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### ► [The SUMMIT Trial: a field comparison of buprenorphine versus methadone maintenance treatment.](#)

Pinto H., Maskrey V., Swift L. et al. [Request reprint](#)

**Journal of Substance Abuse Treatment: 2010, 39, p. 340–352.**

Compared to methadone, buprenorphine is more often chosen in a make-or-break attempt to divorce oneself from illicit opiates found the first large-scale study to compare the drugs in real-life conditions at a British opiate addiction maintenance treatment programme.

**Summary** Arguing that blinded and randomised trials are selective in their intake and divorced from normal clinical practice, the authors compared buprenorphine and methadone as maintenance medications for the treatment of opiate dependence in the usual situation where patient and clinician decide on which to go for and both know what is being prescribed. Of the 555 opiate-dependent patients seeking maintenance treatment at a community drug service in Norfolk, [361 agreed](#) to enter the six-month study. Treatment followed usual clinic practice. In collaboration with their clinicians, nearly two thirds (227) [chose](#) methadone and the remainder (134) buprenorphine. On the assessed variables, their profiles [were similar](#). Among the few significant [differences](#) were [indications](#) that the methadone-choosers had more severe addiction and other problems.

To reduce early drop-out, doses were [adjusted upwards](#) over three days, during which patients attended daily for monitoring. Then (in line with normal UK practice) for a minority take-home doses were introduced when it was felt appropriate and safe. Dose changes could be negotiated with the clinician. Across all patients, average peak doses throughout the trial were 12mg of buprenorphine or 73mg of methadone, ranging up for individuals to 20mg or 170 mg. More patients on buprenorphine chose to reduce than to increase dosage. Patients exited the study if they missed their medication for over a week or were [discharged](#) from the service.

## Greater retention gives methadone the advantage

The primary criteria of success (a 'positive outcome') was retention in treatment or detoxification to the point of being opiate-free at discharge from the service. By the end of the trial, half the patients who had **initially chosen** buprenorphine had achieved a positive outcome, significantly fewer than the 70% who had chosen methadone. Rather than being due to differences between the patients who chose the two drugs, after these had been taken in to account, methadone's **advantage** was even greater.

This advantage was entirely due to better retention. On average, at any given time (and even more so at the end of the six months) **twice** as many patients were retained on methadone as buprenorphine. In an omnibus analysis including the characteristics of the patients, choosing methadone emerged as the strongest predictor of longer retention. Retention was also related to dose, but in different ways for the two drugs. For buprenorphine, doses up to 8mg elevated retention to over 50%, but higher doses were not associated with yet longer stays. For methadone, there was no such ceiling; 60mg was associated with retention elevated to over 70%, but higher doses were associated with yet longer retention, ranging up to 80% plus at over 120mg.

In contrast to retention, a positive outcome in the form of successful detoxification and treatment exit was achieved by a higher proportion of buprenorphine patients – 7.5% v. 0.3% (just one of 361) on methadone. Among retained patients, those on buprenorphine were also more likely to submit **urines** which indicated they had not used illicit opiates; after differences between the groups had been accounted for, the chance of a clear test versus one indicative of opiate use was over twice as high on buprenorphine as methadone. Using a similar metric, buprenorphine patients were also nearly three times more likely to produce a string of six clear urines, indicative of sustained abstinence from illicit opiates. This advantage for buprenorphine did not extend to **other** illicit drugs.

## What did patients think about the two drugs?

Another aim of the trial was to explore patients' beliefs about the two medications. Compared to methadone, typically each patient saw buprenorphine as better at blocking heroin use, less likely to cause overdose, and easier and quicker to withdraw from. Less strikingly, they also saw buprenorphine as less sedating and muddling, and thought that being prescribed it made patients less vulnerable to the charge that they were 'still addicts', having merely swapped one addiction for another. Patients who had opted for buprenorphine were consistently more negative about methadone than those choosing methadone. Not surprisingly, **these beliefs** also featured among the patients' accounts of their reasons for choosing buprenorphine. In contrast, methadone-choosers most often cited past experience. That most buprenorphine-choosers cited dislike of methadone is consistent with the finding that, had methadone been the only option, 28% **would** not have entered treatment. In contrast to the differences in retention and illicit opiate use, changes in self-reported psychological well-being, and in assessments by staff including social functioning, were **roughly the same**, whichever medication had been chosen.

## The authors' conclusions

Despite somewhat more severe problems, patients who chose methadone were twice as likely to remain in treatment for six months as those who chose similar treatment with

buprenorphine. This difference could not be put down to differences in the demography or history of the patients, overcautious induction on to buprenorphine, or inadequate or inflexible dosing. On the other hand, retained buprenorphine patients were much less likely to continue to regularly use illicit opiates and more likely (though still few did so) to exit maintenance via detoxification, and the buprenorphine option enabled 10% of the sample to enter treatment who would not have done so had only methadone been on offer.

These results are likely to be due to an interplay between the pharmacology and reputations of the drugs and the motivations of the patients who chose one rather than the other. Because they eliminate motivational differences between patients, blinded and/or randomised trials have found less difference between how well patients do than this trial, which allowed the patients' motivations to influence their allocation to the drugs. The findings suggest that methadone-choosers were more wedded to continuing to experience opiate-type effects, and more likely to see treatment as a way control their opiate use while still occasionally 'enjoying' heroin, or using it to help them cope. They valued methadone's stronger opiate-type effects and its ability to prevent withdrawal symptoms. Such preferences are less well matched to buprenorphine's pharmacological profile.

In contrast, buprenorphine-choosers more often valued its ability to prevent them feeling opiate-type effects and to pave the way to ending (illicit) opiate use altogether. They seemed more likely to be in treatment for 'cure' rather than 'control' purposes, a mind-set which may also account for higher drop-out when patients fail to achieve these challenging aspirations. The fact that buprenorphine is easier to withdraw from may also partly explain why more attempted this than did so on methadone.

At the time of the study, commissioners had imposed a target of 80% of patients retained for three months, a statistic which partly determined a locality's funding allocation. Due to this and because it costs less, they may prefer methadone. However, buprenorphine's expense may be offset by more patients leaving treatment earlier via detoxification, and its availability extends treatment to people who would not accept methadone. For these reasons, the drug should in principle be available to any patient seeking maintenance treatment. Close monitoring is advisable for the first three months to detect signs that patients may drop out and to offer conversion to methadone if indicated.

## FINDINGS

At what seems a typical English drug dependence treatment unit, and when patients can (with their clinicians) exercise choice, buprenorphine's reputation (built on personal experience and its pharmacological profile) lends itself more to a 'make or break' attempt at doing without illicit opiates and, for a minority, rapidly attempting also to manage without legal substitutes. These are the patients who no longer wish their days to be clouded by opiate-type effects and are looking to end or radically contain their relationship with heroin. In contrast, the methadone-choosers were stocked with somewhat less of the 'recovery capital' in the form of relationships and psychological and physical health which would help them climb out of their addiction. More often they were as yet unwilling to attempt to forgo opiate-type effects which to buprenorphine-choosers had become aversive, such as sedation and mental clouding, but which methadone patients still saw as positive advantages.

However, for nearly half the buprenorphine patients (63 of 134), within six months their attempt at treatment had ended with unplanned drop-out, forced discharge, or arrest and detention. The study could not follow up these former patients, begging the question of what happened once they were no longer sheltered by a maintenance prescription. Had their heroin use been able to be reflected in urine test results, the gap between the two drugs would probably have been narrowed, and possibly the two deaths in the methadone cohort would have been matched among former buprenorphine patients. While still in treatment at the service, buprenorphine patients were much more likely to do without illicit opiates than methadone-choosers, but how many managed this and how often is not reported; from a [small pilot trial](#) at the same service, **we can expect** that continued use of illicit opiates was the rule at first but became marginally the exception once the sample had been whittled down to patients prepared and able to stick with treatment.

Results from the featured study can be contrasted with the much less clear-cut differences between retention and illicit opiate use when patients have been randomised to the two drugs and steps taken to conceal which one they were taking. In [studies](#) which like the featured study dosed flexibly, methadone retained its retention advantage, but it was **much reduced**, and it was **not at all clear** that buprenorphine does block 'on-top' opiate use any better than methadone. This attenuation of the differences between the two drugs suggests that the much bigger differences seen in normal clinical practice in the featured study were largely (but not entirely) due to the kinds of patients (or the stages they were at in their addiction and treatment careers) who chose one drug rather than the other.

### Policy implications

The featured study hails from a time when retention for 12 weeks was the prime benchmark of effective treatment and partly determined local funding. Now the emphasis across the UK ([1 2](#)) is on moving patients through and out of treatment to (it is hoped) secure recovery via social reintegration and particularly employment, while recognising that some will not be able to make this transition, or not for many years. If like the previous benchmark, the forthcoming '[payment by results](#)' commissioning structure in England enshrines this ambition in funding criteria, then buprenorphine's ability to help patients take a half-step away from reliance on opiate-type effects and its greater 'leavability' could become valued more, while methadone's 'stickability' is already being seen not as a strength, but a liability.

Variation between results in usual UK practice and randomised trials from abroad call in to question the salience of an [assessment of the two drugs](#) conducted for the UK's National Institute for Health and Clinical Excellence (NICE). Based largely on randomised trials, it found that methadone's retention advantage in flexible-dose studies translated in to slightly greater improvements in (largely health-related) quality of life. Since methadone also resulted in lower health care costs, it was judged more cost-effective than buprenorphine.

Grounded more in UK practice, experts and advisers convened by NICE put a [different spin](#) on largely the same evidence. Their advice was that the choice between the medications should be made "case by case", based on issues like whether

buprenorphine's safety was a priority in that individual case, whether the patient was aiming to withdraw from opiate-type drugs altogether (easier with buprenorphine), and patient preference. When for an individual the medications were equally appropriate, methadone might take precedence because it cost less and on average extended the benefits of being in treatment. Current [UK prescribing guidelines](#) take a similar line. Buprenorphine's better safety profile and its attraction for a less severely affected caseload commend it particularly to primary care settings; [in Birmingham](#) for example it was twice as likely to be prescribed as a maintenance drug by GPs as by specialist addiction services.

### Featured study reflects national trends

The study's focus on the comparison between buprenorphine and methadone should not distract attention from the commonalities. What is striking is how little improvement there was in psychological health regardless of which drug was prescribed, and despite the remission in illicit opiate use, a finding replicated on a national scale in the English [DTORS study](#). It suggests that while providing a legal substitute dampened the need for illicit opiates, the (initially and then maybe less often) weekly keyworking sessions were insufficient to address the underlying problems which led to the need for opiates, legal or illegal.

As in the featured study, [at specialist addiction clinics in London](#) it was also the case that patient preference largely determined whether methadone or buprenorphine was prescribed. Preferences were in turn based on beliefs about the negative effects of the two medications. Here too there was general endorsement by both buprenorphine- and methadone-prescribed patients that methadone was more likely to cause sedation and intoxication. In [another English study](#) first published as a [report](#) in 2007, the consequences of a mismatch between user preferences and service policies was visible in the early drop-out of would-be patients denied buprenorphine, which many valued for [what they saw](#) as its superior opiate-blocking properties. Staff from the same services said buprenorphine's restricted availability was partly due to its expense.

Cost was also the reason why by 2007 the NHS treatment service in the English county of Cornwall had curtailed its buprenorphine programme, which in 2004 had as many patients as were on methadone. A [survey](#) of its patients revealed that most had experience of both drugs, but when this was not the case, familiarity largely determined which one they preferred. Given this tendency, the preference for methadone noted in the featured study may be a legacy of methadone's dominance in areas less willing than Cornwall to prescribe buprenorphine. As in the featured study, in Cornwall too, buprenorphine was much more likely to be seen as better at suppressing heroin use, despite being less effective at suppressing craving for heroin. This apparent contradiction is explained by the dominant feeling that using heroin 'on top' of buprenorphine would give less of a 'buzz' than using on top of methadone; buprenorphine left the user wanting heroin, but also [aware](#) that if they gave in to this temptation, they would be disappointed at the results. This pattern of beliefs could partly account for greater drop-out from buprenorphine; patients left craving heroin would believe they had to leave their buprenorphine treatment in order to satisfy their cravings. In Cornwall, methadone was also generally seen as better at controlling negative emotional states like anxiety, while buprenorphine left the user more clear-headed, and presumably more vulnerable to their emotions.

Another way the featured study reflects the national picture is in buprenorphine patients being less likely to continue to use illicit opiates. In 2006 [a survey](#) of drug service users in England found that nearly half prescribed buprenorphine said they never used illicit drugs compared to just over a quarter prescribed methadone. Among those who did use 'on top', heroin was the drug most commonly used. The fact that in the featured study buprenorphine was more often a positive choice to progress the patient's aspirations, and methadone more often chosen because it was familiar, seems in line with the [national finding in England](#) that patients prescribed buprenorphine are more likely to be satisfied with their treatment than those prescribed methadone. This finding may also reflect the greater flexibility and patient-centredness of services prepared to

offer buprenorphine as well as methadone. Despite problems accessing a buprenorphine prescription, [by 2005 in England](#) buprenorphine accounted for 16% of the opiate substitute prescriptions dispensed by pharmacies, up from just 1% ten years before. [Other reports](#) suggest that around the years 2005 and 2006, buprenorphine was prescribed to over a quarter of patients in opiate substitute treatment, having rapidly gained ground over the previous years.

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

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