**International evidence on HAT individual and community outcomes**

1. **Effectiveness**

Strang, J., Groshkova, T. and Metrebaian, N.***New heroin-assisted treatment: recent evidence and current practices of supervised injectable heroin treatment in Europe and beyond*.** European Monitoring Centre for Drugs and Drug Addiction

<http://www.emcdda.europa.eu/attachements.cfm/att_154996_EN_Heroin%20Insight.pdf>

The international evidence base for the effectiveness of HAT is primarily based on 6 RCT studies from Europe and Canada. Each of the evaluations had a different profile and used different methodologies in terms of target population, nature of interventions and measures, reflecting the different treatment systems and policy environments in the countries involved. However, the main underlying objective of the trials in Germany, Spain, the Netherlands, Switzerland, Canada and the United Kingdom has been to determine the therapeutic value of medical heroin prescription as second-line treatment for high-risk heroin users for whom such benefits cannot be expected or achieved from existing treatment options

Eligibility criteria

Participants across the six trials were daily heroin users with a stipulated minimum history of opiate dependency ranging between two (Switzerland (1) and Spain) and five (the Netherlands, Germany, Canada) years, commonly between 18 and 65 years of age at enrolment, who were residents of the supervised injecting clinic area. Also, they had a history of at least two unsuccessful treatment attempts, although there was variation with regard to their current treatment status at the time of enrolment, with the differences across the trials described in more detail below. Exclusion criteria, where specified, included the presence of active symptoms of a severe psychiatric disorder, a pending prison sentence, a recent (past 12 months) episode of abstinence, a severe physical disorder or pregnancy.

Retention

Retention in treatment appears to be similar or greater for patients in SIH than those engaging in oral methadone substitution therapy. Although this effect varied significantly across the trials, trials consistently reported good retention in the SIH group. Retention in the control groups was more varied.

‘Street’ heroin and other drug use

Compared with oral methadone substitution, treatment with heroin brings about additional reductions in illicit heroin use, although in both treatments this is markedly reduced. Cocaine use, where it was reported, had either not changed or reduced at a comparable rate across the two treatment types.

Health, health-related quality of life and social functioning (integration at work, family relationship)

Patients undergoing SIH treatment have experienced significant physical and mental health improvements compared with patients receiving conventional oral substitution prescribing. However, heroin treatment has not been consistently or substantially superior across all studies and outcomes, particularly the health and psychosocial functioning domains.

Criminal offences

Trials that have reported findings in the crime domain stated that crime — self-reported or reported by official databases — had reduced, compared with levels at entry to SIH treatment and where available to controls (with the exception of the Spanish and the Canadian trials).

Safety

More SAEs have been reported to occur in patients receiving SIH than in those receiving oral methadone. This suggests that SIH may be less safe and therefore requires more resources and clinical attention in order to manage greater safety issues.

Impact of supervised injectable heroin clinics and service provision on local communities

While a definite conclusion is difficult, owing to the small study samples and the fact that many extrinsic factors may be involved in shaping the process around observed local crime and disorder trends, available data consistently suggest no positive or negative effects of SIH clinics on public safety. Future research attention will also need to address the perceived public nuisance, security and potential for diversion where SIH unfolds outside of the research context.

Long-term trajectories

The findings of extended (2- to 6-year) follow-up studies are an important addition to the shorter (6- to 12-month) data available about treating this most difficult group of heroin users. Retention in SIH treatment is still high at 2- (44 %; Oviedo-Joekes et al., 2010), 2.5- (50 %; Rehm et al., 2001), 4- (56 %; Blanken et al., 2010) and 6-year (40 %; Güttinger et al., 2003) follow-up. There is consistency in the finding of sustained and additional benefit in terms of reduced drug use and improved health status and social functioning. Different studies, however, have used different outcome measures, making direct comparisons difficult and presenting challenges for sought-after firm conclusions about the long-term benefit of SIH treatment. It is imperative that the collection of comparable data is continued as we begin to develop an evidence base, capturing any remission to illicit drug use, elimination of related problems and, more importantly, enhanced quality of life and social functioning of patients in long-term SIH treatment.

Patients’ perspectives

A qualitative study (Romo et al., 2009) involving 21 patients receiving SIH treatment was conducted in the final phase of the RCT of injectable treatment in Spain. The findings of this study recognised that SIH treatment not only offered patients ‘legal medicine’, that is pharmaceutical-grade heroin, but also fundamentally changed the situation in which heroin was acquired and administered by patients. In addition, the contextual change was associated with improvements in a range of areas of patients’ lives, such as physical and mental health, family relationships and work. Blanken et al. (2010b), based on the qualitative accounts of 24 patients receiving heroin in the Dutch trials, provided further evidence for the consistency in patients’ appreciation of the quality of prescribed heroin and the positive experience of the structure provided by the injectable maintenance clinics, as well as the availability of a secure supply of pharmaceutical heroin.

1. **Cost effectiveness**

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Two publications from Switzerland (Gutzwiller and Steffen, 2000) and Holland (Dijkgraaf et al., 2005) and an unpublished economic analysis from Germany (Haasen, 2009) were identified. The three countries that have evaluated the costs and outcomes of heroin treatment have chosen different approaches to economic evaluation. The selection of one or another approach for economic analysis, that is cost–benefit (in the Swiss experiment) or cost–utility (within the German and Dutch trials), determines which cost categories are included in the analyses. Therefore, inclusion or not of different cost categories differ between the different studies. More importantly, the aim and outcome measures of the evaluations differ and thus prevent comparison between the findings of the different research groups.

The reported cost per patient per year in an HAT maintenance programme was between EUR 12 700 and EUR 20 400. The lowest cost was reported by Switzerland at between EUR 12 700 and EUR 14 500, depending on the capacity of the outpatient treatment programme; EUR 19 000 was reported for Germany and EUR 20 400 for the Netherlands. SIH cost was substantially higher than the cost of oral methadone maintenance treatment provision at EUR 1 600 (the Netherlands) and at EUR 3 500 (Germany). This was largely because of higher staffing requirements for SIH provision — at least two staff members must be present at all times and it is necessary to supervise all injecting of heroin medication at the clinic. Therefore, clinics had to be open daily, and for extended hours. In addition, all programmes had employed therapists, social workers and other staff members to help clients deal with drug-related health and social problems.

Studies consistently demonstrated a considerable economic benefit of HAT, particularly from the reduction in the cost of criminal procedures and imprisonment. Based on the results of the studies from Germany and the Netherlands, which directly compared the cost and cost utility of heroin and oral methadone maintenance treatment, methadone maintenance appeared to be the less costly programme to provide. However, when costs of crime are included, heroin maintenance appeared to be more cost-effective.

The Swiss study reported an annual socio-economic benefit of EUR 13 000 for each patient in heroin treatment, which was comparable to the finding of the Dutch group for a societal saving of EUR 15 000 per year for every patient maintained on heroin treatment. In the German cohort, HAT treatment generated savings of about EUR 6 000 per year from improved health, reduced offending and regained productivity. The German and Dutch studies reported a significant improvement in the quality of life in the heroin-maintained patients.

1. **Informed consent**

At the same time research into the effectiveness and cost-effectiveness of HAT has been carried out, prominent bioethicists have debated whether or not a heroin addict can give informed consent to HAT. Charland (2010), among others, argue that it cannot be taken for granted that heroin addicts can give informed consent to this treatment modality, while this view has been opposed by bioethicists such as Foddy and Savulescu (2005). Carter (2008) suggests that “Conflicting motives for providing such treatment (e.g. improving the personal health of addicts and protecting public health and order) can also influence what individuals are required to consent to, and how that consent is obtained” and attempts to develop an ethical framework for obtaining informed consent in this context.

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