Does methadone maintenance treatment based on the new national guidelines work in a primary care setting?

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SUMMARY
Background: General practitioners (GPs) are being encouraged to treat more drug users but there are few studies to demonstrate the effectiveness of primary care treatment.

Aim: To determine whether patients retained on methadone maintenance treatment for one year in a modern British primary care setting, with prescribing protocols based on the new national guidelines, can achieve similar harm reduction outcomes to those demonstrated in other settings, using objective outcome measures where available.

Design of study: Longitudinal cohort study.

Setting: The Primary Care Clinic for Drug Dependence, Sheffield.

Method: The intervention consisted of a methadone maintenance treatment provided by GPs with prescribing protocols based on the 1999 national guidelines. The first 96 eligible consenting patients entering treatment were recruited; 65 completed the study. Outcome measures were current drug use, HIV risk-taking behaviour, social functioning, criminal activity, and mental and physical health, supplemented by urinalysis and criminal record data.

Results: Frequency of heroin use was reduced from a mean of 3.02 episodes per day (standard deviation [SD] = 1.73) to a mean of 0.22 episodes per day (SD = 0.54), (\(\chi^2 = 79.48\), degrees of freedom \(df = 2\), \(P<0.001\)), confirmed by urinalysis. Mean numbers of convictions and cautions were reduced by 62% (\(z = 3.378\), \(P<0.001\)), for all crime. HIV risk-taking behaviour, social functioning, and physical and psychological wellbeing all showed significant improvements.

Conclusion: Patients retained on methadone maintenance treatment for one year in a primary care setting can achieve improvements on a range of harm reduction outcomes similar to those shown by studies in other, often more highly structured programmes.

Keywords: heroin; addiction; methadone maintenance treatment; primary care.

Original papers
drug dependence.7 These guidelines and the associated launch of the new national guidelines for the treatment of secondary care service in the city. years previously to the overstretched consultant-led service was the existing waiting list of long-term heroin users, some of whom had been referred more than two months, and 12 months. followed up for one year and interviewed at baseline, three months, and 12 months.

Method
Setting
In Sheffield prior to 1999, in common with many other areas,16,17 there was a very low level of interest among GPs in undertaking work with drug users. In order to break through this barrier, a primary care clinic was set up in 1999, led by GPs with a special interest (Box 1) and supported by a city-wide pharmacy scheme to dispense methadone with or without supervision. The main target group for the new service was the existing waiting list of long-term heroin users, some of whom had been referred more than two years previously to the overstretched consultant-led secondary care service in the city.

The new clinic opened in April 1999, shortly after the launch of the new national guidelines for the treatment of drug dependence.7 These guidelines and the associated research evidence were used as the basis of the clinical protocols for the clinic18-26 (Box 2).

In accordance with the primary care emphasis of the clinic, after an initial nursing assessment patients received ‘case working’ almost exclusively through their 10-minute doctor consultations. On the other hand, a well-developed pharmacy scheme was available to support the clinic so that doses of methadone could be dispensed under daily supervision with a system of reporting back missed doses and other problems to the prescriber.

Study design
This study employed a longitudinal design. The cohort was followed up for one year and interviewed at baseline, three months, and 12 months.

Ethics
The study was approved by the South Sheffield Research Ethics Committee.

What does this paper add?
This study uses urinalysis and criminal record data to supplement self-reporting in a UK primary care setting with prescribing protocols based on the 1999 national guidelines. It shows that, in this setting and using objective outcome data, methadone maintenance treatment is effective in reducing illicit drug use, reducing crime, and producing improvements on a range of harm reduction outcomes.

What do we know?
Drug dependence treatment has been shown in a number of studies to reduce illicit drug use, crime, and risk-taking behaviour among heroin users, and to improve mental and physical health. Most of these studies were, however, carried out in highly structured programmes very unlike the modern pragmatic model of methadone prescribing that is current in the United Kingdom, and many of them rely heavily on self-reported data.

How this fits in
Harm reduction rather than abstinence-based approach 24-26 Adequate doses of methadone prescribed 20-23 Emphasis on retention in treatment18,19 No tablets or injectables prescribed • Widespread use of supervised dispensing • Prescribing within licensed indications of medication • Avoidance of benzodiazepine prescribing • United Kingdom modified Opiate Treatment Index • Emphasis on retention in treatment18,19 • Adequate doses of methadone prescribed20-23 • Harm reduction rather than abstinence-based approach24-26

Participants
Following a pilot study of patients retained in a general practice setting,27 it was estimated that approximately 50 cases would be adequate to demonstrate a treatment effect. Anticipating a drop-out rate of up to 50%,1 which has been demonstrated in other recent research,13,28 it was decided to recruit approximately the first 100 consenting patients entering treatment from the waiting list. To be eligible for inclusion in the study, participants were required to be over 18 years of age, addicted to heroin, with no existing co-morbid psychiatric diagnosis, no concurrent serious physical illness, not pregnant, with no contraindications to methadone, and not currently in methadone treatment. Addiction to heroin was established by a nurse specialist during assessment and was confirmed by drug-using history, clinical examination, and urinalysis. No patient who met the inclusion criteria refused to participate. Ninety-six patients were finally recruited to the study.

Measures
United Kingdom modified Opiate Treatment Index. The Opiate Treatment Index assesses current drug use, HIV risk-taking behaviour, social functioning, criminality, and health and psychological wellbeing, using an interviewer-administered questionnaire.29 The version used for this study has been modified and validated for use in the UK.30
**Objective measures.** In addition to the self-reported outcomes measured by the Opiate Treatment Index, urinalysis results were collected to show illicit drug use, and criminal records were identified. Convictions and cautions in the 12-month period prior to entry into treatment were compared with those for the first 12 months in treatment. Crimes were broken down into categories: acquisitive crimes (crimes such as shoplifting, burglary, fraud), drug-related crimes (such as possession or dealing), and other crimes (typically driving offences or failure to attend court).

**Interview procedure**

Participants were interviewed on a total of three occasions to coincide with their routine clinic appointments. The first interview took place before treatment started. The next interview took place three months after the start of treatment and the final interview was then carried out after 12 months in treatment. All interviews were conducted by a team of researchers who were trained to apply standardised interview techniques.31

**Data collection procedure**

Results of urine tests were extracted from clinical records and in each case the sample provided on the actual date or within two weeks of the interview was used for analysis. Information on convictions and cautions was extracted from the criminal records of participants provided by South Yorkshire Police.

**Results**

Ninety-six eligible patients were recruited to the study and entered treatment. Eighty-four were still in treatment at three months and 81 completed three-month interviews. Of these, 68 were still in treatment at 12 months, of whom 65 completed the final interview. Twenty-five participants left the study after dropping out of treatment; of these, 13 were discharged from the clinic after failing to attend appointments, two went to prison, two moved away, two were discharged for poor compliance, and six were discharged drug-free. A further six patients were lost to the study after being repeatedly missed by the researcher when they came to the clinic for their appointments. There were no statistically significant differences between those who dropped out of treatment and those who remained in treatment for one year in terms of demographic characteristics or baseline measures.

**Sample characteristics**

The final cohort comprised 65 participants, 82% of whom were male, with a mean age at study intake of 28 years (SD [standard deviation] = 6 years). The majority of participants were white (97%), single (60%), and unemployed (85%). Fifty-four per cent had previously spent some time in custody. Mean age at first daily heroin use was 20 years (SD = 4 years) with a mean number of years of using heroin of 10 (SD = 6 years).

**Drug use outcomes**

**Heroin.** Substantial reductions in the frequency of heroin use were seen with respect to both the self-reported scores and urinalysis results (Table 1). Over the 12-month period a highly significant reduction was seen in the number of heroin use episodes per day, from 3.02 (SD = 1.73) to 0.22 (SD = 0.54) (Friedman $\chi^2_r = 79.48$, df [degrees of freedom] = 2, $P<0.001$).

**Other drugs.** Similar improvements were also seen in the self-reported use of cocaine, benzodiazepines and other illicit opiates (Table 1), although despite reasonable concordance, the proportion of positive urinalysis tests for cocaine and benzodiazepines did not change significantly.

**Crime**

**Convictions and cautions (from criminal records).** In the 12 months prior to the commencement of treatment the mean number of convictions and cautions received by the cohort was 3.14. This fell by 62% to 1.21 for the year post-treatment. Convictions and cautions for acquisitive crime fell by 69%, from 1.69 per year to 0.52 per year; those for drug-related crime fell by 83% and those for other crime (such as driving offences) fell by 33%. With the exception of ‘other crime’, all reductions were statistically significant (Figure 1).

**Criminal activity (self-reported).** Only property crime was disclosed as being committed at a level high enough for subsequent analysis. Forty-nine per cent of the cohort admitted to carrying out a property crime in the month preceding the initial interview, falling to 10% at three months and 5% after one year (Cochrane’s Q = 36.64, df = 2, $P<0.001$).

**Other outcomes**

**HIV risk-taking behaviour and social functioning.** Significant improvements in overall HIV risk-taking behaviour were observed (Table 2). The improvement in risk-taking behaviour was owing to improvements in injecting drug use ($\chi^2_r = 48.92$, df = 2, $P<0.001$) rather than sexual behaviour, which did not change. At the baseline interview 80% of the cohort had injected one or more drugs in the previous month, falling to 43% after three months and 36% after one year in treatment ($\chi^2_r = 63.24$, df = 2, $P<0.001$).

**Social functioning.** Similar improvements were seen with respect to social functioning (Table 2). Sixty-two per cent of the cohort reported that more than half of their associates were illicit drug users at intake, falling to 21% at three months and 12% at one year.

**Physical and psychological (GHQ-28) wellbeing.** Six of the eight physical health categories of the Opiate Treatment Index showed significant reductions in morbidity (Table 3). Overall, physical health showed a 46% improvement at both three and 12 months. Significant differences were also observed for all GHQ-28 subsections, with anxiety, depression, social dysfunction, and somatic symptoms all improving substantially.
Discussion

These results confirm that methadone maintenance treatment, when prescribed in accordance with the 1999 national guidelines, is associated with highly significant improvements in illicit drug use, risk-taking behaviour, crime, and physical and mental health, and that this can be achieved in a primary care clinic setting. Outcomes based on self-reporting are substantiated in this study with urinalysis and criminal record data.

This study looks at the early stages of development of a GP-led service providing methadone maintenance treatment for heroin users. Ideally, services might provide a range of counselling and support services for patients and elements of shared care with other services, but in the early days of the Sheffield service none of these options were available on a regular basis and the study therefore looks almost exclusively at the effects of methadone treatment itself.

The most striking thing about the results is that, in spite of the relative lack of support services and case working, experienced GPs prescribing methadone on a harm reduction basis and with the support of a well organised pharmacy...
scheme, were able to produce significant harm reduction outcomes for patients retained within the programme. As is the case with other recent studies in the field, randomisation of participants to a control group could not be considered ethically acceptable. The study of a cohort with repeated measures has for this reason been widely used in studies of this kind.\textsuperscript{13,15}

The focus of this study is on the harm reduction effect of long-term maintenance treatment and outcomes for the cohort who succeeded in remaining in treatment. Those who dropped out of treatment were therefore not followed up, although it is notable that the attrition rates were in fact unusually low (see below) and a number of patients left treatment because they were drug-free.

The harm reduction outcomes demonstrated in this study reflect those found in different primary care settings by the National Treatment Outcomes Study (NTORS)\textsuperscript{15,28} and the Glasgow scheme\textsuperscript{13}; and in outcome studies in a variety of other, non-primary care settings.\textsuperscript{1-3,10,18} This may lend weight to the suggestion that the core element of such programmes, the methadone treatment itself, is a major determinant in harm reduction irrespective of other elements of treatment. It has been noted by other commentators\textsuperscript{32} that, as in this study, many of the major improvements seen in methadone maintenance treatment become apparent as early as three months into treatment.

\begin{table}
\centering
\caption{HIV risk-taking behaviour and social functioning subscale scores.}
\begin{tabular}{|l|c|c|c|c|}
\hline
 & \textbf{HIV risk-taking behaviour scale (HRBS)} & \\
 & \textbf{Baseline} & \textbf{Three months} & \textbf{12 months} & \\
 & \textbf{SD} & \textbf{SD} & \textbf{SD} & \textbf{Statistical tests ($P$-value)} & \\
\hline
\textbf{HRBS} & \\
Total score,\textsuperscript{a} mean (SD) & 9.98 (6.84) & 5.20 (5.15) & 5.50 (5.17) & <0.001 \\
Drug use, mean (SD) & 6.47 (5.52) & 1.90 (3.14) & 1.47 (3.24) & <0.001 \\
Sexual activity, mean (SD) & 3.52 (4.28) & 3.30 (4.39) & 4.03 (3.89) & 0.320 \\
\hline
Number of times injected drugs within the last month, \textit{n} (%) & \\
None & 13 (20) & 35 (57) & 41 (64) & <0.001 \\
Less than once a day & 9 (14) & 23 (38) & 17 (27) & \\
More than once a day & 42 (66) & 3 (5) & 6 (9) & \\
\hline
Social functioning & \\
Social functioning score,\textsuperscript{b} mean (SD) & 23.48 (7.19) & 17.40 (6.24) & 16.00 (6.18) & <0.001 \\
\hline
Proportion of associates who are illicit drug users \textit{n} (%) & \\
None & 12 (19) & 32 (52) & 41 (64) & <0.001 \\
Less than half & 12 (19) & 17 (27) & 15 (23) & \\
More than half & 39 (62) & 13 (21) & 8 (12) & \\
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\begin{table}
\centering
\caption{Mean physical and psychological wellbeing scores.}
\begin{tabular}{|l|c|c|c|c|}
\hline
 & \textbf{Baseline} & \textbf{Three months} & \textbf{12 months} & \textbf{Significance level ($P$-value)} & \\
 & \textbf{(SD)} & \textbf{(SD)} & \textbf{(SD)} & \\
\hline
\textbf{Mean physical health scores} & \\
General health & 6.83 (2.41) & 4.02 (2.51) & 3.72 (2.40) & <0.01 \\
Genitourinary & 0.67 (0.67) & 0.57 (0.59) & 0.47 (0.54) & NS (>0.05) \\
Gynaecological \textit{(n = 12)} & 0.67 (0.49) & 0.67 (0.65) & 0.42 (0.51) & NS (>0.05) \\
Cardiorespiratory & 4.17 (2.49) & 2.47 (2.05) & 2.42 (2.16) & <0.01 \\
Injection-related & 1.42 (1.27) & 0.42 (0.79) & 0.52 (0.87) & <0.01 \\
Musculoskeletal & 1.30 (0.89) & 0.65 (0.84) & 0.68 (0.75) & <0.01 \\
Neurological & 3.60 (2.30) & 2.03 (2.08) & 2.47 (2.13) & <0.01 \\
Gastrointestinal & 3.18 (1.51) & 1.38 (1.33) & 1.33 (1.22) & <0.01 \\
Total health score\textsuperscript{a} & 21.30 (7.89) & 11.67 (7.57) & 11.68 (7.16) & <0.01 \\
\hline
\textbf{GHQ-28} & \\
Anxiety & 4.13 (2.37) & 2.06 (2.30) & 2.51 (2.47) & <0.01 \\
Depression & 3.38 (2.66) & 1.02 (1.85) & 1.23 (2.12) & <0.01 \\
Social dysfunction & 3.43 (2.22) & 1.15 (1.88) & 1.55 (2.02) & <0.01 \\
Somatic symptoms & 3.28 (2.17) & 1.55 (2.00) & 1.81 (2.09) & <0.01 \\
Total score\textsuperscript{b} & 14.21 (7.77) & 5.79 (7.10) & 7.11 (7.56) & <0.001 \\
\hline
\end{tabular}
\end{table}

\textsuperscript{a}The HRBS is a composite scale of 11 questions that comprises two separate subscales (intravenous drug use and sexual activity). The range is from 0 to 55, where 0 is better. \textsuperscript{b}Social functioning score is a composite score of 12 questions in three areas — employment, residential stability, and interpersonal conflict. The range is from 0 to 48 where 0 is better.

\textsuperscript{a}The physical health scale is produced from a checklist of symptoms related to the eight categories. The total score is given by the summation of all present symptoms. The range is 0 to 52 where 0 is better. \textsuperscript{b}The GHQ-28 total score is produced by the summation of each of the four subscales. The range is from 0 to 28 where 0 is better. NS = not significant.
The primary care clinic that forms the setting for this study is part of a heterogeneous nationwide development of primary care-led schemes. It is not necessarily representative of the type of practice used by all GPs, and many primary care-led programmes now offer more shared care or psychosocial support, but it does represent one example of the modern, pragmatic approach to methadone prescribing undertaken in many UK primary care settings. The outcomes of this study support the view that GP-led schemes can deliver the harm reduction outcomes reported in studies of other, often more highly structured settings.

We can conclude that for heroin-addicted patients who are retained in methadone maintenance treatment in a primary care setting of this kind, with protocols based on the 1999 national guidelines, there is a likelihood of achieving very significant improvements on a range of outcomes, many of which affect the wider society as well as drug users themselves.

References
27. Keen J, Rowe S, Mathers N, et al. Can methadone maintenance for heroin dependent patients retained in general practice reduce...


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