

Injectable heroin (and injectable methadone)

Potential roles in drug treatment

Executive summary

May 2003

1. Background

The Government has recognised that the existing Department of Health 1999 guidelines *Drug misuse and dependence: guidelines on clinical management* (henceforth the *Clinical guidelines*) gives only limited guidance on the topic of injectable opioid substitution treatment. Additional guidance on the prescribing of injectable opioids is timely as new evidence has emerged in recent years. In addition, *Models of care* (National Treatment Agency, 2002), the major new commissioning framework for drug treatment, requires that prescribing drug treatment modalities should be fully integrated within a wider, co-ordinated system. Hence the role of injectable maintenance prescribing requires further clarification within this context.

This document provides initial guidance for practitioners in drug treatment services on the potential role of injectable heroin and injectable methadone substitute maintenance prescribing in local drug treatment systems.

Published by the National Treatment Agency (NTA) and based upon consultation with expert groups, it presents the outcome of a majority consensus approach, based on the evidence available to date and on the experience of expert practitioners.

The guidance is designed to be consistent with the *Clinical guidelines* (1999) and provide additional advice on the basis of expert review of the evidence.

2. Summary of key messages

The document has four key messages:

1. The prescribing of injectable substitute opioid drugs for maintenance may be beneficial for a minority of heroin misusers. The document makes preliminary recommendations on eligibility criteria.
2. Future maintenance prescribing of injectable diamorphine or injectable methadone should only be undertaken if it is in line with eight principles identified by the expert groups. This is essentially a new standard of injectable drug treatment to that previously provided in England. Applying these principles in practice sets a high standard for delivery of this treatment intervention, in recognition of the risks involved.

3. Services should be improved for patients already in receipt of injectable maintenance prescriptions for heroin or methadone. Where patients are stable, maintaining this stability is paramount.
4. Priority should be given to improving the effectiveness of oral maintenance treatment (on methadone or buprenorphine) for the majority of patients in all drug action team areas in England.

3. The evidence base

The published evidence base on injectable maintenance treatment is weak in many respects. However, the expert group agreed that some conclusions could be drawn from both international and UK studies. These are that:

- injectable maintenance treatment is most appropriate for long-term heroin addicts who have not responded to oral maintenance treatment
- where injectable heroin and methadone maintenance prescriptions are provided as part of a comprehensive treatment programme, both may have beneficial effects on health, social functioning and crime reduction.

However, since the majority of evidence relates to patients who have “failed” oral programmes, there is a need to probe the causes of “failure”.

Poor outcomes from oral maintenance programmes may relate to the characteristics of the patient, or to the way in which the treatment is delivered. There is good evidence about the components of effective oral maintenance treatment, but in practice many services fall far short of delivering to optimal standards. Particular areas for improvement relate to increasing average maintenance dosage levels, improving care planning, addressing the lack of supervised consumption and encouraging patients to have psycho-social support including education and housing.

4. Principles guiding injectable maintenance prescribing

This guidance recommends that injectable maintenance prescribing should only be undertaken in line with eight principles.

1. Drug treatment comprises a range of treatment modalities which should be woven together to form integrated packages of care for individual patients.
2. Substitute prescribing alone does not constitute drug treatment. Substitute prescribing requires assessment and planned care, usually with other interventions such as psycho-social interventions. It should be seen as one element or pathway within wider packages of planned and integrated drug treatment.
3. Within the substitute prescribing modality, a range of prescribing options are required for heroin misusers requiring opioid maintenance. Some options may carry more inherent risks than others (e.g. injectable versus oral options). Patients who do not respond to oral maintenance drug treatment should be offered other options in a series of steps. This would normally include:
 - oral methadone and buprenorphine maintenance, specifically optimised higher dose oral methadone or buprenorphine maintenance treatment, then
 - injectable methadone or injectable heroin maintenance treatment (perhaps in combination with oral preparations).
4. Injectable maintenance options should be offered in a local area that can offer optimised oral methadone maintenance treatment including adequate doses, supervised consumption and psycho-social interventions. This is essential to ensure oral drug treatment options have been fully explored prior to a trial of injectable maintenance treatment and to ensure smooth transition back to oral treatment if required.

5. Injectable and oral substitute prescribing must be supported by locally commissioned and provided 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 long-term treatment with long-term resource implications. Clinicians should consider the move from oral to a trial of injectable preparations carefully, including long-term implications for the patient and drug treatment systems and involvement of services.
7. Specialist levels of clinical competence are required to prescribe injectable substitute drugs. Heroin prescribing also requires a Home Office licence.
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 drug treatment modalities.

This guidance also recommends that there is need for further work around identifying the most effective models of delivery.

5. Clinical eligibility

The expert group reached some consensus on eligibility criteria, precautions and outcome measures. However, guidance on issues such as dose or the prescribing of combinations of oral and injectable preparations will require further work.

The agreed criteria are set out in the full report and relate to factors such as:

- age and drug usage
- willingness to comply with conditions such as supervision and monitoring, engagement in a range of care options, avoidance of some risky behaviours and of diverting prescriptions into illicit markets
- persistence of poor outcomes within an optimised oral programme.

The document outlines a range of precautions and outcome measures.

6. Optimised oral methadone services

The key elements of an optimised oral methadone service are described, with the following four crucial components being highlighted from the evidence-base:

- adequate doses following proper individualised assessment are important. Daily doses of 60mg to 120mg have consistently been shown to be more effective
- services with adequate supervision and monitoring of patients including care planning and supervised consumption (during initial stages or periods of instability) are more effective in reducing harm and improving outcomes
- services that strongly encourage involvement in psycho-social services (including counselling, education and support) have patients with better outcomes
- services with competent staff who can develop positive relationships with patients have better outcomes.

The expert groups noted that enforced detoxification or reduction regimes are associated with poor patient outcomes and are not recommended.

7. Additional issues raised by the expert group

7.1 Injectable treatments are falling

In recent years there has been a reduction in injectable prescribing in both absolute terms and as a proportion of overall opioid substitute treatments. This is partly because of the rise in oral methadone treatment. The availability of doctors who are licensed to prescribe heroin also varies widely between regions. Nationally there is a lack of specialist clinicians and in some regions the shortages are chronic.

7.2 Increasing reluctance of doctors to prescribe

Recent evidence has given some insights into reasons for the increasing reluctance of doctors to prescribe. They include concerns about:

- the lack of arrangements to supervise consumption
- resources to provide the service safely
- a perceived limited evidence base for the effectiveness of injectable maintenance treatments
- the appropriateness of this form of treatment
- risks of drug-related death and professional reprimands
- commitment to a long-term treatment.

7.3 Issues around supervised consumption

UK policy recognises that it is desirable for the consumption of all substitute drugs to be supervised during the initial stages of drug treatment and if a patient becomes unstable. This can reduce the risk of harm to the user from accidental overdose and the risk of diversion to illicit markets. However, in practice many local areas do not have arrangements for patients to consume substitute drugs under supervision. The expert group highlighted this issue as a source of concern.

7.4 Costs of injectable prescribing compared to oral programmes

Injectable maintenance treatment appears to be an expensive option. Whilst reliable figures are difficult to obtain, it is estimated that injectable maintenance treatment can cost between 5 to 15 times as much as oral maintenance treatment programmes. The NTA will explore costs in greater depth in 2003. However, it is important that commissioners and providers ensure that any new service responses to a lack of injectable treatment do not undermine the overall provision of drug treatment and that injectable maintenance treatment is targeted appropriately.

Recommendations

The key recommendations are that:

- optimised oral methadone maintenance should be the maintenance treatment for the majority of heroin users
- injectable heroin and methadone treatments should be considered only for the minority of patients who are genuinely unresponsive to an optimised oral maintenance treatment approach
- injectable heroin and injectable methadone treatments based on this guidance should be seen as a new drug treatment modality requiring the development of new integrated care pathways.