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▶ Time limiting opioid substitution therapy.

Advisory Council on the Misuse of Drugs.
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Rather than being 'parked' on methadone, generally Britain's heroin-addicted patients leave too soon to fully benefit, argue official government advisers on drug policy. Their report unambiguously countered concerns within the current UK government over methadone maintenance.

SUMMARY The Advisory Council on the Misuse of Drugs is the official advisory body to the UK government on matters pertaining to the Misuse of Drugs Act 1971. The featured report is their response to a request for advice to the UK government's ministerial-level drug policy committee on:
• whether the evidence supports the case for time-limiting opioid substitution therapy [such as methadone maintenance]; and if so, what would be a suitable time period and what would the risks and benefits be?
• additionally, if this is not the case, how can continuing opioid substitution therapy be optimised in order to maximise outcomes for service users?

The report notes that in 2011/12 in England, 197,110 patients had been treated for drug problems, including 159,542 for heroin dependence of whom 146,100 were in opioid substitution therapy. In the same year another 2871 patients were in opioid substitution therapy in Northern Ireland and Wales. Latest data for Scotland showed 22,224 in opioid substitution therapy in 2007/08. The substitution treatment population in England is an ageing, older cohort, often unemployed for many years and with long-term health and social problems.

Main findings

How long do patients need to be in opioid substitution therapy to benefit?

International research evidence indicates that longer treatment periods are associated with improved outcomes (including reduced use of other opioids and reduced criminal activity), while short-term methadone maintenance is associated with poorer outcomes. A US study which followed up methadone patients for 30 years found that the 40% who had achieved stable remission had been on methadone for five to eight years. Some US authors argue that the minimum time to achieve better and sustained benefits is a year.

How long is it desirable to be in opioid substitution therapy?

Studies find that patients have a range of opinions on whether they are maintained on opioid substitutes for too long. A recent study of 30 heroin users in treatment in England found all wanted to be free from heroin and from prescribed substitute medicines, and often they were impatient with the detoxification process. Some reduced their doses of substitute medication faster than prescribers recommended, often resulting in cross-addiction, relapse and slower recovery attempts. The authors concluded that recovery-oriented treatment can prompt heroin users prematurely into detoxification and abstinence programmes with negative consequences, and that the experiential knowledge of heroin users who have personally attempted recovery is a crucial resource.

Length of opioid substitution therapy in the UK

No current data on length of time in treatment was available from Wales, Scotland or Northern Ireland. For England, an analysis of national drug treatment data for 2005 to 2011 reported that heroin users were typically in contact with the treatment system for about four years, though perhaps not continuously. After typically two years in and out of treatment, around half of heroin users left treatment and did not return. Most patients still in treatment were a mix of recent entrants and those known to treatment for some time and had several treatment journeys; a third had been in and out of treatment at least three times. About one in ten heroin users had been in long-term continuous treatment. Over this period the caseload included an increasing proportion of older heroin users who had been in treatment longer than average, were more complex to treat, and less likely to complete treatment.

Using the same data source an analysis was conducted for the featured report of the 50,224 patients who started an episode of opioid substitution therapy in England in 2007/08, following them up over the five years to 2012/13. Typically they spent nine to ten months in uninterrupted treatment. About four out of ten left treatment within six months and 55% within a year, rising to 85% within five years. About half had multiple treatment episodes, reflecting the relapsing nature of addiction. For the remainder, their one uninterrupted treatment episode typically lasted just over two years. Just 15% of all the patients had remained in uninterrupted treatment over the whole five years.

These studies show that contact with opioid substitution therapy in England is typically episodic, marked by periods in treatment, drop-out or attempts at abstinence, relapse, and return to treatment. For most, treatment is episodic and relatively short. A small minority (10–15%) have been in continuous treatment for five years or more. A larger minority may not be in treatment long enough to derive long-term benefit. The 'being parked' analogy may not be correct: most people get out of the car and walk away.

Impact of time-limiting therapy

There is evidence that time-limiting opioid substitution therapy would have serious negative unintended consequences and very little evidence that it would be beneficial.

There is strong evidence that time-limiting therapy or enforced detoxification from heroin would lead to increased rates of relapse and that the course of heroin dependence is prolonged and relapse is common after leaving treatment – even if a service user wants to achieve abstinence. Limited but compelling evidence from the USA shows that introducing time limits is related to high rates of relapse to opioid use and other unintended consequences, including a review of 20 studies which found high rates of relapse to opioid use after methadone treatment was discontinued. Increased opiate use has been reported during mandatory tapering of prescriptions. Furthermore, a higher rate of illicit opiate-positive clients has been found in clinics oriented to time-limited treatment as opposed to long-term maintenance.

There is strong evidence that withdrawal of opioid substitution programmes would increase acquisitive crime. In California withdrawal was associated with more crime, drug dealing, and heroin users' contacts with the criminal justice system. Two recent UK analyses found that the rise in heroin use accounted for 40% of the rise in acquisitive crime in England and Wales from 1981 to its peak [in the

mid-1990s]. Similarly, providing opioid substitution programmes is thought to be associated with 25–33% of the fall in some types of acquisitive crime. Time-limiting the treatment is therefore likely to significantly increase acquisitive crime.

There is strong evidence that time-limiting opioid substitution therapy would increase the spread of blood-borne viruses. Stopping the therapy can lead to an increased risk of viral transmission and overdose, and treatment orientated to rapid abstinence produces worse outcomes than treatment initially oriented to maintenance. Increasing provision of the therapy reduces the spread of blood-borne viruses. Retention in opioid substitution therapy reduces injection frequency and, combined with the availability of needle and syringe programmes, reduces the risk of blood-borne viruses, in particular transmission of hepatitis C among injectors. Opioid substitution therapy also reduces the risk of transmission in prisons. There is strong evidence that opioid substitution therapy can prevent the spread of HIV infection.

There is strong evidence that time-limiting opioid substitution therapy would increase the rate of overdose deaths. While in treatment, a patient's risk of heroin overdose death is greatly reduced (1 2), but then doubles following detoxification from the treatment. In the USA, ending programmes greatly increased death rates among heroin users following discharge. Expanding the treatment can reduce the overall rate of overdose deaths in the community. In prison the treatment is thought to reduce self-inflicted death at the start of imprisonment, and provided prior to release can reduce (1 2) the high risk of fatal overdose during the first month of liberty and subsequently.

There is evidence that a blanket policy of time-limiting opioid substitution therapy would lead to medico-legal challenges and may not be implementable. The treatment is recommended by the UK's National Institute for Health and Clinical Excellence (NICE) and in UK clinical guidelines. Prescribers (usually but not exclusively doctors) have clear guidance from the General Medical Council (GMC) to "provide effective treatments based on the best available evidence ... If patients are at risk because of inadequate premises, equipment or other resources, policies or systems, you should put the matter right if that is possible. You must raise your concern in line with our guidance and your workplace policy." Time-limiting opioid substitution therapy would put a doctor in a position where they are ignoring guidance from their professional regulator. It is our expert opinion that many would be reluctant to implement such a policy against their professional judgment, based on individual clinical assessment. They might find alternatives such as very slow detoxification regimens. This could result in ineffective low-dose treatments and potentially create an 'underground' prescribing system and make it difficult to exercise quality control.

There also may be medico-legal challenges if opioid substitution therapy was time-limited or contracted to be provided outside NICE guidelines. In 2006 there was a legal challenge from 200 ex-prisoners who claimed they had been given inadequate treatment for opiate withdrawal in prison. The Home Office settled out of court and had to pay damages. There might also be legal challenges on the grounds of discrimination if opioid substitution therapy was restricted. In the USA, the Legal Action Centre (2011) concluded that denying access to the treatment in the criminal justice system, as part of a blanket prohibition or without individualised evaluation, violated the Americans with Disabilities Act and the Rehabilitation Act. They argued that attempts to justify denied access on the grounds that it is "substituting one addiction for another" or is not a valid form of treatment should not defeat a claim under the Acts, as such views run counter to objective evidence concerning treatment for opiate addiction. Furthermore they advised that denial of access pursuant to a larger policy prohibiting the use of any prescribed controlled substance is also likely to violate the Acts, due to their disparate impact on opiate-addicted individuals receiving or in need of opioid substitution therapy.

The authors' conclusions

The overall conclusion of this report is that the evidence does not support the case for imposing a blanket time limit on opioid substitution therapy for heroin users, and this approach is not advised by the Advisory Council on the Misuse of Drugs. Evidence strongly suggests that time-limiting the treatment may have significant unintended consequences, including increasing drug-driven crime (and national crime statistics), heroin overdose death rates, and the spread of blood-borne viruses including hepatitis and HIV. Those implementing this approach could also face medico-legal challenges.

Rates of relapse are high when heroin users voluntarily detoxify and complete the treatment, illustrating the difficult, relapsing nature of heroin addiction and the challenge we face in enabling heroin users to achieve a range of recovery outcomes – particularly with our ageing heroin population with limited recovery capital. The current trends of use of opioid substitution therapy indicate that most heroin users are not 'parked' for long periods of time. Use of the treatment appears to be similar to use of heroin for the majority: that is, episodic and characterised by periods of treatment, attempts at abstinence, relapse and return to treatment.

We are concerned that more individuals appear to be in opioid substitution therapy for too short a time to benefit than are in it for more than five years. For those who need the treatment, access should not be limited, but rather enhanced. It is therefore crucial that we explore why people drop out of opioid substitution therapy, particularly when discharge is unplanned.

The Advisory Council notes there is strong evidence that opioid substitution therapy can be a very helpful part of treatment and recovery for those with heroin dependence, but thinks that is unhelpful to focus on the medication alone. It recommends continued support for high quality opioid substitution therapy with comprehensive psychosocial and recovery interventions, which evidence shows is more likely to support individuals ultimately to achieve abstinence and other recovery outcomes. We note that 'medication alone' without concomitant psychosocial interventions and recovery support is not in line with national guidelines, and limited recovery outcomes are likely.

FINDINGS **COMMENTARY** This report comes on the heels of the 2012 report of an expert group convened for the UK Department of Health on how methadone and other medications can more fully aid recovery. That group revisited some of the issues the following year in response to a request channelled through the Chief Medical Officer about how often treatment should be reviewed to check whether alternatives should be tried, suggesting that government concern over patients 'getting parked' in maintenance programmes had not been assuaged by the initial report. These two incidents may have been among the four referred to by Paul Hayes, the former head of England's National Treatment Agency for Substance Misuse. In 2013 he commented, "There's still an appetite in bits of government to re-ask the question about time-limited methadone ... which in my time they asked four times and always got the same answer. They keep hoping they'll finally find someone to tell them what they want to hear, but the evidence remains the evidence."

June 2014 was the date of the further request to the Advisory Council which resulted in the featured report, so similar government requests must now total at least five. Such persistence seems a sign of the deep-seated hostility to widespread, indefinite maintenance prescribing within parts of the UK government, expressed in 2012 in the Putting Full Recovery First report from the same ministerial drug policy committee behind the latest request. They aspired to bring an "urgent end to the current drift of far too many people into indefinite maintenance, which is a replacement of one dependency with another". A similar stance had been even more trenchantly expressed in Conservative Party policy in the run up to the May 2010 election, characterising methadone maintenance as "drug dependency courtesy of the state".

This latest government request to consider the issue was the one which in public most explicitly sought grounds for setting time limits to opioid substitute prescribing. The resulting rejection of limits was also the most explicit to surface from an official body. In direct and unambiguous language, not only did the featured report foresee negative health and crime consequences from time limits or otherwise curtailing prescribing, it turned the tables by arguing that far from being in treatment too long, generally patients in England were there too short a time, and that rather than restricting access to maintenance, access should be increased. In this they echoed the comments of US recovery 'guru' William White for a Scottish report which, as in England, responded to government concerns over the role of methadone in recovery: "In the US, there are periodic moral panics about the idea of patients being on methadone for

prolonged periods – an image that obscures the real problem which is that most patients are not on methadone long enough, eg, high rates of early drop-out, administrative discharge and rapid resumption of opioid addiction." The Advisory Council also extended the argument to medical ethics and practical feasibility, resulting in a report which can be seen as comprehensively repelling the anti-maintenance lobby within government discerned by Paul Hayes.

However, in the person of Work and Pensions Secretary Iain Duncan Smith, that lobby remains unconvinced. A few days after the featured report was released he responded in the *Sunday Telegraph* newspaper. As the newspaper group's web report put it, he urged his colleagues "to fight 'vested interests' in pharmaceutical companies and treatment centres who profit from 'merely replacing one addiction with another' by keeping addicts hooked on legal heroin replacements." Despite the evidence gathered for the report, he stuck by his "parked on methadone" analogy, and accused his own government's official advisers as "providing cover for perpetuating drug addiction in the UK" – an accusation the gravity of which can hardly be exaggerated.

Professor Neil McKeganey represents the academic arm of the lobby concerned that too much methadone is prescribed for too long. His response to the featured report charged it with a "regrettable reluctance to subject the [UK methadone] programme to much needed critical scrutiny," citing the possible inapplicability of US research, methadone-related deaths, and research from Scotland suggesting "those drug users who were prescribed [methadone] stood less chance of recovering than those who were not". In that study a small minority of heroin users attending a primary care service were not prescribed substitute drugs. Assuming long-term cessation of injecting equates to recovery, they did indeed get to this point much more quickly than the prescribed patients. However, the study was unable to disentangle whether the relative brevity of their injecting careers was due to their not being prescribed substitute drugs, or whether they were not prescribed because they and/or their doctors thought they would soon stop injecting. Even if that was the case, in the teeth of an HIV epidemic, not prescribing seemed extraordinarily risky: a quarter died within 25 years of their first injection compared to just 6% in maintenance treatment for over five years.

Professor McKeganey's main point was that regular and thorough assessments should seek to determine whether each individual patient is continuing to benefit from methadone; if they are, prescribing should continue; if not, it should he says cease. This formulation brings him close to the mainstream view, sharing with the report its central recommendation – that there should be no *blanket* time limits on opioid substitute prescribing. What might also have received the assent even of its critics was the report's echo of an earlier UK expert group's call for substitution therapy to become 'recovery-oriented' by allying medications with comprehensive psychosocial and recovery interventions. It was through these rather than blanket time limits that the Advisory Council saw patients being able to achieve "abstinence and other recovery outcomes". However, "the reality of scarce health resources and economic austerity" which Professor McKeganey saw as demanding limits on methadone prescribing might even more decisively limit the extent to which it can be supplemented by expert and expensive therapies. Criticising methadone programmes for failing to ensure patients receive psychosocial counselling, Iain Duncan Smith saw this as an argument for restricting those programmes, not funding them more generously.

Drug and Alcohol Findings has traced the recent history of opposition to maintenance in Britain in a hot topic entry, which dated the current debate back to the mid-2000s and the preceding Labour government's concern to contain cost and free up treatment slots by getting patients to the point where they could leave treatment, partially reversing the previous emphasis on retention.

Thanks for their comments on this entry in draft to Annette Dale-Perera, co-chair of the committee of the Advisory Council on the Misuse of Drugs responsible for the featured report, and to Neil McKeganey of the Centre for Drug Misuse Research in Glasgow in Scotland. Commentators bear no responsibility for the text including the interpretations and any remaining errors. At the time the featured report was being drafted, the author of this analysis for the Effectiveness Bank was also a member of the committee, though not a member of the Council itself and not involved in drafting the report.

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