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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▶ Treatment retention, drug use and social functioning outcomes in those receiving 3 months versus 1 month of supervised opioid maintenance treatment. Results from the Super C randomized controlled trial.

Holland R, Maskrey V., Swift L. et al.

Addiction: 2014, 109(4), p. 596–607.

Unable to obtain a copy by clicking title? Try asking the author for a reprint by adapting this prepared e-mail or by writing to Dr Holland at r.holland@uea.ac.uk.

A randomised trial conducted in England found that the (at the time) recommended three months of supervised consumption of prescribed opioid substitutes like methadone conferred no significant advantages over supervising only for up to the first four weeks of treatment, but the findings applied only to the minority of patients for whom random allocation was thought feasible and safe.

SUMMARY Prescribing opiate-type drugs such as methadone to substitute for illegally obtained heroin and similar drugs is intended to protect the health of the patient, help them address their addiction, and safeguard the community, particularly from revenue-raising crime to pay for illegal drugs. However, because these prescribed drugs have opiate-type effects they can be fatal in overdose, especially when taken by people unused to them, and they have a 'street value' which can tempt some patients to sell them or pass them to other people – possibly dangerous for the recipients, and paving the way for the patient to return to illegal heroin use with all its risks.

To prevent these unwanted consequences, at the time of this study UK guidance advised that patients be observed for normally the first three months while taking their medication at the clinic or pharmacy to ensure it is taken as intended, known as 'supervised consumption'. The procedure has other possible advantages and disadvantages. Regular daily contact with pharmacy or clinic staff possibly enhances treatment, but supervision may also be seen as implying a lack of trust, and imposes on patients the burden of daily visits to take their medication.

The featured trial – the only major randomised trial of supervised consumption in the UK – tested whether supervision can be reduced from three months to under a month without affecting the safety or effectiveness of the treatment. Of 627 patients in England assessed for the study, the trial excluded 236 because they were judged to need supervised consumption (202), or not to be suitable for this procedure. In the end, 293 patients prescribed methadone or buprenorphine were included, randomly allocated to supervised consumption for three months (normally followed by unsupervised dosing), or to a comparison group supervised only for an induction period lasting a week to four weeks when doses were adjusted and patients stabilised. Supervision took place six or seven days a week at a local pharmacy. After their initial few weeks on supervision, the comparison set of patients picked up their medication on the same days to consume away from the pharmacy.

In the event, 60 of the 293 patients did not receive their intended supervision regimen, 29 for clinical reasons, meaning that 322 of the 627 patients assessed for the study – just over half – could not for clinical reasons be allocated at random. In effect, the study had narrowed down to one of post-induction supervised versus unsupervised consumption among the minority of patients who, it was judged, could safely and feasibly be allocated to either, reducing the chances of finding one option preferable to the other.

Main findings

Nearing the end of the three-month supervision period, at 12 weeks into the trial 69% of patients allocated to be supervised throughout were still in treatment compared to 74% allocated only to initial supervision, a small and not statistically significant difference which might have been due to chance. Questionnaires completed by patients and urine tests revealed no significant differences in illegal drug use or drinking or quality of life. Over the last month of the first three months of the trial, 67% of patients supervised throughout said they had used heroin compared to 60% supervised only during induction. Differences based on urine tests or all available data were similar. There were, however, significant differences in self-reported crime, which since the

start of the trial had become less common and less frequent among patients allocated only to initial supervision compared to those allocated to be supervised throughout this period. Additionally, very few (5% supervised, 2% unsupervised) patients said they had let another person have their medication. By six months, when both sets of patients had normally been allowed unsupervised dosing for at least the past three months, the same proportion (55%) were retained, though patients allocated to three months of supervision tended to have left considerably sooner.

These results included 60 patients who did not receive their intended supervision regimen. Reanalysing the data in terms of the regimen patients actually received produced similar findings, e that the gap in retention became greater, to the point that the time retained in treatment was significantly shorter among the supervised patients. Also, at the 12-week follow-up a significantly higher proportion of the supervised group (73% versus 52%) had used heroin. These findings might, however, have been partly due to the reasons why patients changed from their intended regimens in the first place or the kinds of patients who changed, rather than due to the regimens themselves.

Interviews at the end of the three months' supervision period with 29 of the patients revealed what from their points of view were the pros and cons of supervision. Generally they preferred not being supervised, but in the short term, supervision was deemed acceptable and useful in helping to establish a regular daily routine. A period of supervision also helped develop positive relationships with pharmacy staff. On the other side of the balance, being supervised intensified experienced stigma, especially for patients in rural areas where the pharmacy serves a small community. Patients appreciated the greater flexibility allowed them by being unsupervised, saw this as a sign they were trusted, and welcomed a move to unsupervised treatment as representing a regaining of control.

The authors' conclusions

The authors said their findings did not support the imposition of the then recommended three months of supervision, and suggested that relaxing that requirement early may help extend retention and reduce heroin use and crime. Stigma may be perpetuated by continued supervision, and long-term supervision may negatively impact on the treatment experience.

FINDINGS COMMENTARY Current recommendations on supervised consumption in UK clinical guidelines are relatively (eg, in comparison with the USA and Australia) relaxed about this safeguard against diversion, largely leaving it to clinical discretion. Without stipulating this, they recommend that in most cases it will be appropriate for new patients to be required to take their daily doses under the direct supervision of a professional for a period of time (no longer specified at three months) to allow monitoring of progress and an ongoing risk assessment. In some cases, assessment will suggest supervision is needed for an extended period, in other cases, only for a short period. Duration of supervision should, say the guidelines, depend on assessed clinical need, not be arbitrarily determined.

The featured study suggests this discretion need on average do no harm, and that if anything insisting on three months of supervision risks early dropout from treatment – very risky for the patient and perhaps entailing resumed high levels of crime – and more illegal opioid use.

An earlier pilot study from the same lead author conducted in Scotland had trialled continuing supervision after an initial three months when all patients were supervised. It recruited 60 patients who had complied with the initial three months, who for the next three months were randomly allocated either to continue to be supervised typically six days a week at the pharmacy ('daily'), only twice a week, or not at all. On non-supervision days, the last two groups still had to collect their medication daily from a pharmacy.

Substance use and retention differences between patients allocated to the three supervision regimens were not large and – with just 46 patients contributing data at the end of the trial – generally not statistically significant. There was, however, a clear and statistically significant divide in patients' reactions to their regimens. Two-thirds of those relieved of the need to take their medication at the pharmacy were happy about their allocation, compared to only 30% subject to twice-weekly supervision and 14% daily. Given the chance to express their views in their own words, unsupervised patients highlighted reduced stigma, supervised patients, the continued stigma of being exposed as a methadone patient at the pharmacy.

That supervised consumption has yet to be been shown to save lives or reduce illegal drug use was also the conclusion of a review of relevant studies. For more on supervised consumption search the Effectiveness Bank database.

Last revised 20 February 2018. First uploaded 11 February 2018

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