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► [Treatment research in prison: problems and solutions in a randomized trial.](#)

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Addiction Research and Theory: 2010, 18(1), p. 1–13.

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In the first study of its kind, as a way of bridging the period after release opiate-dependent prisoners in Norway were randomly allocated to a six-month implant which blocks the effects of heroin or to methadone which substitutes for heroin. Many prisoners rejected treatment, wrongly believing they would sustain abstinence on release.

Summary This Norwegian study aimed to randomly allocate prisoners who had been dependent on opiates before starting their sentence to either methadone maintenance or to a naltrexone implant as a way of promoting continuity of treatment on release and avoiding relapse to heroin use. Pharmacologically the two treatments are at opposite poles; methadone is an agonist which has effects similar to heroin; naltrexone is an antagonist which has no psychoactive effects of its own but blocks the effects of heroin and other opiate-type drugs. The implant form of naltrexone is inserted under the skin. In [the form used in the study](#) blocking effects last for five to six months, avoiding the need to take the medication daily and in theory overcoming the main shortcoming of naltrexone – that patients usually stop taking the pills and resume heroin use.

In five prisons over one and a half years to January 2007 the study was publicised directly to inmates through prison health services and referrals were also sought from criminal justice staff, prison health services and social workers. Prisoners were free to accept or decline participation with no impact on their sentences. The featured report focuses on the acceptability of the attempt to randomly allocate prisoners to the treatments.

Main findings

Very few inmates contacted the trial directly. Nearly all had been referred by staff. Of the 111 inmates who agreed to see the researchers and were found to qualify for the trial, most (65) subsequently declined to participate, leaving 46 who were randomly allocated

to methadone or naltrexone. All but a few of the 111 intended to and were confident that they could build on their enforced break from opiates in prison by remaining abstinent on release, and this was the main reason for refusing treatment.

A third of the 24 patients allocated to naltrexone withdrew from the study because they wanted methadone. Three of the 22 allocated to methadone withdrew because they wanted naltrexone and another because they had arranged drug-free treatment on release. Other methadone patients were unable to get the required support from community social services and one preferred buprenorphine. The upshot was that 11 started methadone treatment in prison and 16 were implanted with naltrexone – in total 27 of the 111 patients seen by researchers and who had had been opiate dependent before entering prison.

An attempt was made to follow-up the patients six months after their release from prison. Of the 11 methadone starters in prison, six were known to have relapsed to frequent heroin use as were four of the 16 implanted with naltrexone, though none of the 16 had had their implants removed. Of the 19 prisoners who had been allocated to but not started treatment in prison, all 10 who could be traced had relapsed to frequent heroin use.

The authors' conclusions

Despite intending to remain abstinent on release, relapse was the norm (and possibly universal) among patients who did not start treatment in prison; inmates misjudged their ability to maintain abstinence without treatment. At the same time this misplaced confidence and features of the prison environment impeded treatment entry. Motivating inmates to accept treatment in prison involves cooperation between prison health services, criminal justice staff and (to ensure continuity and support on release) community treatment providers, as well as researchers if the treatment offer is part of a study. Prisoners must feel confident that their disclosure of a treatment need will remain confidential. Enrolment in the study was possibly depressed because prisoners could receive methadone treatment in the normal way in the prisons without having to accept the risk of random allocation.

Importantly, none of the prisoners to whom the trial was explained declined it because it involved possible allocation to naltrexone, and two thirds actually allocated to this treatment accepted it. This suggests that implants may have a role in bridging the prison-community transfer period. However, among those prepared to start treatment in prison, methadone was slightly more often the preferred option. Post-prison relapse despite starting methadone in prison may have been partly due to newly released prisoners finding it difficult to comply with the need for daily attendance at the clinic and being discharged from treatment.

The implications of the study are that in-prison treatment should be tailored to the preferences of the prisoner, and that prisoners should be counselled realistically about their chances of remaining heroin-free on release, and told that these chances are improved if they initiate treatment in prison which is continued on release.



In the UK, neither implants nor depot injections of naltrexone have been licensed for medical use; they can still be (and have been; [1](#) [2](#) [3](#) [4](#)) used, but patient and doctor have to accept the added responsibility of a product which has not yet been shown

to meet the safety and efficacy requirements involved in licensing.

Other related reports from Norway have also been analysed by Findings. Among these is another report from the same study which focused on [drug use and other outcomes](#) after six months. Despite the fact that 17 of the 44 patients did not initiate treatment in prison, it found that (compared to the six months before their imprisonment) on average in the six months after release frequency of use of heroin and illicit benzodiazepines had significantly declined. From using heroin nearly every day before prison, after release use was down to 15–20 days a month. Days per month on which crimes were committed also fell significantly by 4–5 days a month to on average every other day. Neither on these measures nor on the days the former prisoners 'survived' before relapsing to heroin use were there any significant differences between prisoners allocated to methadone versus those allocated to naltrexone.

A sister study from the same research team tested [naltrexone implants versus normal aftercare](#) for opiate-dependent patients leaving Norwegian inpatient treatment centres.

Data from implanted patients in these and another Norwegian study have been amalgamated in a report which assessed the degree to which the implants [actually did block](#) the effects of opiate-type drugs and prevent opiate use. Drawing on data from the same patients, a further report assessed how many would continue the treatment by having a [second implant](#) after six months.

Findings from Norway

From these Norwegian reports it seems that six-month naltrexone implants can be an effective and lasting aid to curbing opiate use for the minority of patients motivated to aim for opiate abstinence and prepared to accept that opiate effects may be unavailable to them for six months. Because it does not require the patient to choose to enter aftercare treatment, the option may have a particular role in safeguarding patients emerging opiate-free from prison or other protected environments such as inpatient detoxification centres. However, and despite being motivated to sustain abstinence and being implanted, many if not most patients try opiates again and some do so repeatedly. Details below.

As with oral naltrexone, the main limitation of implant treatment is its acceptability to patients. In Norway acceptability will have been heightened by [restricted access](#) to substitute prescribing programmes, particularly for people unwilling to contract to forgo not just heroin, but persistent substance use of any kind. Nevertheless, recruitment to both studies seems to have been slow. The minority of potential participants who joined were probably highly motivated to sustain abstinence from opiates because they were prepared to risk random allocation to a procedure which promised to enforce this for up to six months. In the aftercare study they had just completed abstinence-oriented residential care and in the prison study were keen to sustain their enforced abstinence on release.

Across the Norwegian studies implant patients substantially reduced their opiate use during the six months the initial implants were active and in the aftercare study, did so substantially and significantly more than patients allocated to [relatively weak](#) normal aftercare arrangements. However, even among this selected and presumably motivated set of patients, the implants did not totally abolish use of opiate-type drugs and nor did they reduce some other forms of drug use. Just over half the implant patients tested the naltrexone blockade by using opiate-type drugs, and about a quarter of the sample did so repeatedly. Most of this opioid use occurred when naltrexone levels were above those known to block the pleasurable effects of heroin and few patients

experienced the usual opiate-induced euphoria or 'high'. Perhaps because nearly a third allocated to implants refused these, in the prison study in particular, the reduction in opiate use was on average modest and no greater than among patients allocated to methadone maintenance.

Of the 61 patients implanted in all the studies, three had the initial implant removed. After six months, 44 said they wanted to be re-implanted and 31 actually were, showing that for some patients the implants can be a long-term treatment rather than simply an enforced break from opiates.

Other studies

In studies a minority of patients experience complications at the insertion site which lead the implant to be removed. Another potential problem is that implants impede opiate-based pain relief. To cater for this, patients [have been given](#) cards to carry which specify the presence of a naltrexone implant, its expected duration, possible pain relief options, and contact details for staff responsible for the implant. Without this (as [reported in Australia](#)) hospital staff sometimes make futile attempts to relieve pain using opiate-type medications.

Other occasionally severe reactions to implants and injections have been observed, but generally side effects are mild and/or short-lived and treatable. As with any abstinence-based treatment, overdose due to lost tolerance to opiate-type drugs is a serious concern. However, the few studies to date suggest these products protect against overdose while they are active, and that in caseloads prepared to undertake these procedures, opiate overdose reductions can outlast the active period of the implants. These findings are consistent with findings from Britain (1) and elsewhere (1 2 3 4 5) tentatively suggesting that long-acting naltrexone can be used to create an opiate-free period which extends beyond the initial blockade, sometimes aided by further administrations (1 2). See [background notes](#) to an earlier Findings analysis for more on these important issues of adverse effects and overdose protection.

This draft entry is currently subject to consultation and correction by study authors.

Last revised 24 February 2012

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