## 8.7 First large-scale randomised trial boosts casefor heroin prescribing

Findings Where oral methadone maintenance has failed, prescribing

heroin can greatly reduce crime and improve health and social functioning. These Dutch findings are the best guide so far to what can be expected from the planned expansion of heroin prescribing in the UK. The study involved long-term addicts who had been treated repeatedly with at least 60mg daily of oral methadone (50mg for heroin smokers) and were enrolled in a methadone programme, yet used heroin daily or near daily and evidenced poor physical, mental, or social functioning. In separate studies for injectors and smokers, 430 were randomly allocated for 12 months to oral methadone only, or to this plus heroin injected or smoked under supervision at a clinic three times a day. Heroin doses were capped at 1000mg daily. They averaged about 550mg supplemented by 60mg oral methadone. The methadone-only group were prescribed up to 150mg daily, averaging about 70mg. To attract and retain patients, Dutch methadone services generally avoid prescribing such high doses that patients can no longer experience heroin. In contrast, the aim (one largely achieved) in the heroin group was to adjust doses to eliminate illicit heroin use. Patients who recorded at least a 40% improvement in one of the areas where they were functioning poorly at intake – without deterioration

elsewhere - were considered to have responded well to treatment.



At the 12-month follow-up, about half the heroin patients had responded well, 24% more than on oral methadone only. The remainder had at least done no worse than on oral methadone. Improvements on heroin were evident across physical, mental, and social functioning but on methadone were much more limited. Some of the largest gains were in reduced criminality. However, cocaine use and contact

with non-drug users improved little. Fewer of the heroin patients (70% v 86%) completed the 12 months of treatment but those who left more often did so for positive (treatment success or progression) reasons, and at 12 months most were responding well to treatment. After the trial ended, patients who had stayed on heroin for 12 months were transferred to oral methadone. Two months later over 80% who had responded well to heroin had relapsed to their poor pre-treatment levels of functioning.

In context The limited evidence suggests that, prescribed flexibly and at adequate doses, heroin can attract and retain opiate addicts who do not benefit from oral methadone, achieving large reductions in drug use and crime and improvements in health and social stability. However, the comparison has usually been with routine oral regimes rather than regimes engineered and resourced to maximise outcomes. On the other hand, there is a limit to how far methadone can be 'pushed'. Patients often resist very high doses, frequent therapeutic contact, or highly structured regimes. Heroin's holding power makes intensive intervention more feasible. In the featured study, this potential advantage was not capitalised on. Equalisation of psychosocial inputs to the generally low Dutch uptake level could be why many heroin patients remained immersed in a drug using lifestyle.

The study involved a highly selected and self-selected set of patients ( flow chart below) likely to be especially motivated to enter heroin treatment. It showed what can happen when heroin maintenance is withdrawn and such patients are forced to revert to oral methadone. Heroin was tapered and methadone doses increased, and a personal treatment plan aimed to help patients manage. Still, relapse was the norm. With the other findings, this constitutes strong evidence that the treatment received at the heroin clinics (and almost certainly the drug component) caused the improvements.

The study also provides the most comprehensive method yet for selecting patients: at least five years' heroin addiction, continued daily use despite adequate oral methadone treatment, and severe drugrelated problems as measured by standard assessment tools. These criteria minimised the number prescribed heroin who would have done well on oral methadone. By the end of the study, only 1 in 8 or 1

in 10 of the methadone patients had improved sufficiently (on the study's own criteria) to no longer be considered for heroin.

Supervision requirements and drug costs mean heroin regimes are more expensive than methadone, but savings in suitable patients are also much greater and substantially outweigh the costs. Heroin's attractions risk prolonging treatment, but where regimes insist on supervised consumption, there are attractive and effective treatments to move on to, and patients can revert to heroin if these fail, the Swiss experience is that most leave after a few years and are no longer involved in an addicted lifestyle.

**Practice implications** Ideally, heroin prescribing would be additional to oral and injectable methadone regimes which have been optimised and made easily accessible. About a fifth of English methadone patients do not gain from current treatments and may be

candidates for heroin. From these could be subtracted patients who would do well in improved oral treatment or on injectable methadone, leaving a residue who will only do well on heroin. To these must be added an unknown number who would enter and/or stay in treatment only if heroin were available.

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Whether this potential demand materialises in patient numbers will depend partly on the restrictions placed on heroin patients due to concern over diversion on to the illicit market. Clinics which require long-term supervised consumption can find it hard to recruit patients. Such regimes are also costly, limiting caseloads. Insisting that used ampoules are returned is a cheaper and less intrusive anti-diversion measure. The inconvenience of on-site consumption can be mitigated by allowing patients to skip visits and take oral medication instead. By law heroin prescribing is virtually restricted to specialist hospital units. Requiring on-site consumption would limit their catchment areas, making the treatment unavailable to many patients.

Therapeutic and cost considerations dictate that explicit criteria be used to select patients based on lack of response to adequate oral regimes. Similar criteria can be used to assess progress to justify continuing on injectables or to adjust the treatment. Cost-effectiveness will be higher if patients are encouraged to try oral methadone first but it is counter-productive to persist with this if illicit drug use and crime continue unabated. Fears that patients will deliberately fail on oral methadone to qualify for injectables seem unfounded.

The local service network should ensure seamless transfer between oral and injectable regimes in both directions, most easily achieved when these are provided by the same service. Acceptable drug-free treatments to move on to and the option to return to heroin if these fail are also likely to be important ways to prevent patients getting 'stuck' on heroin. In Britain a major rationale for prescribing heroin is to prevent illicit heroin use. Monitoring this requires urinalysis equipment capable of distinguishing illicit from prescribed heroin; such tests are feasible but require further development.

Featured studies Central Committee on the Treatment of Heroin Addicts.

Medical co-prescription of heroin: two randomized controlled trials. Central Committee on the Treatment of Heroin Addicts, 2002. Download from www.ccbh.nl/ENG/index.htm.

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STUDY STARTS