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New guidelines for prescribing injectable heroin in opiate addiction[†]

Few treatments are more controversial than the prescribing of injectable heroin (diamorphine) to heroin addicts. This practice is still banned in the USA and Australia, despite the serious drug problems in those countries. At present any UK doctor can prescribe injectable methadone for the treatment of heroin addiction; however, the prescribing of heroin requires a special licence from the Home Office. The National Treatment Agency for Substance Misuse is the statutory body currently responsible for advising purchasers (local drug action teams) in regard to specialist services for addictions. They have recently commissioned and published guidelines for the prescription of injectables in opiate addiction (National Treatment Agency for Substance Misuse, 2003). This follows the report of a Government committee, which stated:

'If diamorphine treatment could be offered to all problematic users who do not successfully access other treatments, we believe it could play a useful part in managing the social problems generated by this group of people' (House of Commons Home Affairs Committee, 2003).

The Government is reportedly committed to ensuring that all those who could benefit from diamorphine on prescription will have access to it in the future.

Guidelines

The National Treatment Agency recommends that injectable maintenance prescribing should only be undertaken in line with eight principles, summarised below (National Treatment Agency for Substance Misuse, 2003):

- (1) Treatment should involve a combination of drug and psychosocial treatments to form an integrated care package.
- (2) Substitute prescribing alone does not constitute drug treatment.
- (3) Patients who do not respond to oral maintenance drug treatment (typically methadone or buprenorphine) should be offered other treatment including high-dose methadone (60–120 mg/day) and then injectable methadone or injectable heroin maintenance treatment.
- (4) Injectable maintenance options should be offered by services that can also provide optimised oral methadone maintenance treatment, supervised consumption and psychosocial interventions.
- (5) Injectable and oral substitute prescribing must be supported by mechanisms for supervised consumption. Injectable drugs may present more risk of overdose than oral preparations and have a greater value on illicit markets and hence may require greater levels of supervision.
- (6) Injectable maintenance treatment is likely to be a long-term, expensive treatment with potential effects on other aspects of a service.
- (7) Specialist levels of clinical competence are required to prescribe injectable substitute drugs.
- (8) The skills of the clinician should be matched with good local systems of clinical governance, supervised consumption and access to a range of other forms of drug treatment.

Clients suitable for injectable maintenance should be over 18 years old with at least 3 years of heroin dependence and regular injecting despite the use of optimised treatment regimens, involving oral substitute medication (typically methadone), for at least 6 months.

The issue of supervision of injectables requires some further consideration. The National Treatment Agency report states:

'The requirement for daily or multiple daily attendance was also discussed as requiring a significant change in current British provision (particularly out-of-office hours). Whilst such requirements may encourage the patient to progress towards improved outcomes, they are also very restrictive of liberty and represent a significant, but positive, change from previous practice in England. Clinicians in the expert groups also give examples of safety measures which could be employed such as occasional supervision of consumption and insisting on the return of used ampoules' (National Treatment Agency for Substance Misuse, 2003: section 6.2).

The Department of Health's guidelines for clinical management of drug dependence (Department of Health, 1999: pp 55–57) recommend that prescribing of injectable methadone and heroin should involve

[†]See pp. 126–127 and 128–130, this issue.



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daily dispensing (but not necessarily supervision) in most situations.

The evidence

'The [UK] Government believes that future research into diamorphine should not delay availability of this as a treatment option now' (National Treatment Agency for Substance Misuse, 2002).

Unfortunately, the lack of research support for injectable opiate treatment is cited in most commentaries (Department of Health, 1999; Zador, 2001). Furthermore, the new guidelines specifically state that 'the published evidence base on injectable maintenance treatment is weak in many respects' (National Treatment Agency for Substance Misuse, 2003). Hartnoll *et al* (1980) reported a UK randomised controlled trial of intravenous heroin *v.* oral methadone in 96 people with heroin addiction: the proportion using illicit opiates daily at 12 months was actually higher in the heroin maintenance group (64% *v.* 59%). There was no difference between the groups for other drug use, health or employment status. Approximately 15% of participants admitted to selling their prescribed heroin. The proportion of clients arrested was 72% in the control group and 52% in the heroin treatment group during the trial. Similar results were reported from a Swiss randomised controlled trial, which studied a group of 51 people who were persistent injecting heroin addicts (Perneger *et al*, 1998); here, the proportion of clients arrested fell from 57% to 19% in the treatment group during the 6-month trial. Although there was a modest improvement in mental health and social functioning, the control group lacked access to the comprehensive psychosocial services provided to the heroin treatment group. Overall, the research evidence shows little difference in outcomes between injectables and oral methadone treatment.

The situation apparently changed in the summer of 2003 following publication of the findings of a Dutch trial (van den Brink *et al*, 2003). Overall, this randomised controlled trial of 549 participants with treatment-resistant heroin addiction provided good evidence to support the prescription of heroin; however, two-thirds of the participants were actually prescribed heroin to inhale rather than to inject. Furthermore, all prescribed drugs were used under direct supervision. This single requirement has profound effects. First, direct supervision eliminates diversion of drugs to the black market. Second, supervision drastically reduces the risk of overdosing and is likely to greatly improve injecting practice. However, even this trial lacked the power to show a significant reduction in mortality between groups. Third, and most importantly, supervised administration dramatically increases the cost.

Opinion

The UK guidelines on injectables lamentably fall short of suggesting the only rational solution to prevent widespread diversion of prescribed heroin – direct super-

vision of all injectable use in a safe injecting room with daily 12–18 h access. The current proposal for the prescription of injectables still permits users to take away prescribed heroin. This greatly increases the risk of these drugs to the client and the community. The widespread illicit diversion that resulted from unsupervised methadone and benzodiazepine prescribing is a clear example of the disastrous policy of prescribing addictive drugs to take away. For example, in the late 1990s it was estimated that 400 people died each year from acute methadone overdose compared with half that number from illicit heroin (Royal College of Psychiatrists & Royal College of Physicians, 2000). Unfortunately, therefore, the results of the excellent trial by van den Brink *et al* (2003) involving supervised consumption of heroin are largely irrelevant to the current British debate.

There are three main problems likely to prevent adoption of the guidelines.

Cost

The National Treatment Agency for Substance Misuse expert committee reported that injectable maintenance treatment can cost 5–15 times as much as oral maintenance treatment programmes. These estimates assumed that injectables are prescribed to take away. Supervised consumption greatly increases the cost of injectable maintenance (to around £12 000 per patient per year in the Dutch trial (van den Brink *et al*, 2003)). Since the majority of community drug teams already have great difficulty in meeting the comprehensive treatment needs of oral maintenance clients, it seems most unlikely that additional resources could reasonably be diverted towards creating an injectable service. For example, in part of my own service there is only one full-time member of staff allocated to provide alcohol services for a population of 250 000 people.

Political and professional opposition

Only 29 of 272 doctors who were eligible to hold diamorphine licences were prepared to initiate heroin prescriptions and only a third actually used their licence at all (Metrebian *et al*, 1996). Similarly, 80% of the general public in one survey opposed the prescription of diamorphine to addicts even to reduce crime (Luty & Grewal, 2002).

Ethics

Prescribing injectable heroin presents health risks similar to those associated with the use of illicit heroin, including deep vein thrombosis, infection and endocarditis. A report commissioned by the Home Office from the Advisory Council on the Misuse of Drugs states, 'Deaths would be reduced if agencies and [general practitioners] ceased to prescribe for drug users controlled drugs in tablet form or in ampoules' (Home Office, 2000). It is difficult to understand how anyone could advocate the use of injectable heroin or methadone as a viable 'therapy' given the definitive nature of this statement. Clearly there is a conflict of interest between the physical



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health of the addicted person and the prevention of drug-related crime. One reviewer has pointed out that the global effect of reducing crime is negligible in the few clients who are likely to be suitable for injectable prescribing (Zador, 2001). These reports make it difficult to advocate the ethical use of prescribed injectables.

Conclusion

The National Treatment Agency guidelines state, 'The expert heroin group was unequivocal that this form of treatment [injectable diamorphine] should be provided in line with the eight key principles or should not be provided at all' (National Treatment Agency for Substance Misuse, 2003). The few enthusiasts of injectable prescribing are likely to continue, regardless of any guidelines. However, mainstream drug treatment services would find it very difficult to create an injectable service in line with current guidelines even if they wished to – which most do not.

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