Interim vs. Standard Methadone Treatment: A Benefit-Cost Analysis

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Abstract

A benefit-cost analysis was conducted as part of a clinical trial in which newly-admitted methadone patients were randomly assigned to interim methadone (IM; methadone without counseling) for the first 4 months of 12 months of methadone treatment or 12 months of methadone with one of two counseling conditions. Health, residential drug treatment, criminal justice costs, and income data in 2010 dollars were obtained at treatment entry, and 4- and 12-month follow-up from 200 participants and program costs were obtained. The net benefits of treatment were greater for the IM condition but controlling for the baseline variables noted above, the difference between conditions in net monetary benefits was not significant. For the combined sample, there was a pre- to post-treatment net benefit of $1,470 (*95% CI: –$625; $3584*) and a benefit-cost ratio of 1.5 (*95% CI*: 0.8, 2.3), but using our conservative approach to calculating benefits, these values were not significant.

Keywords

benefit-cost; methadone treatment; interim methadone

1. Introduction

U.S. Federal regulations require that methadone treatment of opioid dependence must be accompanied by psychosocial support services. Over much of the past 40 years, this requirement has played a role in limiting the availability of methadone treatment. It has done so in two ways. First, because of frequent turnover among counseling staff in many programs, there were often times when programs had to curtail admissions because they had

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All subjects provided informed consent and study procedures were in accord with the standards of the Committee on Human Experimentation of the institution in which the experiments were done or in accord with the Helsinki Declaration of 1975.

too few counselors to meet minimum mandated requirements for psychosocial support (Schwartz, Kelly, O'Grady, Gandhi, & Jaffe, 2011). Second, some states have sharply limited the availability of publicly-subsidized methadone treatment while still allowing the establishment of programs for self-paying or privately insured patients. Therefore, patients without private insurance or the means to pay for treatment themselves were obliged to pay for both the methadone and the mandated psychosocial services. If they could not afford both, they could not have either, even if they might have been able to pay for the cost of the medication services alone. The net effect is that pay-for-treatment programs have high drop-out rates (Booth, Corsi, & Mikulich-Gilbertson, 2004) and in many parts of the U.S. there are still people who want methadone treatment but are unable to access it even while the capacity to provide methadone medication alone is underutilized.

In the 1980s, Yancovitz and colleagues (1991) conducted a study showing that patients receiving methadone alone for four weeks (termed interim methadone [IM] by these authors) had significantly lower rates of heroin use and drug injection as compared to waiting list controls. These results prompted the Food and Drug Administration (FDA) and National Institute on Drug Abuse (NIDA) to draft federal regulations to permit "interim methadone" when waiting lists existed. These regulations, which were not approved until 1993, permitted IM for up to 120 days, but only in not-for-profit Opioid Treatment Programs (OTPs) and only for opioid-dependent adults who would otherwise have to wait at least 2 weeks for standard methadone treatment. They also required that a request for IM be submitted to the Substance Abuse and Mental Health Services Administration (SAMHSA) by the highest health officer in the state, and that each individual OTP receive written approval from SAMHSA before providing IM (Federal Register, 1993).

Due to these restrictions, IM was seldom used by OTPs over the next decade, until Schwartz and colleagues (2006, 2007) conducted a random assignment study comparing 4 months (120 days) of IM to waiting list controls. At 4 months, all IM participants were offered standard methadone treatment. They found that the IM condition had significantly lower rates of opioid positive urine tests at 4- and 10-month follow-up compared to the waiting list condition. Furthermore, only 27.5% of waiting list participants entered standard methadone treatment by the 10-month follow-up.

In the parent study of the present report, Schwartz and colleagues randomly assigned opioid-dependent adults on a waiting list for one of two OTPs to either IM or to methadone with standard counseling (SM) or at one site to methadone with counseling provided by a counselor with a caseload of about half the standard condition (termed restored methadone [RM] because it restored the caseloads to those more common in the early days of methadone treatment). Participants assigned to IM were admitted to standard methadone by the end of the 4th month. At both 4- and 12- month follow-up, there were no statistically significant differences between conditions in terms of self-reported days of heroin or cocaine use, opioid or cocaine positive drug tests, self-reported days of illegal activity, and arrests (Schwartz et al., 2011; Schwartz, Kelly, O'Grady, Gandhi, & Jaffe, 2012) or HIV-risk behaviors (Kelly, Schwartz, O'Grady, Gandhi, & Jaffe, 2012).

Although there have been a number of benefit-cost studies of drug and alcohol dependence treatment (Flynn, Kristiansen, Porto, & Hubbard, 1999; French, Salome, & Carney, 2002; French et al., 2000; Harwood, Hubbard, Collins, & Rachel, 1988; Koenig, Denmead, Nguyen, Harrison, & Harwood, 1999; Salomé, French, Scott, Foss, & Dennis, 2003), relatively few have presented separately the benefit-cost findings associated with methadone maintenance treatment. For example, a 2003 review of published peer-reviewed papers on economic benefits of a variety of addiction interventions identified only 11 economic studies that met criteria for inclusion (McCollister & French, 2003). Although several of the cited

studies included methadone-treated patients among the several modalities of treatment, none broke out separately the benefits and costs of methadone treatment. The one paper that exclusively explored the benefits of methadone treatment was actually a study of the effects of closing a single, publicly-funded methadone program in Miami-Dade, Florida (Alexandre, Salome, French, Rivers, & McCoy, 2002). Not included in the McCollister and French (2003) review was a report on the reduction in criminal behavior in pregnant women treated with methadone (Daley et al., 2000).

Notably, among the studies that presented benefit-cost results of methadone treatment in book chapters and government reports not covered in the review by McCollister and French were those dealing with data from several large multisite studies: Treatment Outcome Prospective Study (TOPS), National Treatment Improvement Evaluation Study (NTIES), and the California Drug and Alcohol Treatment Assessment (CALDATA).Harwood et al. (1988) analyzed data collected in the TOPS study of over 11,000 patients admitted to 41 different programs in the US. This study was limited to the benefits from reductions in crime associated with treatment, including benefits associated with reduced criminal justice system costs, avoided costs to victims of crimes (e.g., value of medical care, property destruction, and lost work and household productivity), and the value of the methadone patients' potential lost productivity resulting from their pursuit of criminal activity rather than legitimate earnings. The study concluded that the benefits to society (including the patients) for an average episode of methadone treatment were about equal to the costs of treatment and the benefits to the non-treated population were four times as great as the treatment costs. However, they noted that benefits were negligible or even negative for treatment of the most criminally active patients.

Flynn et al. (2002) utilized findings from DATOS (carried out in 1991–1993) which included interviews at baseline, and at 3 months and 12 months post index treatment admission at one of 16 OTPs that provided usable cost data in eight cities. Only patients who were still enrolled in treatment at the 3-month follow-up and who completed the 3-month follow-up interview were included in the analysis. As inHarwood et al. (1988), Flynn and colleagues focused on benefits associated with decreased crime and included as benefits the avoided tangible costs to victims of specific crimes and presumed productivity losses associated with patients' careers in crime. The number and types of individual crimes before, during, and after treatment were based on patients' self-reports. Using this general methodology, Flynn and colleagues found that the benefits of treatment exceeded the costs of treatment (in 1992) dollars) both for those who were discharged prior to one year (net benefit of $5,923 and benefit-cost ratio of 3.06) and for those who remained in treatment for a full year (net benefits of $7,168 and benefit-cost ratio of 2.86) with an overall benefit-cost ratio of 3.00 for the total sample.

Flynn and colleagues (2002) also summarized the findings from two other multi-site benefit-cost analyses that are available only as government reports. The benefit-cost ratios for the NTIES (Koenig et al., 1999) and CALDATA (California Department of Alcohol and Drug Programs, 2004) studies were presented as both benefits to taxpayers (later called non-treated populations) and benefits to society (including patients). For both approaches in both studies, the costs to victims, criminal justice system, and health care utilization were included. In addition, in both studies analyzed from a taxpayer perspective, the cost associated with theft and welfare payments were considered. In the CALDATA analysis from a societal perspective, the patients' potential lost earnings had they been in legitimate employment was considered whereas in the NTIES analysis from a societal perspective, the increase in legitimate earnings was considered. The benefit-cost ratios for non-treated populations in CALDATA were 12.6:1 for those discharged and 4.8:1 for those continuing in treatment, whereas the benefit-cost ratios from a societal perspective were −2.98 for

discharged patients and 4.66 for continuing patients. For NTIES the benefit-cost ratio to non-treated populations was 4.90 and the ratio for society was 2.0.

Three peer-reviewed benefit-cost studies which included methadone treatment were published subsequent to the McCollister and French review (Ettner et al., 2005; Godfrey, Stewart, & Gossop, 2004; Salome et al., 2003). Godfrey et al. used data collected in the National Treatment Outcome Research Study (NTORS) of 54 residential and community drug abuse programs in the United Kingdom. Although they also looked at health care costs, these authors found that the benefits exceeded the costs of treatment, but that most of the benefits were due to reduced crime and costs to victims of avoided crimes. Although the sample included 250 patients in methadone maintenance (and 107 on methadone dose reductions), the benefits and costs of these patients were not broken out by treatment modality.

One of the few peer-reviewed published studies that did break out benefits and costs of methadone maintenance was that of the California Treatment Outcome Project (CalTOP) by Ettner et al. (2005), which included data on 2,567 patients in 43 treatment programs across 13 counties in California. However, there were only 3 methadone programs included in the study with a total sample size of 115 participants. In this study, the methadone patients appeared to exhibit smaller reductions in crime and smaller increases in earnings than patients in outpatient or residential treatment. Even though the authors included the benefits associated with avoided costs to victims of crime in their analyses (as did Harwood et al., 1988 and Flynn et al., 2002), they could not reject the null hypothesis that the benefits of methadone treatment were zero, even though the average benefits were greater than the average treatment costs. The authors believed that the inability to show statistical significance in the benefit-cost ratio for methadone treatment may have been due to the small sample size and inadequate power.

Although Ettner et al. (2005) found that about half of the benefits of methadone treatment were due to patients' avoided health care costs, other studies have found that reductions in crime constitute the main driver of societal benefits. In both the NTORS and CalTOP studies, as in the overall conclusion from the McCollister and French review, most of the benefits of treatment were due to reductions in criminal justice systems costs and costs to victims of crime, with relatively small changes in the utilization of high cost emergency room and hospitalizations. Nevertheless, it is possible that avoided health care costs could be substantial for certain populations.

A benefit-cost evaluation was planned as part of the clinical trial described above (Schwartz et al., 2011, 2012), in which newly-admitted methadone patients were randomly assigned to receive IM or methadone with standard or restored counseling. Using the societal perspective, this paper reports on: (1) the costs, benefits, net benefits, and benefit-cost ratios of the study treatment conditions; (2) comparison of IM to the combined SM/RM conditions on net benefits and benefit-cost ratios at follow-up, adjusted for baseline differences; and, (3) the costs, net benefits, and benefit-cost ratios of methadone treatment (of both conditions combined) during the trial. All costs and benefits are expressed in 2010 dollar units. There are three reasons for reporting on the benefit-cost analyses despite the lack of statistically significant differences between conditions on the outcomes reported in our prior work from the parent grant (Kelly et al., 2012; Schwartz et al., 2011, 2012). First, as mentioned above, there is a relative paucity of benefit-cost analyses (BCA) of methadone treatment. Second, several outcomes important to BCA (such as earned income and emergency room and hospital utilization) were not included in our previous papers. Finally, the cost of providing the treatment in each of the study conditions was not previously reported.

2. Methods

2.1. Description of the Trial

Participants—The participants in the parent study (*N*= 230), which is more fully described in Schwartz et al. (2011, 2012), were recruited from heroin-dependent adults enrolling in one of two Baltimore Opioid Treatment Programs (OTPs) who had been placed on waiting lists. Participants were randomly assigned to receive methadone alone (Interim Methadone [IM], *n* = 99), methadone with standard drug abuse counseling with a caseload of no more than 50 patients (Standard Methadone [SM], *n* = 104), or, at one clinic only, methadone with drug abuse counseling provided by a counselor with a reduced caseload of no more than 25 patients (termed Restored Methadone [RM], because it restored lower caseloads that were typical in the early days of methadone treatment in the US; *n* = 27). Participants were assessed at baseline, and 2, 4, and 12 months post-baseline. Data necessary for the benefit-cost analysis were missing on 30 participants in the RCT at one or more points during the 12-month follow-up period. As a result, the sample for the present benefit-cost study included 200 of the 230 participants in the RCT for whom economic data were available. A χ^2 test of independence showed no significant differences in the relative frequency of IM participants *vs*. SM/RM participants with missing data who were not included in analyses for this study (10/99 IM participants [10.1%] *vs*. 20/131 SM/RM participants [15.3%]; *p*=. 25).

Procedure—The study was approved by Institutional Review Boards of the Friends Research Institute and of the participating OTPs and informed consent was obtained from all participants. Interim Methadone was provided in accordance with the federal regulations governing such treatment (Federal Register, 1993). IM participants were required to receive directly-observed methadone 7 days per week for up to 120 days. Take-home doses were not permitted. Counseling was available for emergencies only for participants receiving IM. When methadone treatment slots with counseling became available in the program (on an average, 113 days post-baseline), all IM participants were able to transfer directly into those treatment slots and to thereby receive counseling. The standard and restored methadone treatment conditions began with directly-observed methadone seven days per week. Individual and group counseling were available to SM/RM participants and they were able to earn take home doses after 90 days of demonstrating progress in treatment (negative drug tests and complying with program rules). The number of participants recruited was less than planned because on several occasions both programs closed their admissions process for periods of weeks to months because of "counselor shortages."

2.2. Benefits of Treatment

Benefits Questionnaire—A questionnaire was administered at each follow-up interview in which participants were asked about the number of services they received at the program and the number of days they visited the emergency room (ER) for treatment for medical or psychiatric problems; spent overnight in the hospital for medical or psychiatric problems (and why); and spent in residential drug abuse treatment. Data were also collected on the number of days incarcerated, the number of times arrested, and the amount of legal income (including wages and disability, alimony, child support, welfare, and retirement) since their last research interview. Thus, economic data included health service utilization, criminal justice-related costs, and labor market/employment factors.

2.3. Benefit Outcomes

Benefits were calculated based on the self-reported items from the questionnaire described above, except for arrest data which was drawn from a publically-available database of judicial records for the State of Maryland.

Emergency Room and Hospital Utilization—At baseline, participants were asked to report the number of days they had been treated in the emergency room or hospitalized overnight for medical or psychiatric problems in the preceding 12 months. At each follow-up interview at 2, 4, and 12-months post-baseline, participants were asked to report the number of days they had been hospitalized in the period of time since their last scheduled interview as well as the name of the hospital and the principal reason for hospitalization. Over the 12 month follow-up period, 80% of the hospital days and 27 of 40 hospital episodes were spent in four of the hospitals located in Baltimore City (University of Maryland, Mercy, Sinai, and Harbor hospitals). Therefore, to estimate the average cost per hospital day, we utilized the charges for the average cost of a hospital day for these four hospitals. The charges in Maryland are set and regulated by the state's Health Services Cost Review Commission (2012). This average figure was $2,560 per day for medical problems and $1,794 for psychiatric illness, a significant underestimate of the costs of a period of hospitalization because it does not include professional fees, medications, laboratory, and imaging. The average cost of a "bundled" ER visit, including ancillary services, was obtained from the literature (French & Martin, 1996). This cost was updated to 2010 dollars using the All Items Consumer Price Index (CPI), yielding an estimated cost of $813 for each ER visit. This is a conservative estimate given the average cost for an ER visit in 2009 was $1,318 in the US (Agency for Healthcare Quality Research, 2009).

Arrests—Although the number of arrests was obtained by self-report from each participant during each follow-up period, we did not obtain self-reported number of arrests in the 12 months prior to treatment entry. Hence, we chose to use what we believe to be more reliable estimates of arrests obtained from public judicial records available in Maryland (http://casesearch.courts.state.md.us/inquiry/processDisclaimer.jis.). The average cost of an arrest was obtained from the literature from average cost per criminal justice processing in Metropolitan Miami Dade County in 1987, as reported in Cohen et al., 1994. Costs were adjusted for 2010 using the All Items CPI. The cost in dollars of an arrest represents the average cost per case for investigation and arrest, booking, screening and pre-filing process, arraignment, pretrial hearings, and sentencing, but not costs associated with any associated incarcerations. The inflation-adjusted cost of an arrest was estimated to be $4,568.

Incarceration—Participants were asked at baseline the number of days in which they were incarcerated in the previous year and asked again at each follow-up interview. The cost per incarceration day included the cost of resources used for staff time, food, medical, and support, as well as overhead costs. The cost information was obtained from the Maryland Department of Legislative Services (2008) and updated to 2010 values using the All Items CPI. The cost of an incarceration day was estimated to be $89.

Residential Drug Abuse Treatment—Participants were asked at baseline the number of days in which they were in residential drug treatment in the previous year and asked again at each follow-up interview. The cost per day for inpatient residential treatment was obtained from French et al. (2002) and updated to 2010 using the All Items CPI. It was estimated to be $126 per day, which is consistent with the amount paid for residential treatment by the city's substance abuse treatment authority.

Legal Income—Legal income earned (including on-the-books work, disability payments, welfare, retirement, alimony, and child support) was asked at each interview. Responses were categorical in increments of $5,000. We added the average of each category to determine the approximate amount of legal income for each participant.

2.4. Costs of Treatment

The costs for the treatment conditions are described below and did not include costs associated solely with research or the costs to the participants associated with adherence to treatment.

Our cost approach used a combination of cost data collected from the Drug Abuse Treatment Cost Analysis Program (DATCAP) and from administrative data. The DATCAP is an easy-to-use, valid, and reliable data collection instrument that enables uniform and comparative measurement of substance abuse treatment costs including methadone maintenance programs (French, Dunlap, Zarkin, McGreary, & McLellan, 1997; French et al., 2002). The DATCAP was completed by the Program Administrator at each site for the 2010 fiscal year and reviewed by one of the authors (P.A.). Costs were calculated as opportunity costs, that is, all resources used in the delivery of treatment services in the treatment programs were identified and valued at their market value, including those services that were subsidized or obtained free of charge.

Costs Associated with Standard and Restored Methadone Treatment—After cost data were gathered, we calculated total costs of the programs, mean weekly cost per patient, and mean cost per treatment episode. To estimate the costs associated with treatment for the SM/RM treatment conditions, individual records were reviewed to determine the total number of weeks in treatment for each participant at each treatment site. The cost of a treatment episode for each participant was estimated by multiplying the mean length of stay in methadone treatment (in weeks) by the corresponding mean weekly cost of treatment per participant during the 12 months of follow-up. The weighted mean cost per participant (for both sites combined) was then estimated through proportional weighting. This was accomplished by multiplying the number of participants at each site × the mean number of weeks in treatment and dividing that product by the sum of the products of the number of participants × the mean number of weeks in treatment at each site.

Costs Associated with IM—Because in the US, IM can only be provided by an accredited program that meets approval standards of both Federal and State regulators, we calculated the costs of adding a limited number of IM patients to an already functioning program, i.e., the implementation costs. In the two programs we studied, no additional medical exams were required at the time of transfer to SM or RM. Current US regulations prohibit take-home doses for patients receiving IM. Because the two programs we studied ordinarily operated 7 days a week, there were no additional costs incurred for accommodating the 7 day a week requirement for IM patients. Also, in the case of the two programs studied here, it was possible to arrange the medication dispensing time to accommodate the approximately 20–30 IM patients treated at any given time without adding more nursing staff or expanding clinic hours. Costs would have been higher had the clinic been required to open additional hours to accommodate the IM patients. These two clinics utilized computerized dispensing of liquid methadone, which required about two minutes per patient for each dose dispensed and observed. The direct costs to the programs were only those of the methadone itself (about 32 cents per 100 mgs). The cost of urine testing was low because only 3 tests per participant were required to be obtained during 4 months of IM as per US federal IM regulations (Code of Federal Regulations 42 Part 8, 2001).

2.5. Analysis

We compared the net benefits of IM with those of methadone with scheduled counseling consistent with the reporting of results in Schwartz et al. (2011). As part of this analysis, we first compared IM and SM/RM conditions on the relevant variables for the 12 months prior to treatment entry (baseline) to determine if, despite random assignment, there were

statistically significant differences between the two conditions at baseline. Results of overdispersed Poisson regression analyses of each of the potential benefit variables showed significant between-condition differences for the number of days incarcerated (56.7 *v.* 24.8 days for IM and SM/RM, respectively; $p = .001$), the number of days in residential treatment (5.1 *v.* 1.0 days for IM and SM/RM, respectively; $p < .001$), and the amount of legal income earned (\$5,000 *v.* \$7,590 for IM and SM/RM, respectively; $p = .011$) in the 12 months preceding treatment.

In order to adjust for these pre-baseline differences, we compared the treatment conditions on the total monetary benefit for the 12-month follow-up period controlling for total monetary benefit for the 12-month period prior to baseline. A composite variable was created to represent total monetary benefit for each participant for the 12-month follow-up period. This variable was calculated from the legal income earned during the 12-month follow-up period minus the sum of costs of emergency room visits for psychiatric or physical problems, days hospitalized for psychiatric or physical problems, days of residential drug treatment, days incarcerated, and number of times arrested during the 12-month follow-up period. A composite variable similarly constructed using legal income and the seven costs reported at baseline served as a covariate. Standard errors and confidence intervals were obtained for the difference between conditions in total monetary benefit for the 12-month follow-up period using bootstrapping techniques.

Finally, in order to compare overall benefit-cost of the entire treatment sample with prior research, we conducted a benefit-cost analysis for the total sample of 200 participants to examine pre-treatment to follow-up differences without adjustment for baseline variables. Treatment benefits were first calculated for each of the 8 relevant variables by subtracting pre- from post-12-month values for each participant, then multiplying the difference by the monetary values (adjusted for inflation to 2010) drawn from literature and local Maryland data (for the cost of a day in the hospital and a day incarcerated) as described above. Bootstrapping (10,000 samples with a percentile estimation approach) was then used to obtain standard errors and confidence intervals for total mean treatment benefits, net benefits (benefits minus costs), and benefit-cost ratio (benefits divided by the cost).

3. Results

Participants

The mean (*SD*) age of the 200 participants was 43.6 (7.7) years old; 69.5% were men, 80.5% were African American, and 19.5% were White.

3.1. Costs Associated with IM and SM/RM

Costs—Table 1 shows the cost estimates in 2010 dollars for SM/RM and IM treatment. Table 1 presents the mean length of stay (in weeks), weekly mean cost per participant, cost per treatment episode (defined as the mean length of time during which the participant was enrolled in treatment) at each site, and the weighted mean cost for the two sites combined. On a weekly cost basis, the estimate of cost during the first four months of IM treatment was \$3.50 per participant for both sites. The direct costs to the programs for IM were only the cost of methadone itself (about 32 cents per 100 mgs). The cost of urine testing was low because only 3 tests per participant were required to be obtained during 4 months of IM as per US federal IM regulations (Code of Federal Regulations 42 CFR Part 8, 2001). There were very rare instances of the use of emergency counseling among participants in the IM Condition. Hence, the cost of providing IM at the margin (for adding each additional participant to an existing OTP) was about \$3.50 per participant per week.

Cost per treatment episode for the IM condition over the 12 months following study enrollment was $1,760 at site 1 and $3,117 at site 2. Because the number of IM participants treated at the two sites and their lengths of stay were unequal, the weighted mean cost at both sites combined for an episode of treatment was $2,052. The cost per treatment episode for the SM/RM condition was $2,809 at site 1 and $4,144 at site 2. The higher cost at site 2 was mostly attributed to the greater number of personnel at that site. The weighted mean cost for both of these sites combined was $3,411.

3.2. Benefits

SM/RM condition—As noted above in methods, there were statistically significant differences between the IM and SM/RM conditions in the number of days of incarceration and the number of days of residential drug abuse treatment in the 12 months prior to treatment entry. The IM condition had significantly higher rates for both variables as well as a significantly lower amount of legal income. We expected that these differences would result in substantially more benefits for the IM group compared to the SM/RM group in terms of post-treatment reduction in days incarcerated, days in residential drug treatment, and in legal income. The expectation proved to be the case. The 111 participants in the SM/RM treatment group had a change (slight increase) of 0.1 days in ER use for medical problems (from 0.1 days pre- to 0.2 days post-entry) and 0.3 days hospitalized for medical problems (from 0.5 days pre- to 0.8 days post-entry) with net benefits of -$29 for ER use and -$784 for days hospitalized. They experienced a reduction in days of incarceration from an average of 24.9 days pre-entry to 10.8 days post-entry, with a mean net benefit from avoided incarceration of $1,263. This group experienced a change in arrest of .02 (from 0.61 arrests pre- to 0.63 arrests post-entry) for a benefit of -$82, and while their self-reported legal earnings increased from $7,590 at baseline to $8,355, the increase was only $766. The sum of all benefits was $1,164. The net benefit was -$2,246 and the benefit-cost ratio was 0.3.

IM condition—In contrast, for the 89 IM participants, there were substantial reductions in days in residential treatment (5.1 pre- *v.* 0.3 post-entry) yielding a benefit of $595, reductions in days incarcerated (56.7 pre- *v.* 7.8 post-entry) yielding a benefit of $4,380, and a change of 0.1 in number of arrests (0.5 arrests pre- *v.* 0.4 arrests post-entry), yielding a benefit of $565. Self-reported legal income increased from $5,000 pre-entry to $7,500 post-entry for a benefit of $2,500. The sum of all the benefits was $7,991. The net benefit was $5,939 and the benefit-cost ratio was 3.9.

IM condition compared with SM/RM conditions for 12-month follow-up period after adjustment for baseline differences—As shown in Table 2, there were no significant differences between treatment conditions in total treatment monetary benefits for the 12-month follow-up period, once we controlled for the pre-baseline benefit composite variable (IM – SM/RM mean difference: *b*=$2,155; *95% CI*: -$582, $5015; *p*>.05). A second analysis that included all 8 pre-baseline monetary benefit variables (instead of the composite) and a third analysis that controlled only for the three variables at baseline that were significantly different between conditions (e.g., days of incarceration, days of residential treatment, and earned income) likewise showed no significant difference between treatment conditions in total treatment monetary benefits in the 12 months following study enrollment (both *p*s>.05, respectively).

Total sample—As shown in Table 3, the mean post-treatment entry benefit for the total sample (*N* = 200) was $4,202. The major contributors to this overall benefit were reduction in days of incarceration ($2,650) and increases in legal income ($1,538). Of note was a modest increase in the number of days of hospitalization, resulting in a negative benefit

(loss) of $512. Thus, the provision of methadone treatment in this study (on an intent-to-treat basis) without accompanying primary care medical services did not lead to a decrease in hospital utilization.

As shown in Table 4, the mean cost for a methadone treatment episode (both sites and both conditions combined) was $2,732 and the mean benefits were $4,202, yielding a net benefit of $1,470, and a benefit-cost ratio of 1.5, which was non-significant (*95% CI*: 0.8; 2.3).

4. Discussion

In our previously reported RCT comparing IM and SM/RM (Schwartz et al., 2011, 2012) we found no statistically significant differences between the treatment conditions on the most commonly reported treatment outcome measures such as retention in treatment, self-reported drug use, self-reported arrests, urine tests positive for illicit opioids or cocaine, and all ASI composite scores including alcohol, drug, legal, employment, medical, family/social, and psychological domains. In the present economic analysis from that trial, we examined: (1) the costs, net benefits, and benefit-cost ratios of the two treatment conditions; (2) the comparison of the net benefits and benefit-cost ratios between the two conditions controlling for baseline differences; and (3) the net benefits and benefit-cost ratios of the total sample.

We found that the costs of adding a limited number of IM patients to existing programs can be substantially lower than for SM/RM. If clinics would offer interim methadone treatment near its minimal cost, it could expand access to treatment for people without health insurance, for those whose insurance does not cover methadone treatment, or for those who for other reasons do not wish their insurers to know of their treatment for opioid addiction. Difficulty in paying for methadone maintenance treatment is a significant factor in drop out rates (Booth et al., 2004).

Because the results of the RCT showed no significant difference in treatment outcomes between IM and SM/RM conditions and the benefit-cost ratio comparing conditions and controlling for baseline differences was not significant, we believe it is reasonable to conclude that IM treatment was not associated with clinical disadvantage to the participants or economic disadvantage to society. Indeed, the IM condition did not differ from the SM/RM condition, despite the regulatory requirement that participants in the IM condition were not eligible for the motivational incentive of obtaining a take-home dose for negative urine drug tests after the first 90 days of treatment.

The findings here for the total sample of a benefit-cost ratio of 1.5 for outpatient methadone treatment are largely consistent with those of previous benefit/cost studies that presented the costs and benefits for methadone treatment broken out separately from other treatment modalities, in that most of the benefits of treatment result from reductions in costs related to the criminal justice system (Flynn et al., 2002; Harwood et al., 1988; Koenig et al., 1999). We found no reductions in the utilization of hospitals and emergency rooms, and only small increases in legitimate earnings. Our findings are consistent as well with more recent research (Ettner et al., 2005) in that after bootstrapping to establish confidence intervals for benefits, we could not state that the benefit-cost ratio was statistically significant using our conservative methods. The criminal justice system-related benefits would have been greater had we elected to include the avoided victim costs, both tangible and intangible (Ettner at al., 2005; Flynn et al., 2002; McCollister & French, 2003; Harwood et al., 1988), and reductions in money spent on illegal drugs, or had we tried to adjust for the underestimation of the number of crimes committed that results from using only recorded arrests to calculate CJS-related savings (Ettner et al., 2005; McCollister & French, 2003), or used self-reported arrests rather than official arrest records. The benefits might be considerably higher than the

costs over a longer period that might include multiple episodes of treatment (Zarkin, Dunlap, Hicks, & Mamo, 2005).

It is possible that patients in programs providing direct primary medical care would show reduced utilization of hospitals and emergency rooms. Overall benefits also would have been greater had we attempted to monetize improvement in quality of life of the patients and their families, potential savings from avoidance of drug use-related HIV and hepatitis risk behavior, and the likely medical problems associated with hepatitis and HIV infection. On the other hand, treatment costs would have been higher if we had included the travel and opportunity costs to patients associated with program participation. Considering the differences outlined above between our conservative methods and previous research, the differences in the treated populations, and the 30 year time period over which the reviewed studies were done, the differences between the findings reported here and those previously reported in the literature are relatively small.

While our findings of greater benefits than costs (though non-significant) may be of interest to policy makers, to the best of our knowledge, in the entire spectrum of medical interventions, it is only in the area of treating substance-using adults that we judge the value of treatment primarily by the savings to non-treated populations rather than the benefits of those treated.

In addition to methodological issues mentioned above (e.g., the decisions not to include reductions in costs to crime victims as benefits or to inflate the public records of arrests to more realistically reflect reductions in crime) there are several additional factors which limit the generalizability of these benefit-cost findings. The most obvious of these is that we studied only two treatment programs in one East Coast City in the US at one point in time during which unemployment for those with limited education was high. Although the number of participants (*N*=200) in our study is larger than the 115 participants in the three programs included in Ettner et al. (2005), it is nevertheless a small and perhaps unrepresentative sample of the universe of methadone maintenance patients in the US. Finally, the cost data for these two programs may not generalize to other programs in the US or beyond. An additional limitation to the benefit-cost analysis is that the parent grant was powered only to detect differences in clinical outcomes, and, as such, it may not have been adequately powered to detect differences in cost between the two conditions.

The present study which found comparable benefit-cost outcomes for interim and standard methadone raises an important question: Should patients seeking methadone treatment who cannot afford both the psychosocial treatment and supervised methadone be deprived of the option of receiving methadone alone? Private for-profit OTPs in the Baltimore area typically charge $10 or more per day of treatment, an amount that substantially exceeds our estimate of the marginal cost of treating a patient in IM. For some opioid-dependent individuals who are without insurance coverage, four months of IM at a modest fee in a private treatment program could be an important step in changing their lives.

When a regulatory entity requires a minimum number of services and also requires that individuals pay for the services themselves, thus denying some elements of treatment to those who cannot afford the full range of services, there should be evidence that the individual services used separately are in some ways harmful either to the patient or to society. For example, diabetic patients treated with insulin who are unable to afford dietary coaching or depressed patients treated with anti-depressant medication by a family physician who cannot afford psychotherapy are not deprived of the benefits of insulin or antidepressants.

There are data from other countries demonstrating that treatment with methadone offers substantial benefits when psychosocial services are not mandatory (and sometimes are not provided at all). The benefits to patients include reductions in drug use (Gossop, Marsden, Stewart, Lehmann, & Strang, 1999; Lewis & Bellis, 2001; Teesson et al., 2008) and drug-related HIV-risk behavior (Gossop et al., 1999; Teesson et al., 2008), criminal behavior (Gossop et al., 1999; Keen, Rowse, Mathers, Campbell, & Seivewright, 2000; Teesson et al., 2008), and mortality (Clausen, Ancherson, & Waal, 2008; Degenhardt et al., 2009; Gibson et al., 2008; Zanis & Woody, 1998). Benefits to society often include reductions in antisocial behaviors and drug-related incarcerations. There have been three random assignment studies in the US showing that patients receiving only supervised methadone do not have worse outcomes in terms of reduced drug use and other traditional measures compared with those receiving methadone plus required psychosocial group or individual drug counseling, at least as such services have been delivered in most programs (Gruber, Delucchi, Kielstein, & Batki, 2008; Schwartz et al., 2012; Senay, Jaffe, diMenza, & Renault, 1973). Similar findings have been observed in patients treated with buprenorphine in a primary care clinic (Fiellin et al., 2006) and in a multi-site study (Weiss et al., 2011).

The data presented here should not be used to argue that psychosocial services are of no benefit. Furthermore, because we did not conduct a cost-effectiveness study, we can not say which of the study conditions was more cost effective. Nevertheless, there have been a number of studies demonstrating that under appropriate conditions such services increase treatment retention and decrease alcohol and/or cocaine use (Burke, Arkowitz, & Menchola, 2003; Knapp, Soares, Farrel, & Lima, 2007; McCambridge & Strang, 2004). However, the findings presented here do argue that the best can be the enemy of the good. Participation in psychosocial services should not be a mandatory condition for patients to enter and remain in opioid maintenance programs. Patients deriving benefit from methadone maintenance treatment should not be discharged from treatment if they choose not to participate in counseling. These data can also argue that State and Federal regulations that make IM excessively burdensome for non-profit programs should be revised, as should the regulations that limit both the duration of IM treatment and prevent any take-home doses for IM patients no matter how well they are responding to treatment.

Acknowledgments

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Table 1

Costs per Participant for Standard/Restored Condition and Interim Methadone Condition in 2010 dollars (*N*=200)

Sites	Standard/Restored Methadone Condition (up to 12 months)			
	Mean length of Stay [weeks] (*SD*)	Weekly Cost	Mean Cost for Treatment Episode (*SD*)	Weighted Mean Cost [both sites] (*SD*)
Site 1 (*n*=61)	46 (12)	$61	$2,809 (702)	$3,411
Site 2 (*n*=50)	37 (16)	$111	$4,144 (1,797)	(1,307)

Interim Methadone Condition

Sites	(i) Interim Methadone (IM) Treatment (up to 4 months)			(ii) Standard Methadone Treatment (following IM for up to 8 months)		(i + ii) Costs for Interim Methadone Condition		
	Mean Length of Stay [weeks] (*SD*)	Weekly Cost *	Mean Treatment Cost (*SD*)	Mean length of Stay (Weeks)	Weekly Cost	Mean Treatment Cost (*SD*)	Cost for Treatment Episode (*SD*)	Weighted Mean Cost [both sites] (*SD*)
Site 1 (*n*=66)	171 (3)	$3.50	$581 (10)	271 (12)	$62	$1,702 (756)	$1,760 (761)	$2,052
Site 21 (*n*=23)	171 (1)	$3.50	$601 (2)	281 (13)	$111	$3,058 (1,445)	$3,117 (1,446)	(975)

Note: A treatment episode is defined as the period of time (in weeks) during which the participant was enrolled in methadone treatment.

The cost for methadone treatment episode for the Standard/Restored condition at each site was estimated as the product of the mean length of stay in treatment (in weeks) and the weekly cost of treatment per participant over the 12 months in treatment. The weighted mean cost per participant (for both sites combined) was estimated through proportional weighting. This was accomplished by multiplying the number of participants at each site × the mean number of weeks in treatment and dividing that product by the sum of the products of the number of participants × the mean number of weeks in treatment at each site.

The cost for methadone treatment episode for the IM condition at each site was estimated as the sum of: mean treatment cost over the 4-month Interim Methadone period and the mean treatment cost over the 8 months while receiving standard methadone treatment (with counseling). The weighted mean cost per participant (for both sites combined) was estimated through proportional weighting in a manner similar to the approach described above.

*
The implementation cost for adding a limited number of IM patients to an existing methadone program (as in the present study) if there is no need to operate the clinic for additional hours to accommodate the IM patients.

Table 2

Unstandardized partial regression coefficients (*b*), Standard Errors (*SE*), and 95% Confidence Intervals (*95% CI*) for total monetary benefits for the 12-month follow-up period (*N*=200)

Variable	b	SE	95% CI (Lower, Upper)
Total Benefit for 12 months prior to baseline (composite variable)	$0.24	$0.06	($0.13, $0.36)
Condition (IM *vs.* SM/RM)	$2,155[1]	$1,422	(−$582, $5015)

Notes: Total monetary benefit for 12 months prior to baseline is a composite variable calculated from the legal income earned during the 12-month period minus the sum of pre-treatment costs of emergency room visits for psychiatric or physical problems, days hospitalized for psychiatric or physical problems, days of residential drug treatment, days incarcerated, and number of times arrested.

[1]The *b* associated with treatment condition is the IM mean minus the SM/RM mean, adjusted for total monetary costs for 12 months prior to baseline. The 95% confidence intervals were bootstrapped using the percentile method in 10,000 replications.

Two additional analyses were conducted that similarly showed no significant differences between treatment conditions (both *p*s>.05). The first examined the difference in total monetary benefits between treatment conditions at follow-up controlling for the pre-treatment benefits and costs as separate predictor variables, rather than as part of a composite (b=$1,782; 95% CI: −$1,036, $4,422; *p*>.05). The second analysis examined the difference in total monetary benefits between treatment conditions controlling for only the three variables on which the conditions differed at baseline (legal income earned, days in residential treatment, and days incarcerated during the 12-month period prior to baseline; b=$2,072, 95% CI: −$791, $4,883; *p*>.05).

Table 3

Mean (per participant) methadone treatment benefit ($2010)[a] for Total Sample (*N*=200)

Variable	Total Sample (*N*=200)	Difference in means pre-post	Monetary value ($2010) per unit change	Mean treatment benefit[b] ($)	SE	95% CI (Lower, Upper)
Days in emergency room for physical problem						
12 months prior to baseline	0.14					
12 months following baseline	0.18	−0.03	$813[c]	−$24	$35	(−$93; $45)
Days in emergency room for psychiatric problem						
12 months prior to baseline	0.01					
12 months following baseline	0.02	−0.01	$813[c]	−$8	$10	(−$33; $8)
Days hospitalized for physical problem						
12 months prior to baseline	0.56					
12 months following baseline	0.76	−0.20	$2,560[d]	−$512	$635	(−$1,728; $755)
Days hospitalized for psychiatric problem						
12 months prior to baseline	0.04					
12 months following baseline	0.00	0.04	$1,794[e]	$72	$61	($9; $215)
Days in residential treatment						
12 months prior to baseline	2.80					
12 months following baseline	0.56	2.24	$126[f]	$282	$171	(−$10; $654)
Days incarcerated (jail or prison)						
12 months prior to baseline	39.04					
12 months following baseline	9.45	29.59	$89[g]	$2650	$568	($1,563; $3,796)
Number of arrests						
12 months prior to baseline	0.56[h]					
12 months following baseline	0.52	0.05	$4,568[i]	$206	$327	(−$457; $845)
Legal income						
12 months prior to baseline	$6437					
12 months prior to 12-month	$7975	−$1,538	$1[j]	$1,538	$451	($588; $2,350)
Total				$4,202		

Note: $N = 200$ because 30 participants did not have complete data for the follow-up period. 95% confidence intervals (shown in parentheses) were bootstrapped using the percentile method and 10,000 replicate samples.

[a] Positive values assigned to all differences that represent treatment benefits. Societal perspective is adopted.

[b] Numbers might not be exact due to rounding of the mean values.

[c] Per visit cost based on an estimate from French and Martin (1996) and updated to 2010 using the All Items Consumer Price Index (CPI).

[d] Value represents the average cost for a hospital day for the four most commonly used hospitals by study participants.

[e] Value represents the average cost for a psychiatric hospital day for manic depressive disorder for the four most commonly used hospitals by study participants.

[f] Mean average cost per day for inpatient residential treatment estimated by French et al., 2002 and updated to 2010 using the All Items CPI.

[g] Value represents cost per prison day (staff time, food, medical, support and overhead cost) based on Maryland Department of Legislative Services (2008) and updated to 2010 using the All Items CPI.

[h] These data were obtained from public arrest data base.

[i] Cost per arrest includes cost associated with investigation and arrest, booking, screening and filing, arraignment, and pretrial hearings, but not pre-trial incarceration. Value is based on data from Cohen et al (1994) and updated to 2010 using the Consumer Price Index.

[j] Conversion factor equals 1 given the variable is already in monetary units.

Table 4

Summary of Total Benefits and Costs Associated with Methadone Treatment for Both Study Sites and Standard/Restored and Interim Methadone Conditions Combined (*N*=200) [a]

Variable	Total Sample Estimate 95% *Confidence* Interval (Lower, Upper)
Mean cost per methadone treatment episode per participant	$2732
Mean total treatment benefits per participant	$4,202 ($2,134; $6,321)
Net benefits (benefits minus cost of treatment)	$1,470 (−$625; $3,584)
Benefit-cost ratio (benefits divided by cost of treatment)	1.5 (0.8; 2.3)

[a]Based on the societal perspective.

Notes: A treatment episode is defined as the period of time (in weeks) during which the participant was enrolled in methadone treatment.

The mean cost per methadone treatment episode per participant is the sum of the weighted mean cost of Standard/Restored Methadone Condition at both sites (as shown in Table 1 as $3,411) plus the weighted mean cost of the Interim Methadone Condition at both sites (as shown in Table 1 as $2,052) divided by two.

95% confidence intervals (shown in parentheses) were bootstrapped using percentile methods and 10,000 replicate samples.