Supervised methadone in Staffordshire and Shropshire
A study of factors associated with key outcome variables

Drug-related death publications
This series of publications emanates from the Government Action Plan to Prevent Drug-Related Deaths, a response to the Advisory Council on the Misuse of Drugs’ report on drug-related deaths.

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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
To describe the findings of a study into the dispensing, prescribing and supervised consumption of methadone in Staffordshire and Shropshire.

Title
Supervised methadone in Staffordshire and Shropshire: A study of factors associated with key outcome variables

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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
This report describes the findings of a study into the practice of supervised consumption of methadone in Staffordshire and Shropshire, exploring the beliefs and attitudes of professionals involved and also those of service users

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Gateway/ROCR approval
The NTA is a self-regulating agency in relation to the Department of Health Gateway

Disclaimer
This publication is not a journal publication and does not constitute National Treatment Agency or Department of Health guidance or recommendations. The views expressed by this study are not necessarily those of the Department of Health or the NTA, but are based on externally refereed research.
Supervised methadone in Staffordshire and Shropshire: A study of factors associated with key outcome variables

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Supervised methadone in Staffordshire and Shropshire: A study of factors associated with key outcome variables

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1 Aims

- To describe the development and current status of methadone prescribing, dispensing and supervised consumption
- To examine the views, level of involvement, nature and extent of current practice of:
  - General practitioners
  - Specialist prescribers
  - Community pharmacists
- To assess users’ views and experiences of these supervised methadone consumption schemes
- To determine the effects of the introduction of these supervised methadone schemes on drug-related mortality
- To identify the factors in supervised methadone schemes that affect the risks of methadone-related death in the community
- To develop a proposed model for quality improvement and monitoring of methadone prescribing and dispensing for subsequent piloting.

2 Factors of interest

The research explored the effectiveness of supervised methadone systems. The use of a mixed quantitative and qualitative approach allowed the project to explore the experiences and beliefs of users, pharmacists, prescribers, commissioners and policymakers. The project compared four different areas in Staffordshire and Shropshire which have introduced supervised methadone schemes. The study also investigated drug-related mortality in the context of supervised methadone consumption schemes.

3 Background

3.1 Prevalence

The number of prescriptions for methadone in England increased from 425,400 to 1,318,100 annually between 1990 and 2001 (Strang & Sheridan, 2003). Drug-related deaths in the UK have increased from 821 in 1997 to 1524 in 2001; methadone was implicated in up to 20 per cent of deaths (np-SAD, 2000). The diversion of prescribed methadone is a substantial problem (Fountain et al., 2000) and this is reflected in the proportion of methadone-related deaths related to illicit methadone (65 per cent) as compared to prescribed methadone (35 per cent) (np-SAD, 2000).

3.2 Drug-related deaths

Evidence of the impact of increased methadone prescribing on drug-related deaths is not consistent. A retrospective study of deaths from drug abuse concluded that the availability of methadone is not a factor involved in the increase in the number of drug-related deaths (Oliver & Keen, 2002). A retrospective study of drug-related deaths in Scotland found that the introduction of a methadone maintenance programme in 1994 was followed by an annual 100 per cent increase in these deaths. This increase was halted with the introduction of supervised methadone consumption in 1996, which produced a 48 per cent decrease of in methadone-related deaths in 1997 (Seymour et al., 2003). Thus the evidence indicates that supervision is a key factor in reducing methadone-related deaths.

3.3 The role of pharmacists and prescribers

A study of general practice management of drug problems in Scotland identified a gap between evidence and practice with regard to compliance with guidelines (Matheson et al., 2003). A variety of studies has addressed the participation of community pharmacists in services for drug users. Involvement in Scotland increased dramatically from 1995 to 2000, with 65 per cent of methadone being supervised in 2000, compared with 33 per cent in 1995 (Matheson et al., 2002).

In England, there have been similar increases in the volume of activity (Strang & Sheridan, 2003). Investigation of the feasibility and acceptability to pharmacists of such services showed that pharmacists who took part became more positive about their contribution over time. A recent review of a shared care scheme involving specialist drug workers, prescribers, pharmacists and drug users reported that there was a high level of enthusiasm for such services from methadone patients and professionals, despite problems with under-resourcing and high numbers of supervised prescriptions (Keene et al., 2004).

3.4 User views

There is a paucity of literature documenting user views on supervised consumption. A study of 124 illicit drug users in Scotland elicited views on good and bad services and possible improvements (Matheson, 1998). A recent study in England surveyed views on supervised methadone from 100 current users, a local users’ forum and a national users’ forum (Stone & Fletcher, 2003).

4 Methods

Ethical approval for the study was obtained from the North Staffordshire local research ethics committee.
4.1 Methodology
This was a complementary qualitative and quantitative study of supervised methadone schemes in four drug action team areas. The study included the following methodologies:
1 Epidemiological study
2 Service review and evaluation
3 Structured questionnaires
4 Narratives
5 Semi-structured interviews
6 Structured case vignette
7 Focus groups
8 Quantitative and qualitative analysis.

4.2 Data analysis
4.2.1 Questionnaire
Quantitative information from the questionnaire was used to construct the client profiles. Initially, summary statistics were obtained using SPSS for Windows™ to describe the respondents. Attitudes were measured using a number of multi-item scales compiled from topics elicited from previous studies (Matheson, Bond & Mollison, 1999). A five-point Likert scale from “strongly disagree” to “strongly agree”, with assigned values from one to five was used to assess respondents’ level of agreement with each statement. Attitude score was derived from adding the response to each statement, where higher score indicated positive attitude. Categorical analysis with independent variables such as age, gender and drug action team area was carried out and differences between the groups were evaluated and tested for statistical significance. A free text analysis was also carried out regarding respondents’ additional responses at the end of the questionnaire.

4.2.2 Semi-structured interviews
Transcripts of interviews were analysed using NVivo software. Data was coded into categories and constructs created using constant comparative analysis. Interview data was used to rate additional client profiles to validate the findings from the questionnaire.

4.2.3 Focus groups
Transcripts were analysed using NVivo software.

4.2.4 Methadone-related death data
A binary data analysis was applied to evaluate the relative risk of methadone-related death for pre- and post-introduction of the supervised consumption systems.

When reporting extracts from questionnaire free text, interviews and focus groups, the following coding is used: users (U), specialist prescribers (S), general practitioners (G), pharmacists (P), followed by number and source of information (Q for questionnaire free text, I for interview, F for focus group). For example, S 01 F means specialist number 1 from the focus group.

5 Sample group
5.1 Questionnaire phase
The questionnaires were given to specialist prescribers, general practitioners (GPs), pharmacists and users. The GPs and specialist prescribers involved in the study were identified from practice lists and drug action team (DAT) contact lists. The DATs involved were those in Stoke, Telford & Wrekin, Staffordshire and Shropshire. All community pharmacies in the study area were identified from strategic health authority lists; including both those who did, and those who did not, provide supervised consumption. The current prescribed drug users were identified from treatment databases, including those on supervised and unsupervised methadone. The questionnaire sample sizes are

<table>
<thead>
<tr>
<th>Group</th>
<th>Questionnaire phase</th>
<th>No. in semi-structured interview phase</th>
<th>No. in focus group phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. distributed</td>
<td>No. returned</td>
<td>Response rate</td>
</tr>
<tr>
<td>Users</td>
<td>900</td>
<td>350</td>
<td>38.9%</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>166</td>
<td>106</td>
<td>63.8%</td>
</tr>
<tr>
<td>GPs</td>
<td>497</td>
<td>131</td>
<td>26.3%</td>
</tr>
<tr>
<td>Specialist prescribers</td>
<td>29</td>
<td>20</td>
<td>69%</td>
</tr>
</tbody>
</table>

Table 1: Sample sizes for the three phases of the study
shown in Table 1, along with sample sizes of the other phases of the study.

5.2 Semi-structured interview phase
For the semi-structured interviews, a theoretical sampling technique was used to select respondents from the questionnaire phase. The sampling method was designed to select subjects with a maximal variation in attitudes to supervised consumption. Selected pharmacists, general practitioners and specialist prescribers were interviewed at their place of work. Users were interviewed by a trained peer interviewer when they were attending for treatment at clinics.

5.3 Focus group phase
The focus group participants were selected from homogeneous groups according to profession (GPs, specialists, pharmacists and users). Participants were selected from those who had indicated in the questionnaire phase that they were prepared to take part in this component of the study. Informed consent was obtained prior to the focus groups.

6 Measures
The study used a variety of measures to assess methadone prescribing. Information was obtained from a standardised questionnaire administered to each group. Demographic characteristics were considered for each of the group shown in Table 1 (see also Table 2). In addition, a measure of attitudes to supervised methadone was constructed. Narratives on the operation and effectiveness of supervised methadone schemes from the perspective of users, prescribers and pharmacists were obtained.

7 Findings

7.1 Prescribing-dispensing supervised consumption systems
There are four drug action teams within the study catchment area. Analysis of the documentation from these DATs, coupled with a web-based survey, identified a core structure that was common to all four areas and was based on the framework provided in Drug Misuse and Dependence – Guidelines on Clinical Management (DH, 1999) and Reducing Drug-Related Deaths (Advisory Council on the Misuse of Drugs, 2000). Further information was obtained from web-based surveys of DATs.

<table>
<thead>
<tr>
<th>Group</th>
<th>Users</th>
<th>Pharmacists</th>
<th>GPs</th>
<th>Specialist prescribers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>63.7</td>
<td>52.8</td>
<td>59.5</td>
<td>65.0</td>
</tr>
<tr>
<td>Female</td>
<td>32.0</td>
<td>45.3</td>
<td>37.4</td>
<td>35.0</td>
</tr>
<tr>
<td>Age (in years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>30.6</td>
<td>41.6</td>
<td>45.2</td>
<td>45.4</td>
</tr>
<tr>
<td>&lt;20</td>
<td>1.1</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>20-29</td>
<td>44.9</td>
<td>15.1</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>30-39</td>
<td>40.3</td>
<td>30.2</td>
<td>21.4</td>
<td>30.0</td>
</tr>
<tr>
<td>40-49</td>
<td>8.9</td>
<td>24.5</td>
<td>49.6</td>
<td>35.0</td>
</tr>
<tr>
<td>50-59</td>
<td>0.9</td>
<td>19.8</td>
<td>19.8</td>
<td>35.0</td>
</tr>
<tr>
<td>60-69</td>
<td>4.0</td>
<td>6.6</td>
<td>3.8</td>
<td>0.0</td>
</tr>
<tr>
<td>Number of years registered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>41.6</td>
<td>20.9</td>
<td>19.5</td>
<td></td>
</tr>
<tr>
<td>0-10</td>
<td>26.3</td>
<td>9.2</td>
<td>15.0</td>
<td></td>
</tr>
<tr>
<td>11-20</td>
<td>28.3</td>
<td>36.6</td>
<td>25.0</td>
<td></td>
</tr>
<tr>
<td>21-30</td>
<td>25.5</td>
<td>42.0</td>
<td>50.0</td>
<td></td>
</tr>
<tr>
<td>31-40</td>
<td>12.3</td>
<td>8.7</td>
<td>5.0</td>
<td></td>
</tr>
<tr>
<td>41-50</td>
<td>0.9</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>&gt;50</td>
<td>0.9</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Number of years using drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>12.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-10</td>
<td>40.9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11-20</td>
<td>44.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21-30</td>
<td>28.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31-40</td>
<td>3.0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Drug-related deaths. Drugs present in toxicology, potentially fatal, mentioned on death certificates and average levels.
DATs had implemented the current supervised schemes with the aid of written guidelines and protocols. The key elements of the guidelines included:

- The completion of a written contract between pharmacist and patient
- Observation of the consumption of the methadone in a “quiet, private place”
- A responsibility for the pharmacist to contact the prescriber if the patient:
  - Failed to attend
  - Breached the contract
  - Showed evidence of increasing health or emotional problems.

Only one of the DAT guidelines contained recommendations on pharmacist training and this was an advisory recommendation that the pharmacist completes a distance-learning pack on opiate treatment. Analysis of the questionnaire responses and the semi-structured interviews revealed a gap between the contract specifications and the reality of implementation. This is illustrated in Table 3, where it can be seen that many pharmacists (35 per cent) do not have written contracts. A similar number (35 per cent) are not able to provide a place of privacy for consumption. These reports from pharmacists were confirmed in the user questionnaires, where it emerged that 40 per cent of users do not have a written contract and only 49 per cent feel that the pharmacist provides privacy for them when they take their methadone. Furthermore, analysis of the semi-structured interviews also confirmed the validity of the gap between the guidelines and practice.

P 02 I: “I know the contracts do exist, but I haven’t actually had any forms. I never felt the need to. I felt I can handle the situation by talking to them, rather than a piece of paper which is saying like if you misbehave you cannot come back again”

7.2 Methadone dispensing practice

Respondents who had experienced dispensing prescribed drugs for the management of drug misuse (n=102) were asked about their procedures in the management of supervised methadone. A third of the pharmacists reported that there was no physical provision in the pharmacy for patients’ privacy, while 20 per cent provided a separate room, 36 per cent a section screened off from the main area, and three per cent an area to the side of the pharmacy. A written contract between the user and the pharmacist was always instituted by 41.2 per cent of respondents, with 17.6 per cent using a contract sometimes. However, 70.6 per cent of pharmacists always laid down ground rules for a new patient on a methadone prescription, with 17.6 per cent doing so sometimes. Very little was offered by pharmacists in the way of information leaflets or face-to-face advice on drugs or HIV. More than 60 per cent of respondents indicated that they did not provide leaflets, and 44.1 per cent never gave face-to-face advice on the management of drug use, with 74.5 per cent never giving advice on HIV prevention.

7.3 Methadone prescribing practice

The majority of respondents reported that they prescribed supervised methadone (specialist prescribers – 90 per cent, GPs – 79 per cent) and gave supervised methadone to all new patients (specialist prescribers – 94 per cent, GPs – 78 per cent). About 60 per cent of GPs contacted the pharmacist when they started a patient on methadone, compared with 95 per cent of specialist prescribers.

<table>
<thead>
<tr>
<th>In general: do you (n=71):</th>
<th>Always</th>
<th>Sometimes</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lay down ground rules for new person with a prescription for methadone</td>
<td>67.9%</td>
<td>17.0%</td>
<td>6.6%</td>
</tr>
<tr>
<td>Have a written contract with drug misusers</td>
<td>39.6%</td>
<td>17.0%</td>
<td>34.0%</td>
</tr>
<tr>
<td>Ask drug misusers for identification on the first visit</td>
<td>59.4%</td>
<td>22.6%</td>
<td>9.4%</td>
</tr>
<tr>
<td>Ask for identification when they collect their supply</td>
<td>4.7%</td>
<td>47.2%</td>
<td>38.7%</td>
</tr>
<tr>
<td>Make up prescriptions in advance</td>
<td>47.2%</td>
<td>29.2%</td>
<td>15.1%</td>
</tr>
<tr>
<td>Supply information leaflets concerning drug misuse</td>
<td>2.8%</td>
<td>31.1%</td>
<td>57.5%</td>
</tr>
<tr>
<td>Supply information leaflets concerning HIV prevention</td>
<td>0.0%</td>
<td>30.2%</td>
<td>61.3%</td>
</tr>
<tr>
<td>Offer face-to-face advice on drug problems</td>
<td>1.9%</td>
<td>47.2%</td>
<td>42.5%</td>
</tr>
<tr>
<td>Offer face-to-face advice on HIV/AIDS prevention</td>
<td>0.0%</td>
<td>18.9%</td>
<td>71.7%</td>
</tr>
<tr>
<td>Treat drug misusers the same as other customers</td>
<td>72.6%</td>
<td>17.0%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

Table 3: Pharmacists’ responses to questionnaire items on dispensing practice
The length of time for which prescribers continued supervision varied between specialist prescribers and general practitioners, with 28.6 per cent of specialist prescribers being prepared to supervise for less than three months in some cases compared with 4.3 per cent of GPs. The majority of specialist prescribers (69 per cent) described their supervision period as “variable” rather than a fixed three months, compared with 43.8 per cent of GPs.

The Guidelines on Clinical Management of Drug Misuse and Dependence was seen to be influential to some degree in changing clinical practice by 73 per cent of GPs and 94 per cent of specialist prescribers. The guidelines were, however, perceived to be in need of updating to come into line with current evidence-based policy.

7.4 Training

7.4.1 General practitioners

Around half of the GP respondents indicated in the questionnaire that they needed further training (56.5 per cent, n = 74). In the interviews, respondents stated that they already had some skills and knowledge regarding treatment for drug misuse. Topics of training which the respondents thought would be useful included an “ABC of methadone” (how to treat new patients, and when, what and how to prescribe), guidance on methods of supervision, and information on how to deal with potential violence, manipulative behaviour and non-compliance from patients.

7.4.2 Specialist prescribers

Ninety per cent of specialist prescribers who completed the questionnaire felt that they needed more training (n = 18). Potential topics identified included: deciding between maintenance, reducing or stopping the regime, treating pregnant users and updates on drugs such as Subutex® and benzodiazepines. Supervision, support and discussion with peers or senior prescribers were highlighted as being important.

Prescribers should regularly be updated with the evidence-based treatment, especially those who were still in training and those who have just started prescribing.

S 01 I: “How to decide between what is a maintenance supervised methadone regime and when do you engage into reducing and stopping the regime. I think there are loads of uncertainties about this and how long is it safe to prescribe for. People who don’t give negative urine test: what do you do with them? Do you do continue prescribing just as a supplement to the opiate that they continue to use? There are loads of issues which need answers.”

7.4.3 Pharmacists

From the questionnaire responses, it was found that training on drug misuse and blood-borne diseases was needed by 60 per cent of pharmacists. Respondents wished to gain more information, knowledge and training on how to deal with aggression, understanding drug and alcohol addiction, and also on methadone as a treatment for addiction, including its psychological effects on users. They also indicated that in-house training, workshops and role-plays would be useful. It was revealed in the focus group that respondents would like to be better informed about prescribers and the guidelines they use. For pharmacists who were new to methadone supervision, a Q&A session using experienced pharmacists was seen as useful.

P 01 I: “I think dealing with aggression; secondly, just to understand about dependency and addiction. I think we don’t really understand it. I don’t think many people understand it except for the professionals who do it.”

7.4.4 Users

Users expressed the view that pharmacists should know more about methadone and its effects on users. Training on how to deal with methadone patients to prevent stereotyping was also suggested.

U 06 I: “The pharmacist should go on a more in-depth, more intensive course, and their staff that work with them that have actually given methadone should go on some ‘how to’ talk. Basically tell them that you are not all the same. There are individuals and you don’t all go around mugging all people and things like that.”

8 Factors which may affect the risk of methadone-related deaths

8.1 Users’ views

Supervised methadone was thought to reduce the amount of methadone available on the street by only 33 per cent of the subjects who completed the questionnaire, the remainder being unsure or disagreeing with the statement. Twenty-eight per cent of the respondents stated that they knew of cases where people who were not prescribed methadone had died from using street methadone. In contrast to the questionnaires, semi-structured interviewing revealed a more consistent opinion that supervised methadone had reduced availability on the street.

U 10 I: “Well at one time when people weren’t supervised, say, you could pay £10 for 100ml, but now for 100ml you pay £20, because it is now that with so many people being supervised it’s harder to get hold of, which is a bad thing. Well it’s a good thing for the black market.”
The effect of a reduced supply was seen by some users as reducing the risk of methadone-related deaths but by others as increasing the overall risk of drug-related death.

U 08 I: "Users' safety? I think it is worse because people who don’t buy methadone off someone in the street would buy heroin that day."

There was a degree of consensus between users and pharmacists on the effect of supervised methadone on the availability of street methadone (see Figure 1).

8.2 Pharmacists’ views

A third of respondents (34.9 per cent) thought that the prescription of methadone would stop users using street drugs, while the rest either disagreed (42.5 per cent) or were uncertain (21.7 per cent). However, 64.1 per cent of respondents believed that supervised methadone prevented the illicit selling of controlled drugs on the street. The latter view demonstrates consistency with opinions from semi-structured interviews, which were confirmed in focus group discussions. Some respondents did express concerns about the effectiveness of the scheme in reducing the availability of street drugs.

P 05 I: "I can see why they are doing it: to keep methadone off the street, although that hasn’t worked particularly, because they regurgitate it as soon as they go out of the shop anyway."

Regarding methadone-related deaths, information on safe storage of methadone at home was considered to be important for users who were on methadone especially those who have children in the house.

P 03 F: “Another issue, something that we haven’t covered in the past, is giving a message to patients on methadone and Subutex® about storage in the home.

I think, correct me if I’m wrong, there is a high incidence of methadone-related deaths around children taking the medication rather than anybody else."

8.3 Prescribers’ views

The reduced availability of street methadone following the introduction of supervised methadone was acknowledged by the majority of prescribers. Its continued availability, despite the new controls, was still seen as a problem, however, and there was a desire to further reduce its availability. The effects of supervised methadone on reducing methadone-related deaths were seen by some prescribers as very clear (see Figure 2).

S 04 F: “Yes, in our county we have got hard data to show that that happened (supervised methadone decreased methadone-related deaths).”

A contrasting view was expressed by some prescribers and emerged as a strong theme from analysis of semi-structured interviews. It was confirmed in focus groups:

S 05 F: “The other thing about methadone deaths is the issue of how much the trace of methadone was in the deaths. Is methadone the actual big cause in this?" 

G 01 I: “If somebody dies while using methadone, how precise can you be about what it was that killed them if there is evidence that they may have overdosed on opiates?”

Prescribers viewed the availability on the streets of drugs other than methadone as an important factor in drug-related deaths. Drugs such as benzodiazepines, which might increase the risk of death in those misusing methadone, were thought to be widely available (see Table 4).
8.4 Epidemiological evidence

Analysis of deaths of patients treated in the North Staffordshire addiction services was undertaken by linking the methadone treatment database, which contains data on all prescriptions issued for methadone in the addiction unit from 1993 to date, with the NHS electronic death certificate system, which is available from 1996 onwards. Of the 2,376 individuals treated at the addiction unit over this period, 51 had died. Twenty-eight of these had died from drug toxicity, the majority (25) having died from heroin overdose or heroin plus other medications. Only three had died from methadone overdose or methadone combined with other drugs (see Table 5).

While the overall death rate and the drug-related deaths for this group show a decline between the years 1996 and 2003, the number of methadone-related deaths was too small to allow analysis. The proportion of methadone-related deaths to all drug-related deaths (10.7 per cent) was found to be similar to the range seen in national statistics over a similar time period (mean 10.2 per cent: ONS data 1997–2001).

Analysis of deaths of patients treated in Shropshire for the period 1997–2004 was undertaken using data on drug-related deaths supplied by Shropshire PCT. There were a total of 30 deaths during this period, with 12 being methadone-related (see figure 3). Eleven of the 12 deaths were in the period 1997–2000. Only one methadone-related death was reported as occurring after the commencement of supervised methadone in Shropshire. An analysis of this case indicated that this was a death from natural causes in a person who was prescribed methadone; the death was not related to the methadone.

The numbers of methadone-related deaths are not at a level that would allow statistical analysis of the observed trend in Staffordshire and Shropshire towards a reduction in methadone-related deaths. A review of these figures on an ongoing basis would be able to confirm whether the reduction was consistent.

Amalgamation of the data from Staffordshire and Shropshire shows that, in the three years since introduction of supervised methadone, there have been no methadone-related deaths in the treatment population, compared with four in the three years prior to supervised methadone and ten in the three years prior to that.

Drug-related deaths, other than those related to methadone, in those known to treatment services in North Staffordshire and Shropshire, have remained constant over the period 1997–2003 (see Figure 3). There is no evidence of any increase in these

<table>
<thead>
<tr>
<th>Substances and concomitants</th>
<th>Number of deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heroin</td>
<td>13</td>
</tr>
<tr>
<td>Heroin + alcohol</td>
<td>4</td>
</tr>
<tr>
<td>Heroin + cocaine</td>
<td>1</td>
</tr>
<tr>
<td>Heroin + diazepam</td>
<td>4</td>
</tr>
<tr>
<td>Heroin + dihydrocodeine</td>
<td>1</td>
</tr>
<tr>
<td>Heroin + thioridazine</td>
<td>1</td>
</tr>
<tr>
<td>Methadone</td>
<td>1</td>
</tr>
<tr>
<td>Methadone + heroin</td>
<td>1</td>
</tr>
<tr>
<td>Methadone + diazepam + thioridazine</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 5: Drug-related deaths 1996–2003 (patients known to treatment services in North Staffordshire)
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deads following the reduced availability of methadone due to the supervised methadone schemes.

The national substance misuse deaths database (NP-SAD) was used to provide data on deaths reported by coroners for the North Staffordshire and Shropshire areas. The data in this system were subject to limitations in terms of the consistency of reporting and the fact that the cause of death recorded is not always based on toxicological analysis. The available data for 1999–2003 did not show any fall in drug-related deaths following the introduction of supervised methadone. Comparison with the deaths of those known to treatment services showed that the national figures are on average 50 per cent greater than the figures derived from treatment services.

Analysis of the deaths due to drug toxicity in patients known to treatment services in Staffordshire and Shropshire shows that the majority were male (93 per cent) and that the mean age of the group at death was 27.8 years (range 1–47 years). Deaths related to methadone were more likely to occur at weekends (42.8 per cent) compared with death from other drugs (22.7 per cent).

8.5 Analysis of deaths of patients known to treatment services in North Staffordshire

Data for this analysis were drawn from the linkage of the North Staffordshire methadone treatment database (1993–2005) to the North Staffordshire health information system. This allowed accurate identification of service contacts and prescribing information to be linked with the electronic death certificate. Of the 51 deaths identified over the period 1993–2003, 28 of these were classified as due to drug toxicity.

8.6 Time interval between last service contact and occasion of drug-related death

None of the deaths relating to drug toxicity in North Staffordshire was in contact with the prescribing service at the time of death. Seven cases (25 per cent) were in receipt of a methadone prescription in the six months prior to their death, and a further 26 per cent had been prescribed methadone between six and 12 months prior to their death. The remainder had been prescribed three to nine years previously.

8.7 Methadone dose and dispensing arrangements

The mean of the last methadone dose for this group was 40mg (SD=14.5, range 5–65). A review of the prescribing database showed that all had been on a reducing dose at the time of their last prescription. The methadone prescription at the time of the last prescription was being dispensed on a daily basis in 25 cases and weekly in three cases. One case had been assessed for treatment but had not attended for a prescription. Of the 28 cases, three had been on supervised methadone during their last prescribing episode, the remainder had been on unsupervised consumption.

9 Positive and negative factors in the supervised methadone system

9.1 Users’ views

The majority view of users from analysis of attitude scores indicated that supervised methadone was on the whole seen in a positive way. Around two-thirds of the respondents (68 per cent) understood the need for supervised methadone, with the majority (61 per cent) expressing the view that everyone should be on a supervised prescription at first. These positive views were reflected both in interviews and focus groups.

U 04 I: “It has been good because it has helped me to cut down. I’m not in much trouble or anything like that: that’s it really.”

Analysis of the negative aspects of supervised methadone from a user’s perspective showed a series of themes which were consistent from questionnaires and interviews and confirmed in focus groups. These included:

• Lack of confidentiality
• Lack of privacy for consumption
• Inflexibility of consumption times
• Inability to consume the methadone in split dose or variable times
• Conflict with regular work or education
• Conflict between drug testing and treatment order clinics (DTTO) attendance and attending the pharmacy
• Impact on the individual’s self-image.

9.2 Pharmacists’ views

Of the respondents who completed the questionnaire, 77.4 per cent agreed that dispensing controlled drugs as part of a maintenance programme was within a pharmacist’s professional remit (9.4 per cent uncertain, 13.2 per cent disagree). As for the location for supervised consumption of controlled drugs, less than half of respondents (43.4 per cent) believed that it should be done through community pharmacies rather than a central clinic, while 35 per cent of respondents disagreed and 19.8 per cent were unsure. Working with methadone patients was found to be satisfying by 48.1 per cent of respondents and the remainder were equally uncertain and disagreeing.

Supervised methadone was believed to give many benefits for service users, as expressed by respondents in semi-structured interviews.
P 06 I: “Some of them have gone from being supervised to do it all on their own, without being supervised. They take it home and they have been trusted and come in and say: ‘We can cope really well’.”

The relatively limited involvement of pharmacists in the wider clinical team providing the management of the patient was a strong theme emerging from the study.

P 02 I: “Basically it’s just a physical act where they drink the methadone and they do, so being a pharmacist is irrelevant in a way, on that score anyway. You could have any person doing that, couldn’t you? Just to have it supervised.”

The concept of an extended role for the pharmacist was explored in the interviews and focus groups.

P 02 I: “Possibly we could try to be more flexible with the doses. For instance, if they came in with 40ml and wanted to come down and off it, I would ask if they were serious about this and then I would drop them down by 5ml. We should perhaps have the power to do that: to be more proactive, as it were.”

9.3 Prescribers’ views

The prescribers’ views on the positive aspects of supervised methadone can be classified into two main groupings from analysis of the semi-structured interviews: patient safety and prescriber safety. The validity of these groupings was demonstrated in the focus groups analysis. Supervised methadone was seen as providing stability and structure for the user, with an increase in patient safety. Prescribers viewed supervised methadone as a system that gave them increased confidence in their prescribing and was seen as a factor that has encouraged some GPs to move into prescribing.

S 05 F: “It is increasing our confidence. I don’t know that shared care in general practice would be sustainable now without daily supervised. Daily supervised gives GPs the confidence to start a script, especially when they are inexperienced, and feel happy that some of these persons are getting the right dose. So with no daily supervised I think there would be only specialists now.”

S 03 I: “I suppose I’m aware that supervised methadone is as much for me as for them. But that is OK. If I’m going to do this I have to be comfortable with it.”

Prescribers were also aware of the negative aspects of supervised methadone from a user’s perspective. Themes that were identified mirrored those derived from the analysis of user responses and included privacy, confidentiality, inflexibility of consumption times, and conflict with work or education.

Figure 4: Drug-related deaths (all causes) – np-SAD data for North Staffordshire and Shropshire

Additional points were that for some patients there is a need for a seven-days-a-week supervised scheme rather than the current five days with the weekend dose being unsupervised, and the necessity of provision of supervision during national holiday periods.

The balance between the positive and negative aspects was seen as a key issue to improving acceptability of the schemes.

10 Client preferences and needs

Opinions on preferences and needs of users were gathered from the “further information” section in the questionnaire and a question on recommendations for service improvement in the semi-structured interviews and focus group.

10.1 Views on service improvements

Based on patient’s improvement, the consumption system could be more flexible with regards to split doses or variable times:

U 224 Q: “Some people shouldn’t be given supervised methadone, because you don’t necessarily need it in one go and you could use half in the morning and half at night-time when you need it most.”

The clinics need to be more organised and employ more staff so that patients can have one-to-one service instead of viewing users as a big group:

U 03 I: “And when they see you they will take you to one side and will say ‘such-and-such is going on’ and ‘are you getting back together’ and everything. They will make that kind of time, but the time is very precious, obviously, so they can’t spend too much time with you. Obviously, if there is more staff they are able to do more of that …”
The opening times of the chemists should be more flexible for methadone patients especially for those who have jobs and appointments at drug testing and treatment order clinics (DTTO):

U 01 F: “Like I say, the only problem is some mornings. They’ve got 9.30 groups here (the DTTO) and they don’t give the methadone till after ten o’clock. So that is the only problem: when you have to go to a group, you can’t get your methadone.”

U 95 Q: “If you’re at work, you should be allocated a certain time during the dinner hour.”

Information such as leaflets, booklets and posters for users should be more readily available, especially on methadone for treatment and its effects for new users who have just started on methadone. Information on how to get involved in the system (the clinic systems, obtaining prescriptions and access to rehabilitation) and guidance for users’ families were also seen as useful. Community pharmacies, doctors’ surgeries, hospitals, health centres and police stations were some places the users recommended as sites for information provision:

U 01 F: “When you first start taking your methadone, they don’t give you any leaflets on what it is about and what’s the effects, what’s happening, really.”

A separate room or area in community pharmacies to consume methadone was an important feature of the system:

U 02 F: “I was at a chemist at [location] where I went into a little separate room; nobody could see what I was doing. But that was just a small chemist. Now I’m at the [pharmacy name] chemist at [location] where there was no separate room, like I say, everybody looks at you like you’ve got two heads.”

10.2 Views on key issues

10.2.1 Parenting

Users who had children felt stigmatised by the community and would prefer to be able to collect methadone every few days, rather than being supervised daily:

U 12 I: “Because it’s not always that easy to tell, you can take the wrong way in that. It doesn’t make them bad parents. I have my daughter with me and never want her to see anything. She got interviewed: never, ever did she see anything. It doesn’t always have to be that kids suffer. I’m not saying that it is a good thing to do, but my kids don’t suffer at all.”

10.2.2 Employment

Having to come to the chemist’s at certain times every day was found difficult by users if they wanted to have or keep a job:

U 03 I: “Like I say, it’s just the only problem I have with it is, like, I can’t work when I want to. I haven’t always wanted to work, but there have been times when I had to turn jobs down because I’m on supervised script and stuff. So that’s the only problem I can really see with it.”

10.2.3 Confidentiality

From the questionnaire, it was found that 66 per cent of respondents thought that other customers knew why they came to the chemist. In addition, 55 per cent of respondents found it embarrassing to take methadone at the chemists. Similar views had been indicated in semi-structured interviews and focus groups, with an emphasis on meeting people they knew at the pharmacy when they took their methadone. A separate room at the pharmacy was seen as useful, although the experience still caused negative feelings:

U 06 I: “Everyone knows what you do if you walk in a pharmacist and the pharmacist takes a bottle, gives it to me and says ’see you later’. You don’t know anybody else who does that, do you? People will know what you’re doing. And if one of my family comes through the door and sees it…”

11 Quantitative information derived from the study

11.1 Positive users’ attitude towards supervised methadone

A derived attitude score was determined for users from selected items in the user questionnaire. This score was then used to investigate relationships between other variables and positive attitude.

Analysis of the questionnaire data was undertaken to identify variables which might predict a positive user attitude towards supervised methadone schemes. The majority of variables analysed had no significant effect.

- Multiple linear regression analysis showed that sex, age, and status of employment did not account for a significant proportion of the variability in attitude score
- Number of years of using illegal drugs and length of methadone supervision also failed to explain variance in attitude score
- Time needed to arrive at the pharmacy and the physical location of the pharmacy were not significantly associated with attitude score
- No significant difference was found in attitude score of respondents across different clinics and DAT areas
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• No significant difference was found in attitude score towards the statement: “I know people who were not on prescriptions who have died using street methadone” when analysis was carried out among users’ location (Staffordshire and Shropshire).

Only one variable showed a significant effect; the type of pharmacy (single independent pharmacy shop compared with other types of pharmacy) predicted variance in attitude score (p=0.010) with 1.7 per cent of adjusted R-squared (see Table 6). Users attending large pharmacies were significantly more likely to have a positive attitude then those attending single independent pharmacies.

12 The role of drug action teams

12.1 Policy documents

A review of the DAT guidelines and policy documents indicated that they were closely based on the recommendations in Drug Misuse and Dependence – Guidelines on Clinical Management and the report by the Advisory Council on the Misuse of Drugs on reducing drug-related deaths. The main areas in existing guidelines and protocols concerned the documentation associated with the process of supervision including patient contracts, recording of dispensing and procedures for observing consumption. Protocols indicated the circumstances that required the pharmacist to contact the prescriber, including breach of contract, failure to attend and requests for help that the pharmacist was unable to meet.

One of the four policy documents had been authored jointly by the DAT and the local specialist addiction service the remainder were issued by the DATs in conjunction with the local pharmaceutical committee (LPC).

12.2 DAT views

A web-based survey of participating DATs indicated that the communication between prescribers and pharmacists was felt to be adequate but that there had been no formal audits of communication. The DATs’ views of the value of supervised methadone mirrored the national opinion that it reduced the street availability of methadone and the number of drug-related deaths. There was little service user involvement in the design of the schemes, although there was evidence of user involvement in related training.

The problems which DATs perceived in managing supervised methadone schemes were consistent with the themes which emerged from the main body of the study.

• Ensuring standards are maintained i.e. private areas for consumption
• Ensuring good geographical coverage to reduce overloading pharmacies
• The administrative load involved in administrating and auditing the schemes.

13 Study limitations

The findings of this study are subject to the limitations imposed by the methodology and the reliability of the data particularly with regards to both national and local drug-related death figures.

The low response rate of general practitioners means that the GP data in particular may not generalise to those who did not respond.

Some participants in semi-structured interviews and focus groups participants were selected based on convenience rather than on theoretical background, which might have caused bias in the analysis.

The study is based on data from Staffordshire and Shropshire and generalisation should be carried out with caution.

14 Conclusions

The concept of the introduction of supervised methadone schemes into the DAT areas covered in this study had been met with a positive response from the majority of users, pharmacists, prescribers and policy makers. The current study showed, however, that there was a variability of consistency in the practical implementation of the scheme. The issues of privacy,
confidentiality and flexibility were a shared concern amongst all the respondents. The result of this variability was that the positive attitude of the users towards the concept of the scheme was not translated into enthusiasm for the reality of the scheme.

The findings of the study showed that a positive user attitude towards supervised methadone was not determined by variables such as sex, age, employment status or length of drug using career. Users’ experiences of supervised methadone consumption, whilst not universally positive were based on an understanding of the need for supervision. Many users acknowledged that the help and support of the system had enabled them to maintain stability. Addressing the negative aspects of supervision, which included lack of confidentiality, lack of privacy and inflexibility of the system, was seen by users as a key to improving the user experience of supervision.

14.1 Methadone-related deaths

The introduction of supervised methadone schemes in Staffordshire and Shropshire has resulted in a reduction in death related to methadone. Those methadone-related deaths which do occur are often in association with the use of a combination of drugs including benzodiazepines.

Analysis of the causes of death recorded on death certificates is acknowledged to lack consistency (Scottish Executive, 2005) and the classification in the cases reported here did not normally rely on toxicology results. The lack of a standardised system for recording the key factors in drug-related death on death certificates introduces significant limitations to the interpretation of the data.

The finding that methadone-related deaths are more likely to occur at weekends has been reported in a larger study of drug-related deaths in Scotland (Scottish Executive, 2005). Respondents in this study raised concerns that the lack of supervision of methadone over weekends was a risk. There is, however, no clear evidence as to whether this has a direct effect on the observed higher incidence at weekends.

The majority of drug-related deaths in those known to treatment services in this study occurred within 12 months of ending contact with prescribing services. The majority were on a decreasing dose at the point of discharge from treatment but had not completed the planned decreasing regime. The commonest reason for cessation of prescribing was continued opiate use.

14.2 Improving the quality of supervised methadone schemes

14.2.1 The role of the pharmacist

The majority of pharmacists viewed supervision of methadone as an acceptable part of their remit but there was not universal acceptance that pharmacies should be the sole site for methadone dispensing. Some pharmacists saw the possibility of central dispensing clinics for some users as a measure that would reduce the increasing load on existing dispensers.

• The minimal level of involvement in supervision – only observing ingestion of the methadone – was seen by some pharmacists to be irrelevant to their professional expertise and could be performed by a less-qualified person.

• The possibility of an expansion of the role of the pharmacist to include negotiated dose changes with the user was perceived as a more appropriate use of the pharmacist’s skills by some respondents.

• The development of a system for an expanded role for the pharmacist as part of an integrated team would utilise the important skills of the pharmacist to a greater degree than at present.

• The concept of the “specialist pharmacist” as a support for “generalists” should be explored to deliver clinical support and mentoring for pharmacists involved in supervised methadone schemes.

14.3 The extended treatment team

The concept of an extended treatment team including primary care, secondary care and pharmacists did not feature as an expectation either of the DATs or the professionals or users involved in the scheme. There was an agreement from focus groups that better liaison between the pharmacist and the rest of the treatment team would improve the supervised methadone scheme. The level of knowledge of the potential skills and expertise of pharmacists was low, with 69 per cent of GPs in an internet focus group (n=16) acknowledging that they were not fully aware of what skills and expertise a pharmacist could offer with regard to supervised methadone. The views of specialist prescribers on the extension of the pharmacist role were also explored in focus groups and issues of levels of pharmacist’s competence, training and clinical supervision were seen as important to address.

14.4 Privacy and confidentiality

• A practice must match policy with regard to:
  – Privacy
  – Confidentiality
  – Information giving

• Adequate resourcing of the schemes is essential to enable privacy and dignity to be provided during consumption of methadone.
• Concerns about confidentiality for users centres on the perception that other customers are aware of why the users are in the pharmacy. This is caused by either a lack of privacy for consumption or by the provision of a room or area that is used only for methadone consumption.

• The need to provide a part of the pharmacy with “a sufficient level of privacy and safety” is one element of the service outline for supervised administration of methadone (National Primary and Care Trust Development Programme, 2005). The implementation of such a provision needs to take account of the users’ views on the potential stigma attached to the use of such areas for methadone consumption.

• A limit on the number of users who are taken on by individual pharmacists would allow a more individualised approach to be taken and improve privacy and reduce stigma.

14.5 Training

• Training of all staff involved in supervised methadone schemes is essential and should wherever possible be on an inter-professional basis to allow a shared understanding of the relevant skills and expertise of all participants.

• Training should include the management of potential violence and aggression, in addition to the key elements of knowledge of the management of drug dependency.

14.6 The planning and audit cycle

• The involvement of users in planning and audit of services would produce an immediate benefit to DATs in developing service provision.

• Audit of supervised methadone schemes should be based on a multi-professional audit tool which identifies gaps between policy and practice within the whole system from policy making to methadone consumption.

15 Implications for further research and development

• A pilot of a service using a wider team concept with a multi-professional steering group including users and carers.

• The production of a model for inter-professional training schemes by a group with representatives of the appropriate royal colleges and professional bodies should be considered.

• The development of a cross-professional audit tool based on the key findings of the current study, as an aid to quality improvement and monitoring of supervised methadone schemes.

• The development of alternative non-pharmacy based models for supervised consumption, such as centralised dispensing clinics for users who require a more intensive level of supervision or who require a more flexible dosing pattern.

• The development of a standardised recording system and nomenclature for drug related deaths would improve the evaluation of the effectiveness of service improvements in reducing drug-related deaths.

16 References


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