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

Until recently, the UK led the addiction field worldwide as the only country to prescribe diamorphine for the treatment of opiate drug dependence. However, the approach was inconsistent, with development conducted in a haphazard and arbitrary manner (Audit Commission, 2002), with variation in criteria, individualistic approaches and many doctors 'inheriting' patients on these long-term prescriptions from other doctors. There were relatively few restrictions once the doctor had been granted a licence by the Home Office.

There was reluctance by many doctors to prescribe diamorphine, often citing lack of resources as the main factor for this reluctance – i.e. resources to provide the service safely and with supervision – alongside concern about the limited evidence, the perceived lack of need and demand, the lack of guidelines and risk of professional reprimands, and the potential high demand for a service once commenced (Metrebian *et al*, 2002).

The National Treatment Agency (NTA) report (2003) does accept that the published evidence is weak, especially in the UK. However, there has been an emerging evidence base on injectable heroin and methadone treatment, most notably in Switzerland (Uchtenhagen *et al*, 1999), with use of heroin now following the research programme, and in The Netherlands (van den Brink *et al*, 2002, 2003). The review of Stimson & Metrebian (2003) cites much of the available research. The large trials in Switzerland and The Netherlands involved over 1000 patients in supervised delivery systems, with provision of a comprehensive care package. Luty (2005, this issue) appeared to denigrate all the research evidence prior to the research of van den Brink *et al* (2003), stating that the results showed little difference in outcomes between injectable and oral methadone treatment. Although the Swiss trial did not have a control group, it did involve nearly 400 patients in a large number of out-patient centres, with over three-quarters retained for at least 1 year and improvements in many domains of function.

Luty ranked the evidence from The Netherlands trial and reported that this randomised trial of 549 treatment-resistant patients with heroin addiction provided good evidence to support the prescription of heroin. This research noted that those prescribed injectable opioids showed 25% greater improvements in physical health and psychosocial adjustments compared with the control, although these gains were lost shortly after stopping treatment. Luty, however, implies that the issue of supervision was profoundly important, in three respects:

1. elimination of diversion
2. reduction in overdose
3. increased cost.

It is correct to note that there is little research evidence in the UK context; available studies are mostly descriptive.

The work often cited is that of Hartnoll *et al* (1980) (a randomised trial of intravenous heroin v. oral methadone), which Luty noted demonstrated higher use of illicit opiates in the heroin group with no difference between the groups on other drug use, health or employment. Drug consumption was not supervised. The authors of this research did conclude that there was no clear overall superiority to either treatment. There has been further research in the UK, cited in Stimson & Metrebian (2003) and in the NTA guidelines (2003).

Strang *et al* (2000) tested the feasibility of supervised consumption, with use supervised during the week and a requirement to return weekend take-home doses. Improvements were noted on many domains, such as physical and psychological health, with reduction of crime and illegal drug use. While there is a developing evidence base, it is crucial that any expansion in heroin prescribing should be 'systematically monitored and evaluated including a major research trial in a number of different locations, where the effectiveness of heroin prescription is compared to standard methadone therapy' (National Treatment Agency, 2003). This statement is crucial in the development of injectable programmes, although the 'standard' therapy must be optimised therapy.

The *Updated Drug Strategy* (Home Office, 2002) proposed that 'all those with a clinical need for heroin prescribing will have access under medical supervision', but failed to define the clinical need. The NTA, with the Department of Health and a group of experts, produced initial guidance consistent with the Clinical Guidelines (Department of Health, 1999). They reported the principles, as outlined by Luty, that should underpin development of a service and gave tentative endorsement to the establishment of programmes. However, while noting the priority should be optimum oral methadone programmes (they note the requirements of an optimum oral programme), they considered that injectable heroin and methadone treatments should be available only to a minority who were genuinely unresponsive to an optimised oral maintenance programme and emphasised the need for a new and high standard for this treatment modality (National Treatment Agency, 2003). The principles are in my opinion correct, and of a high and exacting standard. In particular, they note that this treatment is not just a prescription, but should be part of a planned, integrated and comprehensive treatment. Should injectable treatment be considered, this should be only after failed optimum oral methadone programmes, and should be delivered with even greater levels of supervision by services with specialist levels of competence, matched with good local systems of clinical governance; treatment is likely to be long-term, be delivered by specialist services with high levels of competence and must be supported by commissioners.

[†]See pp. 123–125 and 126–127, this issue.



This, of course, leads to a very costly service, as pointed out by Luty, which may not get commissioner support. Indeed, some providers may now want to be involved in these developments, with guidelines in place for optimised heroin programmes, although commissioners are reluctant to embark on new and costly services for an undetermined number of people with only limited funding available. A new modality of treatment, which requires careful adherence to procedures and a specialist competence in the workforce to reduce risk, requires new resources. These resources must not be taken from methadone programmes that benefit the majority of dependent opiate users. Luty's article mentions these issues of cost; of importance is the possible diversion of resources to a minority for these optimised new programmes rather than the continued development of optimised oral programmes. There is no doubt that there is still significant progress to be made to optimise all methadone programmes to the standards described in the NTA guidance. Indeed, as noted in Luty's article, the issue of resources for alcohol treatments has not been addressed for many years. The NTA report does note that the provision of injectable drug programmes 'must not undermine the overall quality of care for all patients, where adequate access to oral optimised drug treatment options are not available to the majority, it may be difficult to demonstrate this'.

Luty's article notes that the UK Guidelines 'lamentably fall short of suggesting the only rational solution to prevent widespread diversion of prescribed heroin – direct supervision of all injectable use in a safe injecting room with daily 12–18 h access'. One of the principles of the Guidelines notes the need for supervision – 'injectable prescribing must be supported by locally commissioned and provided mechanisms for supervised consumption'. However, on discussion of the models and their implementation in the body of the report, the group noted, 'there was no consensus in the expert group concerning the best models of service delivery' with further work required. The potential for provision of centralised injectable clinics adapted from international models was noted, although this would require a substantial change in current British provision. The group noted such requirements (daily or several times a day attendance) would be restrictive of liberty but also would represent a significant and positive change from previous practice in England. Some safety measures were cited, such as occasional supervision or return of ampoules. While noting that further work was needed, especially in adapting these programmes to a wider variety of settings (e.g. rural, semi-rural), the group was unequivocal in its recommendation that these new programmes must adhere to the principles outlined. It is, then, of importance that one of the principles is the requirement for supervised consumption, although no details were given. While acknowledging this need for supervision, I do agree with Luty that the emphasis was on the principles, with much need for further work on implementation and the 'how' to deliver a programme.

A further concern noted was the risk involved in prescribing injectables, with Luty noting 'it is difficult to

understand how anyone could advocate the use of injectable', given the statement from the Advisory Council on the Misuse of Drugs' report (2000) on reduction of deaths. He also notes the potential conflict of interest between the physical health of a user and reduction of drug-related crime. While there may be some conflict on the perceived government agenda, the inclusion criteria for injectable prescribing are very narrow, with the emphasis on this prescription to a minority only, who have been given appropriate and optimised oral substitution and comprehensive treatment with little effect. Moreover, the more recent research evidence does note the improvement in physical and psychological care, as well as a reduction in crime.

Moreover, the NTA principles set a new standard of care in recognition of the risks involved. This 'new' modality is an exceptional treatment, considered only for a minority, with risks to the individual and public health reduced by adherence to practices and procedures that increase compliance with treatment – this includes competence of providers, adequate assessment, careful criteria for selection, and prevention of diversion. However, these principles must be fully implemented to reduce risk, not just a 'hoped for' measure.

There may be reluctance to prescribe heroin, but this may be related to training, workforce capacity, and resources to adhere to the new principles. The term 'heroin prescribing' does not capture the essence of the service, that of a comprehensive programme of care for a user, with prescription of injectable heroin and/or methadone as an opiate substitute, with need for careful supervision alongside all other psychosocial interventions. The guidelines do correctly note that injectable treatments should be seen as a new treatment modality requiring the development of new integrated care pathways.

I do agree with Luty that mainstream services will find it difficult to create an injectable service in line with current guidelines, although I do not agree that most do not wish to. Many specialists would like to develop services and add new innovative treatments to those available to improve service quality, patient choice and care, with greater retention in service. The developing evidence base is welcome, the current guidelines are welcome, but without new and adequate resources I suspect there will be even less development of this service. The guidelines correctly demand a high standard. To ensure these exacting principles can be adhered to, and preclude any possible legal challenge, providers may not wish to initiate this service without extra resources.

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