.

<table>
<thead>
<tr>
<th>Region</th>
<th>Number of questionnaires distributed</th>
<th>Number of questionnaires returned</th>
<th>% questionnaires returned</th>
</tr>
</thead>
<tbody>
<tr>
<td>East Midlands</td>
<td>22</td>
<td>13</td>
<td>59</td>
</tr>
<tr>
<td>East of England</td>
<td>37</td>
<td>24</td>
<td>65</td>
</tr>
<tr>
<td>London</td>
<td>59</td>
<td>43</td>
<td>73</td>
</tr>
<tr>
<td>North East</td>
<td>27</td>
<td>19</td>
<td>70</td>
</tr>
<tr>
<td>North West</td>
<td>43</td>
<td>26</td>
<td>60</td>
</tr>
<tr>
<td>South East</td>
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<td>25</td>
<td>52</td>
</tr>
<tr>
<td>South West</td>
<td>37</td>
<td>23</td>
<td>62</td>
</tr>
<tr>
<td>West Midlands</td>
<td>49</td>
<td>39</td>
<td>80</td>
</tr>
<tr>
<td>Yorkshire and Humber</td>
<td>43</td>
<td>27</td>
<td>63</td>
</tr>
<tr>
<td>Unknown</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>365</td>
<td>242</td>
<td>66</td>
</tr>
</tbody>
</table>

Table 1: Number of questionnaires distributed to services by region and the response rate by region13

The response rate by region varied as shown in Table 1. The West Midlands had the highest response rate, returning 80 per cent of questionnaires distributed, and the lowest was the South East region, returning 52 per cent of the questionnaires distributed.

The size of participating treatment services varied with the total number of clients in treatment on the day of the survey ranging from zero to 2,331 with a mean of 213. The number of clients prescribed drugs as part of drug treatment also varied markedly, ranging from zero to 2,228 with a mean of 158 clients prescribed substitutes in each service. The majority of services (n=217, 98.2 per cent) did not have any private clients. Of the four services that did prescribe substitutes to private clients as part of opiate drug treatment, the proportion of private clients ranged from 17 to 100 per cent.

3.3 Methadone

The total number of clients prescribed methadone in each service ranged from one through to 1,829, with a mean of 133. Similarly, the proportion of clients within each service on maintenance versus reduction also varied. On average 66.2 per cent were on a maintenance prescription and 30.9 per cent on a reduction.

However at the extremes, 32 services (14.5 per cent of methadone-prescribing services) had all clients on a maintenance prescription while 23 services (10.4 per cent) had all clients on a reduction prescription.

This is supported by the Clinical Guidelines (DH, 1999). Maintenance prescribing – dosing regime for methadone maintenance, states on page 54:

“There is a consistent finding of greater benefit from maintaining individuals on a daily dose between 60mg and 120mg”

8 Two services did not provide information on the number of clients prescribed methadone, therefore the total number of clients prescribed methadone reported here includes the average number of clients (229) prescribed methadone as a default for these two services.

9 Ten services did not provide information on number of clients on maintenance and therefore there was no information on reduction for 11 services. Default values (average number of clients for maintenance and reduction) were used.

10 This analysis assumes that, for each service, any clients not on methadone maintenance were prescribed methadone on a reduction basis and likewise for buprenorphine.

11 Two services did not provide this information, therefore the total number reported here includes the average number of clients prescribed buprenorphine as a default for these two services.

12 Fourteen services did not provide information on numbers on maintenance (and therefore reduction). Default values (average number of clients for maintenance and reduction) were used.

13 Based on all services sent a questionnaire.
3.3.1 Methadone maintenance dosage

Overall, services tended to prescribe variable methadone maintenance doses on average below the Clinical Guidelines recommended levels for maintenance. The mean methadone maintenance dose (regardless of formulation) was 56.7mg, but ranged from 6.5mg through to 127mg. As Table 2 shows, the majority of services (59.9 per cent) had an average dose that was less than 60mg.

Average daily methadone maintenance dose differed by region (Table 3). London had the highest dose at 59mg and South West the lowest (52mg).

Examining the spread of all methadone maintenance doses prescribed in each service, on average services prescribed maintenance doses of under 30mg to 15.5 per cent of clients, while 48.1 per cent of prescriptions were for 31 to 60mg, 27.9 per cent for 61 to 90mg, 6.6 per cent for 91 to 120mg and only 1.9 per cent for doses greater than 121mg (as shown in Figure 1).

The maximum methadone maintenance dose ranged from 15mg to 340mg with an average of 123.8mg. Just under a third (30.6 per cent) of services had a maximum methadone maintenance dose of 90mg or less, 29.6 per cent 91 to 120mg, 21.3 per cent 121 to 150mg and 18.8 per cent had a maximum dose of more than 150mg.

3.3.2 Formulations and dose

Oral mixture was by far the most frequent methadone formulation prescribed for all types of regimes, not just for maintenance. The mean number of clients per service receiving oral mixture was 128, compared to three prescribed ampoules and two prescribed tablets. Of all methadone prescribed, 96.6 per cent was oral, 1.6 per cent in the form of ampoules and 1.7 per cent prescribed as tablets.

The average dose varied according to formulation. Methadone prescribed in ampoules had the highest mean dose of 76.6mg (and varied the most, with the minimum reported average dose of 1.5mg and the maximum average dose of 250mg) while the mean dose of oral mixture was lower at 53.1mg (minimum dose of 15mg, maximum 97.5mg) and the mean dosage of tablets was the lowest at 51.6mg (minimum 9mg and maximum 100mg).

3.3.3 Methadone dispensing

Services reported that the majority of clients (63.7 per cent) had their methadone dispensed daily or nearly daily (defined as five to seven days).
seven days a week). Only 2.3 per cent had methadone dispensed less than once a week. The percentage of clients picking up methadone three to four days a week amounted to 11.6 per cent, and 22.3 per cent once or twice a week. However, within this there were variations between services. Thirty-two services (15.7 per cent) had all their clients on daily dispensing while one service had all clients picking up their methadone less than once a week and a further 54 services (26 per cent) had some clients who fell into this latter category.

3.3.4 Supervised consumption
A key finding was a bimodal distribution of supervised methadone consumption. Services tended to have their clients either on daily supervised consumption or receiving no supervision, with this pattern more marked in the first 12 weeks of prescribing than after this period.

Nearly all services (92.5 per cent) had some clients receiving supervised consumption, regardless of length of time on a prescription. However, not all of these services had all clients supervised for the whole of the first 12 weeks of prescribing, as recommended by the Clinical Guidelines. Just over half (55.9 per cent) of responding services had all their clients on daily supervision during this initial period, which is also recommended.

Key recommendations on the responsibilities and principles of prescribing for drug dependence states on page 27:

“It is good practice for all new (methadone) prescriptions to be taken initially under daily supervision for a minimum of three months”

As Table 4 illustrates, there was great variability in the percentage of clients in each service receiving daily supervised methadone consumption during the first 12 weeks. Just 13.4 per cent of services had less than 20 per cent of their clients supervised daily, and 4.9 per cent of services had 21 to 40 per cent of clients daily supervised. At the other end of the scale, 4.9 per cent of services had 81 to 100 per cent of clients daily supervised, and the majority of services (73.2 per cent) had more than 80 per cent of clients daily supervised, suggesting widespread commitment to supervised consumption in the first 12 weeks.

Just over a quarter of services (26.4 per cent) had some clients who were not supervised at all, and a minority of services (7.1 per cent) did not have any clients on supervised methadone consumption.

The percentage of clients with no supervision varied greatly by service – 80.6 per cent of services had less than a fifth of their methadone clients without any supervised consumption, 22 per cent of services had 21 to 40 per cent of clients not supervised, 7.4 per cent had 40 to 80 per cent not supervised and 10.1 per cent of services had 81 to 100 per cent of their clients without supervision.

<table>
<thead>
<tr>
<th>In first 12 weeks</th>
<th>After 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of services</td>
<td>% of services</td>
</tr>
<tr>
<td>0–20%</td>
<td>19</td>
</tr>
<tr>
<td>21–40%</td>
<td>7</td>
</tr>
<tr>
<td>41–60%</td>
<td>5</td>
</tr>
<tr>
<td>61–80%</td>
<td>7</td>
</tr>
<tr>
<td>81–100%</td>
<td>104</td>
</tr>
<tr>
<td>Total</td>
<td>142(^{17})</td>
</tr>
</tbody>
</table>

There was some variation in supervised consumption practices reported across regions (Table 5). The South West had the highest proportion of clients supervised daily (97.9 per cent), and the North West the lowest (55 per cent).

Supervised consumption after the first 12 weeks of prescribing was less frequent. Around one-fifth (19.8 per cent) of services had all of their clients supervised, while one in ten services (10.7 per cent) did not have any of their clients supervised during this period. Overall, after the first 12 weeks of prescribing, 53.5 per cent of clients were supervised daily, and 37.2 per cent of clients did not receive any supervision. Again, there was a similar supervision pattern to the one seen in the first 12 weeks of prescribing, with supervision tending to fall into either one or the other extreme categories, either daily supervision or no supervision, with only 4.4 per cent of clients supervised three to four days a week, 2.4 per cent one to two days a week and 0.3 per cent less than once a week.

3.4 Buprenorphine
Buprenorphine was less likely to be prescribed than methadone. There were 213 services (88 per cent of services participating in the survey) prescribing buprenorphine on the day of survey completion, compared to 231 services that were prescribing methadone.

The total number of clients prescribed buprenorphine in each service ranged from one to 299, with a mean of 31.4. On average, 25.9 per cent of all clients prescribed opioid substitutes

\(^{16}\) Based on all services prescribing methadone.

\(^{17}\) A low number of services are reported here because of a low response rate for this question – this table excludes those services that only partially answered the question.

\(^{18}\) As above.
in participating services received a buprenorphine prescription, but this varied by service. Five services (2.8 per cent) only prescribed buprenorphine and no methadone and 14 services (7.8 per cent) predominantly prescribed buprenorphine (where more than 50 per cent of clients were on a buprenorphine prescription).

3.4.1 Maintenance and reduction

The majority of buprenorphine clients (68.4 per cent) were on maintenance prescriptions with 31.5 per cent on reduction prescriptions. Forty services (25.6 per cent) had all buprenorphine clients on maintenance prescriptions, but there were no services that had 100 per cent of clients on a reduction prescription of buprenorphine.

3.4.2 Dose

The average mean daily buprenorphine maintenance dose was 8.9mg, and ranged from 1.4mg to 24mg. The maximum daily buprenorphine maintenance dose was on average 16.3mg, and again this varied by service. The lowest maximum dose reported was 2mg, and the highest 32mg. Low dose prescribing of buprenorphine appears to be widespread with the mean daily dose of 8.9mg well below the suggested typical therapeutic buprenorphine dose of 16mg recommended in the Clinical Guidelines. Advice from the Royal College of General Practitioners (RCGP) in Guidance for the Use of Buprenorphine for the Treatment of Opioid Dependence in Primary Care suggests that abstinence is most likely to be achieved if buprenorphine dose is between 12 to 24mg daily. This is also supported in the Clinical Guidelines. Treatment of the withdrawal syndrome with substitute opiates, states on page 38:

“In well controlled studies, it [8mg] has been reported to be equivalent to 30mg of methadone”

3.4.3 Supervised consumption

Supervision of consumption of buprenorphine was patchy, possibly reflecting the fact that the Clinical Guidelines were published before the launch of Subutex® in 2000, which prompted increased use of buprenorphine within this patient group. Although more frequent in the first 12 weeks of prescribing than after the first 12 weeks, only a minority of services (41 per cent) had all of their buprenorphine clients on daily supervised consumption in the first 12 weeks, while 28.8 per cent of services did not have any buprenorphine clients on supervised consumption in the same period.

A bimodal distribution of supervised consumption was more pronounced for buprenorphine prescribing than for methadone. On average, only 58 per cent of clients on a buprenorphine prescription received daily supervised consumption in the first 12 weeks, while 36.2 per cent did not receive any. Just 3.2 per cent of clients were supervised three to four days a week, 0.5 per cent one to two days a week and 0.2 per cent less than one day a week.

Not surprisingly, like methadone, supervision rates dropped off after the first 12 weeks, with only 31.8 per cent of buprenorphine clients remaining supervised daily, while just over half did not receive any supervision (53.5 per cent). Of the remaining buprenorphine clients, 3.8 per cent were supervised three to four days a week, five per cent two to three days a week and 0.5 per cent less than one day a week.

Fourteen services (12.2 per cent) kept all of their buprenorphine clients on daily supervision, and the proportion of services that had all clients without any supervision increased from 28.7 per cent in the first 12 weeks to 40.2 per cent after 12 weeks in substitute treatment.

3.4.4 Regional variations

There were regional variations in the percentage of clients in each service receiving daily supervised buprenorphine consumption in the first 12 weeks (Table 6). The South West, the South East and Yorkshire and Humber all had at least half of their services (71.4 per cent, 64.7 per cent and 50 per cent, respectively) supervising 81 to 100 per cent of their buprenorphine clients daily (Table 7). At the other end of the scale, the majority of services in both the North East and the North West (81.8 per cent and 66.7 per cent, respectively) had less than a fifth of their clients supervised daily over the same period.

<table>
<thead>
<tr>
<th>Region</th>
<th>% of clients with daily supervision of methadone for the whole of the first 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>East Midlands</td>
<td>86.7</td>
</tr>
<tr>
<td>East of England</td>
<td>76.1</td>
</tr>
<tr>
<td>London</td>
<td>71.9</td>
</tr>
<tr>
<td>North East</td>
<td>82.6</td>
</tr>
<tr>
<td>North West</td>
<td>55.0</td>
</tr>
<tr>
<td>South East</td>
<td>82.6</td>
</tr>
<tr>
<td>South West</td>
<td>97.9</td>
</tr>
<tr>
<td>West Midlands</td>
<td>76.8</td>
</tr>
<tr>
<td>Yorkshire and Humber</td>
<td>86.6</td>
</tr>
</tbody>
</table>

Table 5: Percentage of methadone clients in each region receiving daily supervised consumption of methadone in the first 12 weeks

19 The Clinical Guidelines (DH, 1999) state that “in well controlled studies it [8mg] has been reported to be equivalent to 30mg of methadone”. It appears that there is low dose prescribing of buprenorphine as the mean daily dose of 8.9mg is well below the alleged sub-optimum dose of 16mg.
3.5 Benzodiazepines

The majority of services (71.7 per cent) also prescribed benzodiazepines to some clients. On average 10.9 per cent of clients in each service were prescribed benzodiazepines alongside either methadone or buprenorphine. Benzodiazepines were more likely to be prescribed to clients on a methadone prescription than a buprenorphine one. On average, 12.6 per cent of methadone clients per service were also prescribed at least one benzodiazepine compared to 9.3 per cent of clients on buprenorphine.

3.5.1 Benzodiazepines prescribed

Diazepam was the most commonly prescribed benzodiazepine to be prescribed alongside both methadone and buprenorphine. Diazepam was prescribed in 95.3 per cent of services (164 services) prescribing benzodiazepines to a total of 2,907 clients. The mean dose of diazepam was 22.5mg and ranged from 3.9mg to 192mg. There was no relationship between dose levels across benzodiazepines: high dose prescribing of diazepam was not associated with high dose prescribing of nitrazepam or temazepam.

Seventy-one services prescribed nitrazepam (41.3 per cent of all benzodiazepines prescribing services) to a total of 409 clients, representing on average 1.6 per cent of clients. The mean dose ranged from 3.2mg to 51mg with an average of 11.8mg.

Seventy-five services prescribed temazepam (43.6 per cent of all services prescribing benzodiazepines) to a total of 491 clients, representing on average 1.9 per cent of clients. The mean dose ranged from 10mg to 100mg with an average of 29.4mg.

Chlordiazepoxide was prescribed in 13 services to a total of 28 clients. The mean dose was 47.8mg with a range of 5mg to 200mg. Benzodiazepine misuse is common among both untreated drug-using populations (Kee et al., 1990) and existing treatment populations (Darke et al., 1995; Sunjic and Howard, 1996), and is associated with both polydrug use and overdose (Darke et al., 2005).

Thus a significant proportion of new drug users accessing treatment will arrive with problems associated with benzodiazepine use. These could occur for hedonic reasons related to multiple drug use (Perera et al., 1987), or as (self-)medication for psychiatric symptoms. The Clinical Guidelines do not offer clear direction in relation to either maintenance or reduction prescribing of benzodiazepine, indicating that “there is increasing evidence that long-term prescribing of more than 30mgs per day may cause harm. Doctors should be reluctant to initiate maintenance prescribing of substitute benzodiazepines and should gradually reduce the doses of those already on a maintenance prescription for more than 30mgs per day” (DH, 1999, p41). Similarly, the Clinical Guidelines indicate that concurrent detoxification from both drugs should not be undertaken in community settings. New guidance is expected from the DH on prescribing benzodiazepines to drug misusers shortly. In conclusion, the evidence base around benzodiazepines would suggest that there are clear grounds for concern that prolonged use may result in reduced effectiveness, as well as increased risks of multiple dependence, overdose and diversion of illicit drugs to naïve populations (Best and Ridge, 2003).

3.6 Prescribing duration

3.6.1 Length of time on methadone

Methadone prescribing was reported to be both long-term and stable. On average for each service, the majority of clients (60.2 per cent) had been on a prescription for more than six months (80 clients per service). Only a minority, approximately one in ten (10.8 per cent, 7.5 people), had been prescribed methadone for less than one month, while 13 per cent had been prescribed methadone for one to three months and 15.9 per cent for three to six months (12.7 and 21.3 clients, respectively).

Services also reported that most clients received stable doses of methadone. On average, 41.7 per cent of clients had received their current methadone dose for more than six months, 16.9 per cent had been prescribed their current dose for three to six months (12.7 and 21.3 clients, respectively).

Table 6: Percentage of clients in each service receiving daily supervised buprenorphine consumption in the first 12 weeks and after 12 weeks

<table>
<thead>
<tr>
<th>In first 12 weeks</th>
<th>After 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of services</td>
<td>% of services</td>
</tr>
<tr>
<td>0–20%</td>
<td>56</td>
</tr>
<tr>
<td>21–40%</td>
<td>2</td>
</tr>
<tr>
<td>41–60%</td>
<td>4</td>
</tr>
<tr>
<td>61–80%</td>
<td>16</td>
</tr>
<tr>
<td>81–100%</td>
<td>75</td>
</tr>
<tr>
<td>Total</td>
<td>153</td>
</tr>
</tbody>
</table>

Table 6: Percentage of clients in each service receiving daily supervised buprenorphine consumption in the first 12 weeks and after 12 weeks

20 Based on all services prescribing buprenorphine.
21 A low number of services are reported here because of a low response rate for this question – this table excludes those services that only partially answered the question.
22 As above.
3.6.2 Methadone reduction

Of all clients on a reduction prescription, services reported on average 22.5 per cent had been on a reduction prescription for more than a year, with the mean length of time on a reduction prescription of 7.6 months. This greatly varied from service to service, ranging from an average of three weeks in one service to 51 months in another.

3.6.3 Length of time on buprenorphine

Buprenorphine prescribing (maintenance and reduction) does not appear to be of equivalent duration to methadone (maintenance and reduction) prescribing. Less than half of the clients (on average 39.9 per cent) had been on a buprenorphine prescription for more than six months, with 19.5 per cent prescribed buprenorphine for three to six months, 20.5 per cent for one to three months and 20 per cent for less than one month.

Services reported more fluctuation in buprenorphine dosage than was the case for methadone. Only 24 per cent of clients, on average, have been on their current dose for more than six months, while 33.5 per cent have been on their current dose for less than one month. For one to three months this figure is 22.4 per cent and 20.1 per cent for three to six months.

3.6.4 Buprenorphine reduction

Buprenorphine reduction regimes were reported as shorter than methadone reduction regimes. The mean starting dose was 7.2mg. The mean length of time on a reduction basis was 5.4 months and services had clients on reduction ranging from two weeks to 24 months. On average, only 12.8 per cent of buprenorphine clients on a reduction prescription have been prescribed on a reduction basis for over a year.

3.6.5 Methadone and buprenorphine detoxification

Of services prescribing methadone on a reduction basis, 85.6 per cent reported that they sometimes switched clients to another drug as part of the detoxification process. However, not all clients were automatically switched. On average, one-third (33.1 per cent) of clients in each service were switched from methadone to another drug during detoxification, and this varied according to service. Four services (3.7 per cent), reported routinely switching all clients, while 12 (11 per cent) services switched less than five per cent of clients undergoing community methadone detoxification.

Methadone patients attempting to detoxify were switched to a number of other drugs, but by far the most common was buprenorphine. Of the 155 services switching from methadone to a replacement drug during detoxification, 127 (81.9 per cent) prescribed buprenorphine as a replacement drug to some clients.

Lofexidine was the next most commonly prescribed after methadone as part of a detoxification process (by 53 services, 34.2 per cent). Twenty-one services prescribed dihydrocodeine (13.5 per cent) and 12 services prescribed naltrexone (7.7 per cent) subsequent to methadone in detoxification. Other opiate replacement drugs mentioned, albeit by only a few services, included diamorphine (one service), morphine (one service) zopiclone (two services), and Zimovane® (one service).

The mean dose of methadone at which the client was switched to a different drug differed according to the drug being used as a replacement. When switching to buprenorphine, on average, the methadone dose was reduced to 26.4mg. For lofexidine this was slightly lower at 20.5mg. Of the seven services that switched to naltrexone, all but one required abstinence before antagonists were used. The sample sizes were too low to calculate mean doses for other replacement drugs.

Fewer services switched buprenorphine clients to another drug as part of the detoxification process than for methadone. Fifty-one services (46.4 per cent) prescribing buprenorphine on a reduction basis switched at least some of their clients to another drug as part of the detoxification process. Twenty-three services (45.1 per cent) followed buprenorphine prescribing with lofexidine, 21 services (41.1 per cent) switched to methadone and nine services (17.6 per cent) to naltrexone. Other drugs used by participating

<table>
<thead>
<tr>
<th></th>
<th>In first 12 weeks</th>
<th>After 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of services</td>
<td>% of services</td>
</tr>
<tr>
<td>East Midlands</td>
<td>4</td>
<td>50.0</td>
</tr>
<tr>
<td>East of England</td>
<td>6</td>
<td>40.0</td>
</tr>
<tr>
<td>London</td>
<td>13</td>
<td>48.1</td>
</tr>
<tr>
<td>North East</td>
<td>2</td>
<td>18.2</td>
</tr>
<tr>
<td>North West</td>
<td>4</td>
<td>33.3</td>
</tr>
<tr>
<td>South East</td>
<td>11</td>
<td>64.7</td>
</tr>
<tr>
<td>South West</td>
<td>10</td>
<td>71.4</td>
</tr>
<tr>
<td>West Midlands</td>
<td>12</td>
<td>46.2</td>
</tr>
<tr>
<td>Yorkshire and Humber</td>
<td>10</td>
<td>50.0</td>
</tr>
</tbody>
</table>

Table 7: Percentage of services with over 80 per cent of clients receiving daily supervised buprenorphine consumption in the first 12 weeks and after 12 weeks

23 Based on all services prescribing buprenorphine – regional figures do not add up to the total number of services prescribing buprenorphine, as some services were anonymous and therefore did not provide information on which region they were in.
services in this process were dicyrhodone, physeptone, zopiclone and Zimovane®.

The proportion of clients switched from buprenorphine was lower compared to methadone, with only 14.9 per cent of clients on buprenorphine reduction prescriptions switched to another drug. Again, this differed by service. One service only switched one per cent of its clients, while another service switched 90 per cent of buprenorphine clients to another drug as part of the detoxification process. The mean dose of buprenorphine at the time of drug change varied according to the replacement drug. The mean dose of buprenorphine when switched to methadone was 7.7mg, while the mean dose when switched to lofexidine was 2.8mg.

3.7 Other drugs prescribed

In the survey, 31.7 per cent (n=69) of all services prescribed other drugs (aside from methadone and buprenorphine) as substitutes for opioid dependence. As Table 8 illustrates, the most frequently prescribed alternative was dicyrhodone – 10.7 per cent of services prescribed dicyrhodone to 5324 clients. Diamorphine was prescribed by 19 services to a total of 151 clients and morphine salts (MST/MXL) by 16 services to 65 clients. Although a range of other drugs were also prescribed these were less common.

3.8 Procedures

Services were asked if they had a number of different procedures in place and, if so, to distinguish between having either a written procedure or only a verbal one (Table 9).

With the exception of meetings with pharmacists to discuss issues in place, the majority of services had most of the written procedures that were inquired about in place. A complaints procedure was most likely to be in place with 99.1 per cent of services having a complaints policy in place. A quarter (25.8 per cent) of services had all of the above written procedures in place and just over half of the participating services (53.2 per cent) had all procedures, in either written or verbal form, in place.

3.9 Shared care

The Department of Health definition of shared care is given in the Clinical Guidelines. Shared care and multidisciplinary working – (page 10):

“Shared care is a model that can be applied to any close cooperative work between agencies or services which directly improves the treatment of the individual drug misuser. It most often involves arrangements between specialist and general practitioner services”

The majority of services – 141 (63.5 per cent) – were involved in shared care arrangements in some form, although just over a third did not have any shared care participation. Of those involved in shared care, each service averaged 13.3 GPs involved in a shared care scheme which equated to an average of 36.8 per cent of GPs in the trust area. This varied by service, with three services involved with only one GP, and one service involved with 80 GPs. One service was involved with less than one per cent of GPs in the trust area and, conversely, six services were involved with all of the GPs in their trust area. The number of GP practices involved in shared care arrangements varied, with just under a third (32.7 per cent) of all GP practices in each trust involved on average (26.6 GP surgeries), although this varied markedly.

3.9.1 Regional variation

The regional analysis of primary care involvement is complicated by marked variability in the number of responses provided and so Table 10 should be interpreted with some caution. Nonetheless, the table would suggest that there is marked regional variability within and across each of the shared care measures assessed. Thus, while the East Midlands services participating in the survey reported the highest number of GPs involved in shared care schemes, it also reported the smallest percentage of both GPs and practices within the local trusts participating in the schemes. Similarly, involvement alone is a limited measure, as there are a range of possible activities that can be grouped under the rubric of “shared care”. Table 11 outlines some of the activities that GPs were engaging in.

GPs were most likely to be involved in prescription management (61.1 per cent of GPs were involved in all prescribing management and 34.9 per cent in some). They were least likely to be involved in counselling/key working, and GPs in one-third of services (29.1 per cent) did not have any involvement in this area.

3.10 Overview of findings from the national survey

Overall, the general picture from the main study confirms the findings of the pilot study, in that there are marked variations in substitute prescribing practices across services, both in the quantities of drugs prescribed and the arrangements for consumption. While variation is not a sign of intrinsically flawed practice, and some of this may reflect local needs and the requirements of specific user populations, there is widespread variation in practice that appears to contradict the recommendations made in both the Clinical Guidelines (last published in 1999) and Models of Care (first published in 2002). Although the mean methadone maintenance dose of 56.7mg is lower than the recommended dose of 60mg, and the majority of services (59.9 per cent) had a mean dose under 60mg, the picture in specialist services is typically more in keeping with the research evidence base than that reported by either Strang and

Sheridan (1998) or Strang and Hunt (2005) in relation to methadone prescribing in primary care. This may, in part, reflect the differentiation in the current study between maintenance and reduction prescribing. However, the key finding remains variability, with 7.3 per cent of services reporting mean maintenance doses of less than 40mg and around 40 per cent having mean doses of less than 50mg.

It is also of concern that around one-third of the prescriptions of methadone were on a reduction basis within specialist services. That the average length of time on a methadone reduction prescription was around eight months raises concerns about the aims of this form of prescribing, particularly with clear evidence from NTORS (National Treatment Outcomes Research Study) indicating its limited effectiveness (Gossop et al., 2003). There is a much more encouraging position reported in relation to the formulation of methadone with the majority of prescriptions involving the oral formulation. Although prescribing of methadone tablets still exists, the rates reported are much lower than previously recorded in pharmacy studies in 1995 and 1997 (Strang and Sheridan, 1997, 1998).

There are also concerns about the mean doses of buprenorphine prescribed. The average maintenance dose of buprenorphine was 8.9mg, markedly lower than the 16mg recommended by the RCGP and in the Clinical Guidelines. Despite considerable research evidence suggesting that higher doses are more effective for both buprenorphine and methadone maintenance, the general picture is of low dose prescribing and widespread use of reduction prescribing regimes.

The situation is also mixed with regard to supervised consumption. Although many services adhere to the Clinical Guidelines, it is worrying that 13 per cent of services have less than one in five clients supervised for the first 12 weeks, although this may reflect the availability of pharmacies willing to undertake such actions. The lack of clarity for the supervision of methadone beyond 12 weeks and for supervising the consumption of

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Table 8: Other drugs prescribed as substitutes for opioid dependence

<table>
<thead>
<tr>
<th>Drug prescribed</th>
<th>Number of services</th>
<th>% (of all services prescribing other drugs)</th>
<th>% (of all services)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydrocodeine</td>
<td>26</td>
<td>37.7</td>
<td>10.7</td>
</tr>
<tr>
<td>Diamorphine</td>
<td>19</td>
<td>27.5</td>
<td>7.9</td>
</tr>
<tr>
<td>MST/MXL</td>
<td>16</td>
<td>23.2</td>
<td>6.6</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>8</td>
<td>11.6</td>
<td>3.3</td>
</tr>
<tr>
<td>Morphine</td>
<td>8</td>
<td>11.6</td>
<td>3.3</td>
</tr>
<tr>
<td>Oramorph</td>
<td>4</td>
<td>5.8</td>
<td>1.7</td>
</tr>
<tr>
<td>Codeine phosphate</td>
<td>4</td>
<td>5.8</td>
<td>1.7</td>
</tr>
<tr>
<td>Lofexidine</td>
<td>3</td>
<td>4.3</td>
<td>1.2</td>
</tr>
<tr>
<td>Pethidine</td>
<td>3</td>
<td>4.3</td>
<td>1.2</td>
</tr>
<tr>
<td>Diconal</td>
<td>3</td>
<td>4.3</td>
<td>1.2</td>
</tr>
<tr>
<td>Codeine</td>
<td>2</td>
<td>2.9</td>
<td>0.8</td>
</tr>
<tr>
<td>Oxycodeone</td>
<td>1</td>
<td>1.4</td>
<td>0</td>
</tr>
<tr>
<td>Papaveretum</td>
<td>1</td>
<td>1.4</td>
<td>0</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>1</td>
<td>1.4</td>
<td>0</td>
</tr>
<tr>
<td>Dipipanone</td>
<td>1</td>
<td>1.4</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>97</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 9: Procedures currently in place at each service (n=233)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Written n (%)</th>
<th>Verbal n (%)</th>
<th>No n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse incidence procedure</td>
<td>195 (89.9)</td>
<td>14 (6.5)</td>
<td>8 (3.7)</td>
</tr>
<tr>
<td>Prescribing policy</td>
<td>211 (92.5)</td>
<td>15 (6.6)</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Prescribing review</td>
<td>180 (82.2)</td>
<td>33 (15.1)</td>
<td>6 (2.7)</td>
</tr>
<tr>
<td>Complaints procedure/practice protocol</td>
<td>225 (99.1)</td>
<td>2 (0.9)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Meetings with pharmacists to discuss issues in place</td>
<td>88 (40.0)</td>
<td>109 (49.5)</td>
<td>23 (10.5)</td>
</tr>
<tr>
<td>Risk assessment protocols</td>
<td>197 (88.3)</td>
<td>18 (8.1)</td>
<td>8 (3.6)</td>
</tr>
<tr>
<td>Formal dose titration process for methadone</td>
<td>166 (74.4)</td>
<td>37 (16.6)</td>
<td>20 (9.0)</td>
</tr>
<tr>
<td>Formal dose titration process for buprenorphine</td>
<td>169 (75.1)</td>
<td>34 (15.1)</td>
<td>22 (9.8)</td>
</tr>
</tbody>
</table>

Table 8: Other drugs prescribed as substitutes for opioid dependence

Table 9: Procedures currently in place at each service (n=233)

25 Based on all services.
26 All services answering.
buprenorphine in the Clinical Guidelines are reflected in the huge service-level variability relating to practices in each of these domains. Fewer clients received daily prescriptions for supervised consumption of buprenorphine than for methadone, and for more than a quarter of buprenorphine clients, there was no supervised consumption in the first 12 weeks and lower levels of supervision thereafter.

Although variation in clinical decision making, resources and organisational structures may underpin these variations in prescribing practice, those who adhere to the Clinical Guidelines in one area are more likely to do so in other areas. For example, services that have daily dispensing are more likely to have clients on daily supervised consumption. Similarly, services which provide daily supervised consumption of methadone are also more likely to have daily supervised consumption of buprenorphine ($r=0.56$, $p<0.001$).

Another key area for analysis relates to prescribed benzodiazepines to clients also receiving substitute opiates.

Although the most commonly prescribed benzodiazepine was diazepam, a wide range of benzodiazepines was offered across services, and it is perhaps surprising that temazepam, given its abuse history, is so widely prescribed.

There are some key advances in practice worthy of note. The widespread use of a range of shared care procedures is extremely encouraging, as is the availability of written policies in many of the core domains of client management. Although the results would suggest that inconsistencies need to be addressed, the results of the national survey, although not corroborated through any independent sources, suggest a picture of positive change and commitment to evidence-based practice.
4 National prescribing practice – analysis of PACT/PCA data

4.1 PACT and PCA data

PACT (prescribing analysis and cost data) and PCA (prescription cost analysis) data are available from the Prescription Pricing Authority (PPA) and provide information on the types of drugs prescribed in England and the number of prescriptions dispensed by pharmacists in the community.

These databases differ in that PCA includes all prescriptions dispensed in the community (not just those prescribed by GPs), so this includes any prescriptions dispensed in hospitals, mental health trusts or private prescriptions. PACT data is exclusively concerned with prescriptions written by GPs and dispensed in the community. For the purposes of this report, analysis has been carried out using PCA data due to greater data availability and suitability for the analysis presented below.

The PCA database provides information about the total number of prescriptions dispensed in England, with detail given on the name of the drug, strength, whether it has been dispensed on a drug addict form, and the British National Formulary (BNF) category it was dispensed under (for methadone, this differentiates between prescriptions for analgesic, cough or substance misuse treatment). This data can be analysed both by time (month/quarter/year) and by geographical area (categorised by either strategic health authority or by PCT). However, there are limitations. PCA and PACT data does not provide information on individuals and cannot be used directly to calculate the number of individuals receiving target drugs or the mean doses prescribed (as the unit of analysis is the prescription not the drug user).

4.1.1 Rationale and method

Data was obtained from the Department of Health Statistics Division. Excel spreadsheets on the following:

1. Number of items (000s) and net ingredient cost (NIC) – the basic cost of a drug, but does not take account of discounts, dispensing costs, fees or prescription charges income. This can be measured for methadone and buprenorphine.
2. Number of items (000s) and NIC by methadone (and buprenorphine) drug for all items on a drug addict form, and NIC of items on a drug addict form.
3. Number of items (000s), NIC of items on a drug addict form, NIC of items on a drug addict form by strategic health authority for both methadone and buprenorphine.

4.1.2 Results

The results presented below initially examine methadone prescribing over the last ten years, patterns in reasons recorded for prescribing and methadone formulation. Proportions of prescriptions on drug addict forms are then presented, followed by regional variations. Methadone is then compared to patterns in buprenorphine prescribing for the last three years (the period that buprenorphine has been available as an opioid substitute treatment). Data on methadone prescribing is available on PCA for the last ten years with Figure 2 providing an overview of ten-year trends in the total number of methadone prescriptions, with sub-analysis by the reason given for the prescription, categorised into substance dependence, analgesic purposes and cough suppression. The total number of prescriptions of methadone have increased from 970,900 in England in 1995 to 1,810,500 in 2004 in England (an increase of 86.5 per cent), with the greatest increase occurring between 2002 and 2004. This includes a 13 per cent increase from 2001 to 2002 and a 12.1 per cent increase from 2003–2004. During the same period, prescriptions of methadone identified on the form for substance dependence have more than doubled, from 787,000 to 1,721,100 between 1995 and 2004 (an increase of 118.7 per cent), while methadone use for both analgesics and cough medication decreased markedly in the same period. The number of prescriptions for analgesic purposes dropped from 180,400 in 1995 to 87,800 in 2004 (a decrease of 51.3 per cent), while prescriptions of methadone for cough preparation dropped

28 As of 1 April 2005 available from the Health and Social Care Information Centre (HSCIC).
29 The reason for prescribing methadone (or buprenorphine) for each prescription was ascertained by using BNF coding which classified drug chemical names into either analgesics (4.7), cough preparations (3.9) or drugs used in substance dependence (4.10).
from 3,500 in 1995 to 1,100 in 2004 (a decrease of 68 per cent). As a consequence, the proportion of all methadone prescriptions that are prescribed specifically for substance dependence increased from 81.1 per cent in 1995 to 95.1 per cent in 2004. There has been a similar shift in the formulation of methadone prescribed in the same period, with an increased proportion of oral methadone prescribed and reduced proportions of tablets and ampoules, as shown in Figure 3.

The number of prescriptions of methadone in oral liquid form has increased from 791,800 in England in 1995 to 1,723,500 in 2004, an increase of 218 per cent, with the increase particularly marked between 2000 and 2004 (while the average percentage increase year on year between 1995 and 1999 was 8.3 per cent, the average increase for 2000 to 2004 was higher at 10.7 per cent). In the same period, the total number of prescriptions of methadone tablets has dropped from 94,800 to 45,800 (a reduction of 51.7 per cent) and the total number of prescriptions of injectable methadone has decreased from 84,200 to 40,200 (a reduction of 52.3 per cent). There has been a slight increase in the number of prescriptions of methadone in “other” preparations from 100 to 500 between 1995 and 2004.

Oral methadone made up 81.5 per cent of all methadone prescribed in 1995, and by 2004 this had increased to 95.2 per cent. Conversely, the proportion of both tablets and injectables steadily declined year on year from 9.8 per cent and 8.7 per cent respectively to 2.5 per cent and 2.2 per cent in 2004. A further mechanism for assessing effective regulation relates to the prescription forms used, as shown in Figure 3.

The proportion of prescriptions on drug addict forms has increased from 80.9 per cent in 2001 (the earliest date this information is available for) to 82.7 per cent in 2002, 83.9 per cent in 2003 and 84.8 per cent in 2004 (see Figure 4).

### 4.1.3 Examining prescriptions as a function of the total working population

Figure 6 shows the increase per head in methadone prescriptions for the overall population (based on working population). In this period, the prescription of methadone increased from 43.2 prescriptions per 1,000 members of the working-age population in 2001 to 58.3 per 1,000 prescriptions in 2004, and the increase in methadone prescriptions specifically on addict forms from 35 per 1,000 population to 49.5 per 1,000 population. However, it is important to note that the data does not permit an assessment of how many of these prescriptions are multiple prescriptions over the course of the year to the same individual.

### 4.1.4 Regional variations

PCA data is also available for each of the strategic health authorities and can be aggregated to allow comparisons to be made between the nine Government Office regions, which are also used as the units for performance management of drug treatment provision. Although the national picture identified above is repeated, there are marked regional variations in changes in methadone prescription patterns (see Figure 5).

There is great variation across regions in methadone prescribing, with the highest rate of prescribing by far in the North West for all four years and the East Midlands consistently reporting the lowest rates. For all nine regions, prescribing has either increased each year or has remained stable, (with one exception, the South East region in 2004 – see tables 12 and 13). This variability recurs when the analysis is repeated using prescriptions per head of working-age population. The North West remains with the highest number of methadone prescriptions per 1,000 working-age individuals, but it also displays one of the lowest rates of increase over the four-year window. The lowest rate by working age population was in the East Midlands and the South East (although the former displayed the greatest rate of increase over the four years). This is also shown in Figure 5.

When the analysis is repeated using methadone prescriptions on drug addict forms, the regional picture is equally variable, with geographical differences in the proportion of methadone prescribed on a drug addict form, and inconsistencies in changes over time (as shown in Table 14).

### 4.1.5 Comparison with buprenorphine

Buprenorphine prescribing specifically for substance dependence has also increased during this period, from 3.7 per cent of all prescriptions in 1999 to 72 per cent in 2004, as shown in

30 Methadone and buprenorphine can be prescribed on any form; however, where instalment dispensing is required, a doctor can only prescribe methadone/buprenorphine on a drug addict form. So a drug addict may receive one-off prescriptions on any form, but only receives prescriptions for instalment dispensing on a drug addict form.
19

Table 15, although the initial increase can be attributed to the change in availability at the start of the period described below:

There has also been a substantial increase in buprenorphine prescribed on a drug addict form, increasing from 36.9 per cent in 2002 to 51.4 per cent in 2004. In the same period, there has been a more gradual increase, albeit from a higher baseline, rising from 82.7 per cent of methadone prescriptions on drug addict forms in 2002 to 84.8 per cent in 2004.

Again, marked regional variations in the pattern of prescribing can be seen for buprenorphine with a number of regions showing a dramatic increase in buprenorphine prescribing over the last three years (shown in Table 16). Yorkshire and Humber region showed the largest increase of 176.6 per cent between 2002 and 2004, compared to the South West region which saw a 69 per cent increase in the total number of buprenorphine prescriptions.

As Table 16 also shows, increases in buprenorphine prescribing are not necessarily associated with increases in methadone prescribing in the same regions. Correlations for each year between the percentage increase from 2002 to 2004 for methadone and buprenorphine were consistently positive but non-significant (2002, \( r=0.51, p=0.16 \); 2003, \( r=0.465, p=0.21 \); 2004, \( r=0.07, p=0.86 \)).

4.1.6 Total number of prescriptions – combining methadone and buprenorphine

There has been a steady increase in the total number of prescriptions of methadone and buprenorphine per 1,000 of population of working age, when the number of prescriptions are
combined. In 2001 there were 46.5 prescriptions per 1,000 working-age people, rising to 56.1 per 1,000 in 2002, 67.5 in 2003 and 78.9 in 2004. Again, the regional picture is also variable, with the North West prescribing the greatest number of total methadone and buprenorphine prescriptions in each of the four years (130.3 per 1,000 individuals of working age in 2004). This was more than double that of the lowest prescribing regions, East of England (55.3 per 1,000 in 2004) and East Midlands (61 per 1,000 in 2004).

### Table 13: Regional variations in methadone prescriptions per head of working-age population (per capita 000s) by region, 2001–2004

<table>
<thead>
<tr>
<th>Region</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>North East</td>
<td>34.5</td>
<td>46.0</td>
<td>65.8</td>
<td>90.3</td>
<td>161.7</td>
</tr>
<tr>
<td>North West</td>
<td>97.1</td>
<td>101.1</td>
<td>105.8</td>
<td>108.6</td>
<td>11.8</td>
</tr>
<tr>
<td>Yorkshire and Humber</td>
<td>48.5</td>
<td>54.2</td>
<td>62.3</td>
<td>75.0</td>
<td>54.6</td>
</tr>
<tr>
<td>East Midlands</td>
<td>19.5</td>
<td>22.7</td>
<td>32.1</td>
<td>41.7</td>
<td>113.8</td>
</tr>
<tr>
<td>West Midlands</td>
<td>35.7</td>
<td>39.4</td>
<td>47.3</td>
<td>57.7</td>
<td>61.6</td>
</tr>
<tr>
<td>East of England</td>
<td>28.9</td>
<td>30.1</td>
<td>34.1</td>
<td>37.4</td>
<td>29.4</td>
</tr>
<tr>
<td>London</td>
<td>41.0</td>
<td>42.2</td>
<td>47.8</td>
<td>51.4</td>
<td>25.4</td>
</tr>
<tr>
<td>South East</td>
<td>28.3</td>
<td>30.6</td>
<td>30.8</td>
<td>30.4</td>
<td>7.4</td>
</tr>
<tr>
<td>South West</td>
<td>38.0</td>
<td>40.3</td>
<td>45.7</td>
<td>50.1</td>
<td>31.8</td>
</tr>
</tbody>
</table>

4.2 Overview and conclusions

As reported in the previous chapter, the national picture is an encouraging one. The number of prescriptions of oral methadone has increased markedly, while methadone tablet prescribing has dropped markedly and the proportion of non-oral formulations as a whole has dropped, although there is increasing interest in assessing the effectiveness of prescribing of injectable methadone (Sell and Zador, 2004). Similarly, the use of addict forms has improved for methadone and the level of “coverage” for both methadone and buprenorphine has increased markedly. The reason for including the analysis by head of working population was to illustrate the overall increase in distribution of substitute therapies to opiate addicts, particularly in the period since 2001, with the advent of the National Treatment Agency. However, this general improvement is characterized by huge regional variations in four main domains – the overall proportions of methadone and buprenorphine prescribed in each region, the typical formulations and use of addict forms in each area, the baseline levels of prescribing and the changes in patterns of prescribing over time.

The increase in the uptake and prescription of buprenorphine across England (see Table 15) suggests the widespread availability of an alternative to methadone, but this remains regionally variable (see Table 16). The overall picture from the analysis of PACT and PCA data is of an improving picture and increased adherence to the national guidelines set out in the Clinical Guidelines (DH, 1999) and Models of Care (NTA, 2006) and so is broadly consistent with the findings of the national survey. However, the two databases provide only an overview – one of responding services and the other of gross level prescribing and so there is a significant gap in the conclusions that can be drawn, particularly around primary care policy.

4.3 Summary and implications

The audit used a multi-method approach to assessing national practices around substitute prescribing to drug users in England, while focusing on a national survey of specialist prescribing agencies. This method was selected because of limitations in existing data sources, along with inconsistencies in the availability and quality of information. Although this patchwork of data was not optimal, the findings were sufficiently consistent to support a cautiously optimistic conclusion. In contrast to earlier surveys suggesting sub-optimal prescribing, the national survey reported a mean methadone maintenance dose of 56.7mg, with only 7.3 per cent of services reporting mean dose levels of under 40mg. Additionally, the high levels of shared care arrangements in place with (just under two-thirds of services and one-third of GPs involved in some form of shared care in the national survey) suggest substantial and increasing partnership working in this area.

Although variability remains a significant issue, the survey of specialist services showed that around two-thirds of methadone clients were receiving maintenance prescriptions at doses only slightly lower than that recommended in the Clinical Guidelines, and markedly higher than the mean methadone dose of 47.2mg reported by Strang and Sheridan (2001) in a survey of community pharmacies.31 The increase in dose this implies has occurred in a period in which there has been a vast increase in coverage. The PCA analysis shows that the number of methadone prescriptions has risen by 86.5 per cent to 1,810,500 between 1995 and 2004, an increase that is consistent with the drug strategy objective of doubling the numbers of drug users in structured treatment, particularly as there have also been increases in the number of prescriptions specifically for addiction treatment and prescribed on addict forms. PCA data also shows the recent increase in buprenorphine prescribing to opiate addicts in the period between 2001 and 2004, with no indication that this has reduced the availability of methadone in areas where buprenorphine has become available.

31 The Strang and Sheridan survey would not, however, be restricted to maintenance prescriptions or those from specialist services.

The picture is not, however, universally positive, with the prime concern around consistency of provision. In addition to the inconsistencies in methadone dose indicated by the national survey, a similar inconsistency arises with buprenorphine, but with the additional complication of a much lower baseline. In other words, the mean buprenorphine maintenance dose, of 8.9mg, is markedly lower than the equivalent mean for methadone (8.9mg of buprenorphine equates to just over 30mg of methadone), with the national picture again clouded by marked variability in dose levels across services. The survey also indicated that there are significant variations in the use of supervised dispensing of both methadone and buprenorphine, both in the initial 12 weeks of prescribing and thereafter. While the Clinical Guidelines recommend that dispensing and consumption are supervised in this period, less than three-quarters of specialist services reported that more than 80 per cent of methadone clients were supervised in the first 12 weeks, and just under half of buprenorphine clients were supervised in the same period. The final area of inconsistency is around benzodiazepine prescribing, with around three-quarters of services prescribing at least one benzodiazepine to an average of one in ten patients. Although diazepam was most commonly prescribed (with a mean dose ranging from 3.9mg to 192mg), other benzodiazepines were also used.

So what can we conclude from these variable practices? In some areas, such as the supervision of buprenorphine and the prescribing practices around benzodiazepines, the lack of central guidance may be indicative of a weak evidence base and limited outcome-focused research. Similarly, the variability in supervision

### Table 14: Percentage of methadone prescriptions on an addict form by region, 2001–2004

<table>
<thead>
<tr>
<th>Region</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>% change 01–04</th>
</tr>
</thead>
<tbody>
<tr>
<td>North East</td>
<td>89.6</td>
<td>88.8</td>
<td>87.0</td>
<td>82.4</td>
<td>-8.1</td>
</tr>
<tr>
<td>North West</td>
<td>84.4</td>
<td>86.1</td>
<td>87.5</td>
<td>89.5</td>
<td>7.1</td>
</tr>
<tr>
<td>Yorkshire and Humber</td>
<td>87.0</td>
<td>88.4</td>
<td>89.6</td>
<td>90.1</td>
<td>3.6</td>
</tr>
<tr>
<td>East Midlands</td>
<td>74.6</td>
<td>77.8</td>
<td>78.6</td>
<td>82.0</td>
<td>9.9</td>
</tr>
<tr>
<td>West Midlands</td>
<td>80.8</td>
<td>81.6</td>
<td>82.9</td>
<td>85.9</td>
<td>6.3</td>
</tr>
<tr>
<td>East of England</td>
<td>71.1</td>
<td>75.4</td>
<td>76.6</td>
<td>78.7</td>
<td>10.7</td>
</tr>
<tr>
<td>London</td>
<td>77.6</td>
<td>79.6</td>
<td>81.0</td>
<td>81.5</td>
<td>5.0</td>
</tr>
<tr>
<td>South East</td>
<td>77.7</td>
<td>77.3</td>
<td>77.9</td>
<td>79.3</td>
<td>2.1</td>
</tr>
<tr>
<td>South West</td>
<td>77.6</td>
<td>80.4</td>
<td>82.1</td>
<td>83.0</td>
<td>7.0</td>
</tr>
</tbody>
</table>

### Table 15: Buprenorphine and methadone prescribed for substance dependence as a percentage of all prescriptions, 1998–2004

<table>
<thead>
<tr>
<th>Region</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% buprenorphine</td>
<td>% methadone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>North East</td>
<td>0</td>
<td>3.7</td>
<td>22.7</td>
<td>39.5</td>
<td>56.2</td>
<td>66.4</td>
<td>72.5</td>
</tr>
<tr>
<td>North West</td>
<td>85.7</td>
<td>88.3</td>
<td>90.1</td>
<td>91.8</td>
<td>93.2</td>
<td>94.3</td>
<td>95.1</td>
</tr>
</tbody>
</table>

The Clinical Guidelines do not recommend supervision arrangements for buprenorphine in the initial 12-week period.

### Table 16: Number of methadone and buprenorphine prescriptions (000s) by region

<table>
<thead>
<tr>
<th>Region</th>
<th>Methadone</th>
<th>Buprenorphine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2002</td>
<td>2003</td>
</tr>
<tr>
<td>North East</td>
<td>71.6</td>
<td>102.7</td>
</tr>
<tr>
<td>North West</td>
<td>419.1</td>
<td>441.3</td>
</tr>
<tr>
<td>Yorkshire and Humber</td>
<td>165.6</td>
<td>191.4</td>
</tr>
<tr>
<td>East Midlands</td>
<td>59.1</td>
<td>84.3</td>
</tr>
<tr>
<td>West Midlands</td>
<td>127.3</td>
<td>153.3</td>
</tr>
<tr>
<td>East of England</td>
<td>99.6</td>
<td>113.8</td>
</tr>
<tr>
<td>London</td>
<td>206.0</td>
<td>234.7</td>
</tr>
<tr>
<td>South East</td>
<td>151.1</td>
<td>152.6</td>
</tr>
<tr>
<td>South West</td>
<td>119.7</td>
<td>136.6</td>
</tr>
</tbody>
</table>

---

32 The Clinical Guidelines do not recommend supervision arrangements for buprenorphine in the initial 12-week period.
arrangements may reflect differences in the client groups, in the infrastructure for supervision (for instance, a lack of pharmacies willing to participate) or differences in clinician philosophy and treatment goals. However, as was indicated by the pilot work, one major barrier to improvement in this area is the lack of good quality data on prescribing, held either by the agencies themselves or by partnerships. A number of the agencies involved in the pilot work had to create new databases to respond to the audit, although again this varied hugely from site to site.

The overall conclusion, albeit based on limited data from a single survey supported by prescription monitoring data over time, is that there are grounds for optimism in achieving drug strategy objectives in treatment coverage, and some support for substitute prescribing typically falling in line with the research evidence base where this exists. However, there are a number of areas that need to be addressed urgently. Data quality is far too variable across partnerships in this key domain of treatment provision, while national guidelines should be reviewed to address current omissions in relation to supervision and dose management, particularly related to buprenorphine prescribing. It is also essential that more research work is commissioned around the prescription of benzodiazepines to opiate addicts, and that this should inform public policy. Finally, this audit has provided a baseline for establishing standards and for the Healthcare Commission review process, but it is essential that this work is repeated at national and local level to provide trend information and to allow local interpretation and explanation for the variability that this report has highlighted.
5 References


