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▶ A pilot randomised controlled trial of brief versus twice weekly versus standard supervised consumption in patients on opiate maintenance treatment.

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What happens when opiate-addicted patients are suddenly no longer required to take their methadone under supervision but can take it away from the pharmacy? In Scotland this was tried in the first UK randomised trial; patients stayed longer in treatment and there was no dramatic escalation in heroin use.

Summary Prescribing opiate-type drugs such as methadone to substitute for illegally obtained heroin and similar drugs is intended to safeguard 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 dangerous in overdose or when taken by people unused to them, and they have a 'street value' which can tempt some patients to sell them or give them to other people – dangerous for the recipients, and also meaning the patient may return to illegal heroin use with all its risks.

To prevent these unwanted consequences, since 1999 UK guidance has advised that patients be observed while taking their medication to ensure it is taken as intended, known as supervised consumption. The advice is that this should be continued for at least three months. Regular daily contact with pharmacy or clinic staff possibly enhances treatment, but also implies a lack of trust, and imposes on patients the burden of daily visits to take their medication.

This small scale Scottish pilot study conducted in Glasgow, Aberdeen and the Highland region was the first UK randomised trial of supervised consumption. Rather than testing

the need for the initial three months recommended in national guidance, it recruited patients who had complied with those recommendations, but then for the next three months randomly allocated 60 to either 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. Patients were being treated by nine different doctors at various clinics. Prolonged supervision is the norm in Scotland, so effectively this feasibility study was intended to pave the way for testing the benefits and drawbacks of relaxing current Scottish practice. The sample was too small it was considered for the study to act as a test in itself of those practices.

Of 102 patients approached to join the study, 60 did so; 29 effectively rejected entry to the study and seven were judged clinically unsuitable Typically they were unemployed men in their 30s being treated in Glasgow. At the start of the study, 25 tested positive for continued use of illegal opiate-type drugs, and 15 (often the same people) for benzodiazepines. Despite randomisation there were some appreciable differences between the profiles of the patients in each group.

Of the 60, 46 could be reassessed at the end of the randomisation period. Among the losses were two out of the 19 unsupervised patients whose risky behaviour led to them being returned to supervision.

Main findings

Differences in retention and most of those in substance use between patients allocated to the three supervision regimens were neither substantial nor statistically significant.

Unsupervised patients were however non-significantly most likely to still be in treatment at the end of the study (six months after they started their treatment), those supervised daily, least likely. When the analysis took account of the two patients who changed supervision status, all but one of the 17 unsupervised patients were still in treatment but just 16 of the 22 supervised daily.

Among the 46 who could be reassessed at the end of the study, according to their own accounts to researchers, illicit heroin use was rare at the start of the study (typically one or two days a month) and remained rare at the end, though with slight reductions (from one to zero days) among the supervised patients and a slight increase among the unsupervised (two to 2.5). Their own accounts also revealed no differences in use of other illicit drugs. However, the proportion who were drinking problematically fell from 47% to 33% in those supervised daily but increased or remained the same in the other two groups, creating a statistically significant difference. Urine test results indicated a decrease in use of illicit drugs and in heroin in particular, which was most marked (but not significantly different) among those supervised daily.

Psychological health improved in the twice-weekly supervision group while staying the same or worsening in the other two groups, a statistically significant difference. No significant differences were recorded in physical health, social functioning, crime, quality of life or overall satisfaction with treatment, and no adverse events were recorded in any group. Though with so few patients involved this would not have in any event been expected, patients said there had been no changes in the availability or price of illicit methadone between baseline and follow up; at both times most saw methadone as quite or very easy to access.

There was however a clear and statistically significant divide in patient reactions to their allocation to the groups. Two-thirds of those relieved of the need to take their medication at the pharmacy were happy about their allocation, but only 30% subject to twice-weekly supervision and 14% daily. Given the chance to express their views in their own words, the unsupervised patients highlighted reduced stigma, the supervised patients, the continued stigma of being exposed as a methadone patient at the pharmacy.

The authors' conclusions

Recruitment was slower than anticipated, but this pilot showed that it is possible to conduct a randomised trial of supervised consumption in the Scottish context. Though too small to support anything other than tentative implications, the findings suggest that increasingly frequent supervision shortens retention but may also reduce problem drinking and illicit heroin use – indicative of a dilemma between a harm minimisation approach favouring retention (promoted by relaxing supervision) and a recovery approach where eliminating heroin use is the key objective (which benefits from tighter supervision).

These suggestions were in some respects consistent with the patients' own views. Universally they were happy or did not mind *not* being supervised, but over 4 in 10 of those supervised did not like this. Many patients would it seems rather take their methadone in private. It was clear that stigmatisation in pharmacies remains a major problem. Some may prefer to be dispensed long-term from their drug treatment centres, or to use a pharmacy more distant from their homes.

These results should be interpreted in the light of the fact that all patients still had to attend their pharmacies nearly every day, a less clear change in regimen than for example offering weekly dispensing. Also this study explored the effects of being supervised on the individual patients, yet supervision was initiated in the late 1990s also for its community-level effects of reducing diversion and wider access to illicit methadone. Interestingly however, the results indicated that the price of methadone in Glasgow is approximately half that in Grampian or Highland, despite Glasgow's high supervision rates.

FINDINGS The persistence of unsupervised methadone prescribing in England and Wales (less so in Scotland) is unusual internationally and is also where the preferences of patients (generally against) and national guidance (in favour at the start of treatment) most obviously diverge, setting the stage for a trial of whether despite patient preferences, supervised consumption is worth imposing. The featured study takes a welcome initial step in this direction, but one which still leaves this core feature of modern UK practice unsupported by a rigorous large scale trial.

However, the authors' cautions that this was not an adequate test, but primarily a test of whether such a study was possible, are well taken. Apart from the factors they mention, there seems a strong chance that doctors 'cherry-picked' patients they were prepared to invite in to the trial and risk their being suddenly switched to totally unsupervised consumption. The trial's protocol allowed them to exclude any they thought too severely ill. The facts that recruitment was slow, that typically patients were on their own accounts using heroin very infrequently at the start of the study, few were heavy drinkers, just two had to be switched back to supervision, and that in the absence of supervision six-month retention was almost 100%, all seem suggestive of a relatively stable set of patients. Additionally, 28% of patients who were approached by their

doctors decided not to enter the trial or did not turn up, adding self-selection to selection by their doctors.

Given these considerations, the results could signify not what might happen if *all* patients switched to unsupervised consumption, but what happens when requirements are relaxed on those who have already 'survived' three months of near-daily supervision, and whom their doctors and themselves consider well and stable enough to risk ending supervision. Another consideration is that the sometimes considerable differences between patients in the three groups were not taken in to account in the analysis of outcomes, so it is possible that these reflect pre-existing differences rather than the impact of the supervision changes. Also, with many variables tested for, even the few statistically significant differences might have been chance occurrences.

The findings on which we can place most reliance are the (still not statistically significant) improved retention among such patients when they are relived of the need to take their medication under the eyes of pharmacy staff and possibly too their customers − who could be the patient's neighbours − and the strong preference patients expressed for not having to do this.

In comparison, the findings in respect of substance use are usually minor and at best suggestive. There is however a clear 'non-finding'; that from their own accounts to researchers corroborated by urine tests, among this possibly cherry-picked set of patients, and in a context where illicit methadone was not in short supply, allowing them to take their medication away from the pharmacy did not precipitate escalation in heroin use, as it might have done had they chosen *en masse* to sell their methadone in order to buy heroin.

Other UK studies

Even after this trial supervising consumption has not been subject to large scale evaluation in Britain, yet this was one of the intentions of the NTORS study of addiction treatment in England, which recruited its patients in 1995. The closest the study came to reporting the findings was a comparison between seven GP-led methadone services and eight specialist clinics. The major difference in their prescribing practices was that three quarters of the clinics required patients to take their methadone under supervision, but just one of the GP programmes. Two years after entering treatment, GP and clinic patients had improved substantially and to roughly the same degree, but what differences there were favoured the GPs. GP patients had made significantly greater reductions in use of stimulants and non-prescribed benzodiazepines and greater gains in psychological health. They also tended to stay in treatment longer.

An important reason for supervising consumption is to prevent methadone being sold on the illicit market or otherwise 'diverted' to people other than the patient for whom it was intended, with possibly fatal consequences in the form of opioid overdose. A study of methadone overdoses in Scotland and England suggests these concerns are valid and that supervision does have the desired impact. It concluded that declines in the per-dose rate of deaths due to methadone overdose were due to the spread of supervised consumption, the main reason for a remarkable improvement in the safety of methadone prescribing from 1995 to 2004.

However, the study was unable to determine whether each opiate user in or out of

treatment had become more or less likely to avoid overdose on opiate-type drugs as a whole − heroin as well as methadone − as a result of the introduction of supervised consumption. As well as preventing diversion, supervision should help prevent elevated death rates in the first few weeks of treatment because clinicians can monitor the patients more closely and directly control their methadone intake. It also means the prescriber can be sure that the drug has been taken and that therefore the patient has built up the required tolerance to make such doses safe, and helps assess whether higher doses are required and would be safe. The structure and contact it imposes can also be therapeutic.

Set against this, to the degree that (as some clinicians believe) the supervision requirement causes dependent opiate users to avoid treatment, it would prevent substitute prescribing realising its lifesaving potential. In line with the featured study, other studies have reported that patients who do start treatment find it difficult to comply with long-term attendance or supervision requirements, leading to reduced compliance with treatment and premature drop-out or discharge, impacts which would again reduce the treatment's benefits via reduced retention. How these contrary influences balance out to affect overdose on opiate-type drugs as a whole is unclear.

Practice in Britain

In 2009 some of the same authors conducted a survey of all 42 clinical leads in substance misuse in Scotland to establish the extent and nature of supervised consumption at specialist drug dependence treatment centres. Of the 32 respondents, 20 said they required supervised consumption of new patients for at least three months. For new patients, all but five required supervision six days a week. About half the clinicians said they relaxed these requirements gradually, though it was not unusual for clinicians to support long-term or indefinite supervision. Safety was highlighted as the key reason for supervising consumption, particularly preventing methadone being taken unsafely by people other than the patient.

Based on data from the mid-2000s, another report has related a survey of usual prescribing practices at NHS community drug teams in England and Wales (which treat addiction to drugs including heroin) to a companion survey of the opinions on these policies of patients from one area. All but 3% of the services which responded could arrange supervised consumption of methadone, but 22% said fewer than half their methadone patients starting treatment were supervised. Patients at four community drug teams in South East England were asked if they agreed with guidance that methadone should be taken in front of a pharmacist for three to six months; 52% disagreed, 34% agreed.

The same authors had also phoned 1000 pharmacies throughout England and discovered that a third of patients were supervised and twice as many − two-thirds − were prescribed methadone to take away. Historical practice and the reluctance of many British pharmacies to provide the required facilities make routine supervised consumption of methadone difficult to provide. Since service users too tend to be opposed to supervised consumption, community drug teams may be under pressure from patients to permit methadone to be dispensed to take away.

In 2006 a national survey of Scottish pharmacies found that 91% which dispensed

methadone for addiction treatment provided supervised consumption. Of the methadone patients they served, 57% were supervised, nearly 24% higher than in England.

For a summary of research on these and related issues see this Findings review. Other analyses related to supervised consumption can be found by running this search.

Thanks for their comments on this entry in draft to Richard Holland of the University of East Anglia in Norwich in England and Catriona Matheson of Aberdeen University in Scotland. Commentators bear no responsibility for the text including the interpretations and any remaining errors.

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