Targeting HIV-related outcomes with intravenous drug users maintained on methadone: a randomized clinical trial of a harm reduction group therapy

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two strategies for reducing the risk of human immunodeficiency virus (HIV) infection from drug use and sex were compared in injection drug users in a methadone-maintained programme (MMP). The strategies were standard care (SC) and SC enhanced by a 12-session harm reduction group (HRG) intervention. The multi-session and the single-session risk reduction interventions were both theory-driven, based on the Information-Motivation-Behavioural skills (IMB) model of behaviour change. SC included daily methadone, to a target dose of 85 mg/day (individually adjusted), 2 hours of individual case management or counselling per month, and a single IMB-based HIV risk reduction session. HRG treatment included all of the components of SC, supplemented by the weekly manual-guided HRG intervention (Avants et al. 1999, see ‘Other Publications of Related Interest’ below for bibliographic details).

Type of intervention
Treatment and rehabilitation.

Economic study type
Cost-effectiveness analysis.

Study population
The population comprised individuals recruited from a community-based MMP. To be eligible for the study, patients had to be at least 18 years of age, opioid-dependent and seeking methadone treatment, an injection drug user, and not actively suicidal, homicidal, or psychotic.

Setting
The setting was tertiary care (an inner-city methadone maintenance clinic). The economic study was carried out in Connecticut, USA.

Dates to which data relate
The dates to which the effectiveness evidence related were not reported. Some of the costs and resource use were taken from another study (Avants et al. 1999), while some were calculated. The price year was 2000.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was partially undertaken retrospectively from another study after the effectiveness results were known (Avants et al. 1999).
Study sample
From 251 eligible consecutive admissions, 224 patients agreed to participate and completed the intake battery. Four patients dropped out before beginning treatment. The 220 patients who began the treatment were randomised to either the SC group (n=112) or the HRG intervention (n=108). Of the 220 patients, 190 (86.4%) completed the 12-week programme: 86.1% (93 of 108) completed HRG and 86.6% (97 of 112) completed SC.

Seventy-five per cent of the sample were cocaine users (n=165), and/or met American Psychiatric Association DSM-IV criteria for cocaine dependence (n=101) or abuse (n=53). All were entering a new treatment episode of methadone maintenance. Twenty-four per cent (52 of 220) were first-time methadone patients.

Power calculations were not reported.

Study design
This study was based on a single-centre randomised controlled trial (RCT), with 12 weeks of follow-up. The report presented the results from phase I of a two-phase study. Phase I tested the efficacy of a 12-week harm reduction intervention (phase II re-randomised patients either to receive or not to receive a single booster session after treatment completion). The patients were randomised using a computerised randomisation programme. The same counsellor provided SC to patients in both groups. Receipt of study treatments was verified through attendance records and patients' charts. Receipt of other services in and out of the programme (e.g. medical care, vocational counselling) was assessed monthly using the Treatment Services Review (McLellan et al. 1992, see ‘Other Publications of Related Interest’ below for bibliographic details).

Analysis of effectiveness
The primary outcomes were:

- drug use, assessed by twice weekly urine samples analysed for the presence of opiates and cocaine metabolite benzoylcegonine; and
- self-reported HIV risk behaviour (penetrative sex without a condom, sharing of drug paraphernalia, and reuse of used, not bleach-disinfected, needles).

Harm reduction behaviour and treatment satisfaction were also assessed by self-report. The analysis was conducted on an intention to treat basis. There were no significant differences between the groups in terms of any of the baseline demographic or substance use variables.

Effectiveness results
The results were numerous, so only those that showed significant differences are reported here.

Cocaine use: significantly more cocaine users assigned to HRG than SC achieved 3 or more consecutive weeks of abstinence from cocaine, 51% (43 of 85) for the HRG group versus 34% (27 of 80) for the SC group, (\(\chi^2(1)=4.78\), \(p=0.03\)).

Sex-related risk behaviour: the total number of weeks in which unsafe sex was reported was significantly lower for patients in the HRG group (2.40 +/-3.42) than those in the SC group (3.67 +/-3.89), (\(F(1,218)=6.63\), \(p=0.01\)).

Harm reduction treatment process: patients assigned to HRG scored significantly higher on the more specific drug-related HIV risk reduction knowledge quiz following receipt of the intervention, (\(F(1,210)=15.10\), \(p=0.001\)). Although skills improved in both conditions, patients assigned to HRG showed significantly greater improvement in skills. HRG patients also scored higher in the sex-related HIV risk reduction knowledge quiz post-intervention than did SC patients (\(F(1,207)=12.04\), \(p=0.001\)). Finally, at post-treatment assessment, more HRG patients who, pre-treatment, had reported no intention of using condoms for every sexual encounter in the future, stated that they now intended to always use condoms, 32% (17 of 53) in the HRG group versus 14% (8 of 55) in the SC group, (\(\chi^2(1)=4.66\), \(p=0.03\)). Also, more HRG than SC patients who, pre-treatment, reported that they never used condoms for any sexual encounter, reported at
post-treatment that they now used condoms, 32% (14 of 44) in the HRG group versus 12% (6 of 48) in the SC group, (chi^2(1)=5.04, p=0.02).

Patients assigned to HRG had greater increases in self-efficacy, as assessed by the multidimensional safer sex self-efficacy scale, in potentially unsafe sexual situations (time F(1,199)=17.51, p=0.001; interaction F(1,197)=4.72, p=0.04).

Treatment satisfaction: on a scale from 0 (not at all) to 10 (extremely), patients assigned to HRG reported greater satisfaction with treatment than did patients assigned to SC, 7.63 (+/- 1.75) for HRG versus 6.71 (+/- 2.02) for SC, (F(1,193)=10.99, p=0.001).

There was no significant difference in fidelity of treatment conditions, retention, heroin use and drug-related risk behaviour.

**Clinical conclusions**

The authors stated that the addition of a weekly manual-guided IMB-based group intervention to standard methadone maintenance treatment significantly improved outcomes in comparison with SC that included a single IMB-based risk reduction session. Patients in both conditions reported reduced injection drug use and needle sharing, regardless of study assignment. However, patients receiving the HRG were more likely to reduce sexual-risk behaviour than patients receiving the single-session intervention alone. There were fewer differences between the conditions with respect to drug-related process outcomes. Given that all patients were treatment seeking and maintained on an effective opiate agonist, it is not surprising that motivation and self-efficacy to reduce the harm of injection drug use was high at entry into treatment, and did not change significantly with treatment.

**Measure of benefits used in the economic analysis**

No summary measure of benefits was used. The costs and effects were left disaggregated and the study was, in effect, a cost-consequences analysis.

**Direct costs**

The costs per patient included methadone, urine toxicology screens, individual and/or group counselling, and on-site vocational and medical services. The costing was conducted retrospectively. The primary costs and utilisation data were derived from internal accounting documents and attendance records at the clinic where the study was conducted. The authors used procedures described in another study (Avants et al. 1993). In addition, the costs of treatment were calculated and adjusted to year 2000 dollars. The unit cost of these services included salaries, fringe benefits (24%) and an overhead rate (3.43). Clinicians' hourly counselling rate and cost per 90-minute HRG was then estimated as detailed by Rosenheck et al. (see ‘Other Publications of Related Interest’ for bibliographic details).

Discounting was not carried out, which was appropriate given the short time horizon of the study. The quantities and the costs were reported separately. They were estimated on the basis of actual data and were obtained from the provider. The price year was 2000.

**Statistical analysis of costs**

The costs were treated stochastically. The total programme cost per patient was calculated, based on the services actually received by each treatment completer. The treatment costs were then compared by treatment condition using an analysis of variance (ANOVA).

**Indirect Costs**

The indirect costs were not reported.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total programme costs for the 12-week study period were significantly higher for HRG ($2,337 +/- 350) than for SC ($1,771 +/- 468), (F(1,188)=88.44, p<0.001). The daily cost was $28 (+/- 4) for HRG versus $21 (+/- 6) for SC.

The cost per patient for the 12-week HRG intervention over and above the cost of standard methadone maintenance during the same time period was $566.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors’ conclusions
The enhancement of standard methadone maintenance treatment with a weekly harm reduction group (HRG) intervention based upon the Information-Motivation-Behavioural skills (IMB) model provided significant clinical benefits, by decreasing illicit drug use as well as unsafe sexual practices. The enhancement of methadone maintenance programmes (MMPs) has the potential to be extremely cost-effective, as well as to provide substantial health benefits for the individual patient and society.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was explicitly justified by the authors, as well as the theoretical background used in both groups to administer the sessions. Although methadone maintenance is associated with a reduction in HIV transmission, there is considerably less evidence that MMPs increase condom use or safer sexual practices. You should judge if the comparator is relevant in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on an RCT, which was adequate for the study question. The study sample was representative of the study population. In addition, the patients groups were shown to be comparable at analysis. Appropriate statistical analyses were undertaken to ensure comparability of the patients group. The authors stated that the short term follow-up was a limitation of the study. No power calculations were reported. Statistical analyses were undertaken in relation to the main findings, to account for potential biases and confounding factors. Other strengths were that the study outcomes in both drug- and sex-related domains were evaluated with multiple outcomes, the interventions were standardised, and procedures were in place for assuring the integrity of the treatment conditions.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefits. The reader is thus referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The study had a detailed and explicit costing table, with all relevant categories and items included from the adopted health provider perspective. The unit costs were partially taken from a published study and partially calculated based on services actually received by each treatment completer. The treatment costs were then compared by treatment condition using an ANOVA.

The costs and the quantities were reported separately, which will enable decision-makers to assess the generalisability of the cost results to other settings. The costs were treated stochastically, but no sensitivity analysis of the prices was conducted. This limits the interpretation of the results. Discounting was not necessary since the study had a very short time horizon. The price year was reported, which will aid any possible inflation exercises.

Other issues
The authors made comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The conclusions reflected the scope of the analysis.

The authors recognised some limitations of the study. They stated that future research could address several issues that were not addressed in the study. For example, matching groups by the amount of time spent at the clinic, and estimating the actual number of new cases of HIV averted by HRG compared with SC. According to the authors, it has been estimated that each averted HIV infection saves society approximately $154,000 in discounted lifetime treatment costs of HIV disease, and that five to seven HIV infections are averted for every 100 HIV-negative drug users maintained on methadone for a year. Thus, the benefits of providing the multi-session IMB-based group intervention to drug users enrolled in community-based MMPs are likely to far outweigh the minimal additional cost that would be involved if the results of this trial assessing mainly behaviours are confirmed by future studies assessing "harder" outcomes (i.e. HIV infection) with longer follow-up.

Implications of the study
Although increasing group size would undoubtedly make the intervention more cost-efficient, the potential for a diminished effect on outcome consequent to reduced opportunity for individual practice of skills should be considered.

One potentially important treatment-related variable to be examined in future studies is the use of cognitive remediation strategies, which may facilitate the acquisition and retention of relapse prevention and risk reduction skills.

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Other publications of related interest


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