DRUG & ALCOHOL FINDINGS *Research analysis*

This entry is our analysis of a study considered particularly relevant to improving outcomes from drug or alcohol interventions in the UK. The original study was not published by Findings; click Title to order a copy. Free reprints may be available from the authors – click prepared e-mail. Links to other documents. Hover over for notes. Click to highlight passage referred to. Unfold extra text The Summary conveys the findings and views expressed in the study. Below is a commentary from Drug and Alcohol Findings.



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## ▶ Does following research-derived practice guidelines improve opiate-dependent patients' outcomes under everyday practice conditions? Results of the Multisite Opiate Substitution Treatment study.

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**Journal of Substance Abuse Treatment: 2008, 34(2), p. 173–179.**

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*In everyday practice at methadone maintenance clinics and with the full range of patients, does implementing clinical guidelines lead to better outcomes for patients? Four pairs of US clinics selected for their contrasting adherence to guidelines provide evidence that the relatively high dosing and intensive psychosocial services recommended by guidelines really do make the intended difference.*

**SUMMARY** Many clinicians believe everyday practice is too variable and real-world patients too diverse for practice to be based on trials conducted under ideal conditions. Common reservations about trials and the clinical guidelines they support concern the way trials construct treatment conditions and the way they exclude some patients from participation. Opioid substitution treatment for heroin dependence exemplifies the dilemma. Rigorous randomised trials have yielded important evidence, but many frontline clinicians do not accept these trials as definitive and do not follow the practice guidelines they inform. The Multisite Opiate Substitution Treatment (MOST) study addresses this issue by evaluating whether two opioid substitution practices found efficacious in clinical trials and incorporated into guidelines improve the outcomes of typical opiate-dependent patients seen in everyday practice. The practices evaluated were dosing in the recommended range and providing psychosocial services. Although high doses of methadone and extensive psychosocial services seem well evidenced, many clinics do not provide these.

This study was conducted in the US Veterans Affairs health system for former military personnel, a federal, publicly funded network of clinics and hospitals structured not unlike many European health care systems, such as the UK's National Health Service. All 34 Veterans Affairs opioid substitution clinics US-wide were mailed a self-completion questionnaire assessing their concordance with clinical guidelines regarding doses above 60 mg of methadone a day and providing extensive psychosocial services. Dose data was directly available, but what counts as extensive psychosocial service provision is unclear. As a proxy for this variable, the study assessed the *ability* to provide those services, represented by a higher staff-to-patient ratio.

### Key points
**From summary and commentary**

The issue addressed is whether in real-world, everyday practice at methadone maintenance clinics and with the full range of patients, implementing clinical guidelines will lead to better outcomes for patients.

In four pairs of US clinics for opioid-dependent former military personnel, one in each pair was selected to be either relatively adherent to clinical guidelines recommending doses over 60 mg a day and extensive psychosocial services, or relatively less adherent.

Heroin and other substance use outcomes were better at the more guideline-concordant clinics, suggesting that treatment providers will improve and save the lives of their patients by taking these guidelines seriously and adhering to them.

The 31 responding clinics were ranked on the proportion of their patients dosed in the recommended range and the number of clinical staff available per enrolled patient. These two rankings were averaged to calculate a single rank for each clinic, reflecting its overall concordance with practice guidelines. Four urban clinics in the top half of the ranking (more guideline-concordant) and four in the bottom half (less guideline-concordant) were selected based on their being able to provide sufficient new patients and being located in four different US regions. This strategy helped reduce the chances that outcomes would be biased because different types of patient would select different clinics or attract higher doses or more services. With just 34 clinics across the country, patients must generally attend their local service, and the ranking was based not on the dose or services patients individually received, but on typical practice across each clinic's caseload.

Across the more guideline-concordant clinics, 79% of patients were prescribed in the recommended range compared to 46% at the less concordant clinics. In regard of ability to provide extensive psychosocial services, though the two set of clinics had similar average caseloads (170 in the more concordant, 154 in the less), the more concordant clinics averaged 8.7 full-time equivalent clinical staff compared to 6.4, in the less concordant.

Clinic staff explained the study to all incoming patients. Of those approached, 256 (92%) completed the baseline research interview and 232 (83%) a follow-up interview six months later. On entering treatment all participants were opiate-dependent and on average had used heroin on 22 of the past 30 days, committed crimes on 3–4 days, and worked for on average of about 7 days. At entry to treatment patients at the two sets of clinics were demographically similar and similar on the measures later used to assess their progress, except that they were on average about two years older at the less concordant clinics. To assess the relationship between their progress and the guideline-concordance of their clinics, at baseline and six months later patients were asked about the number of days over the past 30 they had used heroin, committed crimes other than drug use, or been employed. Their mental health was also assessed and past-month urine test results were available at the six-month follow-up for those still in treatment. Results were adjusted for the influence of the region the clinics were in, the patient's age, and the clustering of patients within clinics.

## Main findings

Patients in the more guideline-concordant clinics reduced their days of heroin use by 2.9 more days per month (from 23.0 to 2.8 days per month) than did their counterparts in the less concordant clinics, and their mental health improved more, both statistically significant differences. There were no significant differences in improvement in employment or crime. Among the 164 patients still in treatment and providing urine samples, during the last month of the follow-up the proportion of patients whose tests were free of illicit opiates was significantly higher in the more versus less concordant clinics (61% versus 40%), corroborating the interview findings. Assuming all missed tests were opiate-positive, the difference in favour of the more concordant clinics remained similar.

Outcomes also assessed included alcohol and cocaine use, social functioning, pain and other medical problems, high-risk injection practices, and satisfaction with treatment. Again, the more concordant clinics were associated with better results; 60% of these measures favoured them and the remainder were comparable with those in less concordant clinics.

## The authors' conclusions

Under everyday practice conditions, the MOST study demonstrated the clinical utility of guidelines supported by evidence from research trials. Within the range of real-world practice variation and with unselected and often severely impaired patients, opioid substitute treatment clinics which prescribed more patients in the clinically recommended range and provided more psychosocial services had significantly better substance use and mental health outcomes. The findings suggests that efforts to increase adherence to clinical practice guidelines through measures such as policy changes, performance incentives, and training programmes, will have a positive impact on opioid substitute patients, and that treatment providers will improve and save the lives of their patients by taking these guidelines seriously and adhering to them.

These implications rest on the assumption that the outcomes were attributable to differences in the degree of guideline concordance between the two sets of clinics, but it has to be acknowledged that other factors may have contributed to the results. One possibility is that the clinics attracted different kinds of patients. However, of the measures taken at entry into treatment, patients only significantly differed in age, a difference unlikely to have produced the observed results because age was on average slightly higher at the less concordant clinics, yet older age is associated with better opioid substitute treatment outcomes.

Informal observations suggested that clinics which implemented practice guidelines in an orderly and efficient manner completed most work tasks in the same manner. In contrast, in their interactions with the research team, less concordant clinics were generally less efficient and seemed less able to maintain a steady flow of new patients. It cannot be said that these aspects of work culture helped cause the outcomes, but this observation does at least suggest that efforts to promote implementation of practice guidelines may require changes in other aspects of work culture. Non-concordant clinics also tended to favour withdrawing patients from methadone when possible or terminating treatment in response to infractions.

## Other findings from the study

A cost-effectiveness analysis extended the findings to 12 months after treatment entry, when the proportion of patients treated at the more guideline-concordant clinics who had not used heroin in the past month remained significantly higher (73% versus 54%). Health-related quality of life had also

significantly improved at the more guideline-concordant clinics but not ar the less concordant. A slightly and non-significantly lower proportion of patients had died at the more concordant clinics. Over the year patients were retained longer at the more concordant clinics – on average 8.4 months versus 6.6.

This report confirmed that psychosocial service provision had been more intense at the more concordant clinics, contributing to the fact that per new patient treatment costs over the follow-up year were just over 50% higher than at the less concordant. A major difference was in the provision of group therapy. New patients at the more concordant clinics attended on average 37 group therapy sessions during the follow-up year, significantly more than the 13 at less concordant clinics. The more concordant clinics also provided slightly but significantly more (17.5 versus 16.9) individual therapy sessions. External medical and other care costs did not significantly differ, but the higher cost of treatment meant that over the year total costs per patient were 48% higher ($23,468 versus $15,878) at the more guideline-concordant clinics.

Treatment costs were combined with the estimate that over the follow-up year each patient treated at the more concordant clinics was opiate-free for 334 days compared to 304 at less concordant clinics. The resulting estimate was that each extra opiate-free day gained by providing more concordant treatment cost $126 in extra treatment costs, or $102 if missing data was considered indicative of relapse to opiate use.

Dose was the focus of a report on the patients prescribed only daily methadone and not the long-acting version (LAAM) no longer being prescribed. Of the 222 patients, urine tests indicated that over the follow-up year 168 had gone at least a month without tests indicate heroin use. Nearly 40% had achieved this while prescribed less than the recommended 60 mg a day, and doses ranged from 1.5 to 191 mg, indicating that the absolute dose level was not critical, but rather its adequacy for the individual. However, compared to non-achievers, on average abstinence-achievers were prescribed higher doses and were especially more likely to be prescribed doses towards the top of the range. Across all patients in the study, doses too were on average higher at guideline-concordant clinics – typically 76 mg a day and ranging from 30 to 167 mg, compared to typically 60 mg and ranging from 20 to 100 mg at less guideline-concordant clinics.

Among the factors related to higher dose among abstinent-achievers was attending a guideline-concordant clinic and/or one whose counsellors were less likely to encourage successful (ie, heroin-abstinent) patients to reduce dose or withdraw from methadone. It was already known that patients at guideline-concordant clinic were more likely to avoid using heroin. The analysts interpreted this pattern as suggesting that clinics which are less likely to dose patients adequately and more likely to encourage dose reductions are also less likely to retain patients. In these circumstances it will tend to be the patients who early in treatment can manage on relatively low doses who achieve abstinence from heroin, while those who need longer or higher doses will not become abstinent, leading overall to greater abstinence rates at the guideline-concordant clinics. The implication was that “Encouraging rapid dose titration early in treatment and discouraging attempts at dosage reduction or cessation should improve the percentage of patients who achieve abstinence.”

Three further papers investigated response to treatment among different sorts of patients: those suffering versus not suffering pain or post-traumatic stress disorder, or at least one of whose parents had (according to the patient) versus had not engaged in problem substance use. Patients suffering from pain or trauma-related stress benefited from treatment as much those not affected by those conditions, but remained more severely psychologically distressed despite equivalent improvements in substance use. For patients whose parents were versus were not substance users, different aspects of the quality of treatment seemed most important. With a parental history of problem substance use, only remaining in treatment was associated with greater reductions in substance use at the 12-month follow-up, while for those without this parental history, the psychosocial aspects were prominent, and improved drug use outcomes were associated with greater treatment satisfaction, more individual and group counselling sessions, receiving methadone for fewer days, and attending a clinic whose counsellors were less likely than at other clinics to encourage patients to withdraw from methadone.

**FINDINGS COMMENTARY** The weakness in accepting the implication from the featured report that following clinical guidelines leads to better substance use and other results for patients, is that psychosocial provision was simply assumed to co-vary with patient-staff ratio. However, as well as specifying these ratios (15 patients per full-time equivalent clinical staff in more concordant clinics, 23 in the less concordant), another report confirmed that during the study year new patients at the more concordant clinics attended nearly three times as many group therapy sessions as at less concordant clinics. Also documented was that unbroken retention

was nearly 20% longer (8.4 versus 6.6 months) at the more concordant clinics. For different types of patients, retention was the key to greater substance use reductions, while for others the multiple keys included more psychosocial services and greater satisfaction with treatment. With these advantages and perhaps others available to them, the more concordant clinics generated more abstinence from heroin and somewhat more from other drugs. Especially since the caseload were primary injectors, this finding can be expected to translate into fewer deaths or illness due to overdose or blood-borne diseases.

## Do more intensive psychosocial services really help?

While higher doses are a well established success factor for methadone clinics – not in themselves, but because they achieve at least adequate dosing for more patients than lower doses – the provision of more extensive psychosocial services is less well evidenced, though widely recommended. Across the world, guidelines insist that "psychosocial interventions are … a crucial part" of opioid substitution treatment, and regular counselling may be required by the regulations governing these programmes. The UK's own guidelines also insist that in opioid substitute prescribing programmes, "optimal behaviour change is unlikely without a good therapeutic alliance and suitable psychosocial interventions" and that "Treatment for drug misuse should always involve a psychosocial component to help support an individual's recovery."

Yet in rigorous studies of opioid maintenance programmes, evidence for the effectiveness of extra psychosocial support is surprisingly thin. After looking at such studies, in 2007 the UK's National Institute for Health and Care Excellence could recommend for medication-based programmes only contingency management procedures – not so much therapies as reward and punishment systems – and certain forms of family or couples therapies typically available and applicable to just a minority of patients dependent on illegal drugs.

But even if when averaged across all patients extra counselling and therapy often makes little difference, there are important exceptions, among whom may be the psychologically unstable patients often excluded from trials and multiply problematic clients who without support suffer repeated crises. With its unfiltered patient pool of ex-military patients, the featured study examined just such a caseload, finding that especially when the family environment had not directly modelled unhealthy substance use, patients did benefit from more extensive psychosocial services.

## Ethos, dose, organisation: the three pillars of a pharmacological intervention

The research team's impressions of a more organised and efficient work culture at the concordant clinics is strongly reminiscent of an account of working practices at three Australian methadone clinics, from which the author distilled three pillars supporting successful treatment: ethos, dose, and organisation.

Most fundamental is a treatment ethos, opposed in the Australian study to a 'methadone dispensary' ethos. When treatment is the ethos, infractions and problems become something to be worked with "rather than an irritation or obstacle to the smooth running of the clinic". Such an ethos is represented in the featured study by a greater commitment to psychosocial therapy, to maintenance, and to not terminating patients in response to infractions. A weak maintenance treatment ethos is expressed partly in dosing decisions and whether clinics aim for abstinence, leading in some cases to low doses and pressure to detoxify which shortens retention and impedes impacts on substance use – again, influences apparent in the featured study. Finally, the organisation of the clinic also seems important. For the sake of both patients and staff, treatment should be "Structured and well-organised". Lacking this, despite usual dose levels the dissatisfied patients at one of the Australian clinics had poor outcomes.

Also reinforcing the messages of the featured study are the findings of a seminal US study that methadone maintenance clinics oriented to rehabilitation and long-term maintenance and which delivered more counselling had the best outcomes, results partially confirmed in a replication study of a larger set of US clinics.

*This draft entry is currently subject to consultation and correction by the study authors and other experts.*

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