S Seminal studies **K** Key studies **R** Reviews **G** Guidance **MORE** Search for more studies
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Drug Treatment Matrix cell C3: Management/supervision; Medical treatment

S Leaders affect performance of methadone maintenance clinics (1991). In six intensively documented US clinics, effective and experienced directors were associated with reduced drug use, injecting and crime among patients. "Our interpretation … is that patients in programs with a rehabilitation and long-term maintenance orientation, which also delivered more counseling services to patients and had more effective directors, tended to have better outcomes than patients in programs … where there was emphasis on administrative functioning rather than provision of services."

S Methadone minus counselling can be suboptimal (1993) From Philadelphia a randomised trial analysed in these background notes (2006; see under the heading, "Are cut-down services a viable alternative to more comprehensive programmes?") found barebones methadone maintenance much less effective at suppressing illegal opiate and cocaine use than weekly counselling. Supplementary social and other services helped even more, though weekly counselling was most (1997) cost-effective. Related studies (1 2) and reviews (1 2) below seem to have varying implications. For discussion click and scroll down to highlighted heading.

K No added benefit from counselling in methadone maintenance (2012). US randomised trial found cut-down methadone programmes reduced substance use and crime (and risk of blood-borne disease; 2013; free source at time of writing) as effectively as standard programmes with more counselling, including among patient under criminal justice supervision (2013; free source at time of writing). Related studies above and below and reviews below (1 2). For discussion click and scroll down to highlighted heading.

K No added value from psychosocial therapy for buprenorphine patients (2013). Across relatively uncomplicated patients treated at a primary care clinic, US study found no benefit from supplementing buprenorphine maintenance with cognitive-behavioural therapy. Related studies above (1 2) and reviews below (1 2). For discussion click and scroll down to highlighted heading.

K Supplementing medical care with drug counselling does not improve opioid detoxification outcomes (2011). From the USA, a large-scale trial involving patients dependent on prescription opioids found that despite wanting to detoxify, all but a few relapsed after withdrawal from buprenorphine. Random allocation to specialist drug counselling did not improve on medical care alone. Related review below. For related discussion click and scroll down to highlighted heading.

K Training leads doctors to see methadone maintenance as a medical treatment (1996). Based on experience in Australia, how to train-out socially derived attitudes derived from seeing methadone maintenance as a policy solution to a social problem, and train-in attitudes based on locating the treatment within mainstream medical practice. Findings were incorporated in an article (2000) from the same author on quality improvement in methadone services.

K Training in client-centred approach needs receptive trainees (2004). US study at a medical centre's addictions programme suggests that recruiting the 'right' clinicians who have not been trained in motivational interviewing would be better than choosing the 'wrong' ones who have been, and the former gain most from training. Simple indices of experience and qualifications did not identify proficient clinicians.

K Supervising medication consumption cuts methadone deaths (2010). From the mid-1990s British addiction treatment clinics started to routinely require patients to take their methadone under clinical supervision. Records suggest that by preventing diversion to non-patients, the change prevented thousands of overdose deaths. Related studies (1 2 3) and review below focusing on impacts on the patients themselves. For discussion click and scroll down to highlighted heading.

K No benefits for UK patients from enforcing three months' supervised consumption (2014) Found that the (at the time) recommended three months of supervised consumption of methadone or buprenorphine conferred no significant advantages over supervising only for up to the first four weeks among patients for whom random allocation was thought feasible and safe. Earlier trial (2012) from same lead author found that at Scottish clinics extending supervision beyond three months meant more patients left treatment and did not further curb heroin use, though it may have reduced heavy drinking. Related studies above and below (1 2) and review below. For discussion

click and scroll down to highlighted heading.

K Methadone programme loosens up, increases capacity, patients do just as well (2004). Canadian study documents what happens when you 'deregulate' methadone prescribing (relaxing supervised consumption and urine tests and not insisting on abstinence from illegal drug use) and permit greater patient choice in treatment and treatment goals: room for more patients, less conflict, and no decrease in effectiveness. At the time of writing the two cited articles are freely available (1 2). Related studies above (1 2) and below and review below. For related discussion click and scroll down to highlighted heading.

K British GPs as effective as specialist methadone clinics (2003). A two-year follow-up of opiate dependent patients sampled by the national English NTORS study showed that experienced or supported GPs can provide methadone maintenance treatment at least as effectively as specialist clinics. The clinics' imposition of supervised consumption was a major difference in the regimens. Related studies above (1 2 3) and review below. For related discussion click and scroll down to highlighted heading.

K Why not let methadone patients choose their dose? (2002). US study shows that methadone maintenance patients allowed to set their own doses do not escalate excessively. Benefits may include improved patient-therapist relations and reduced illicit drug use. Extended text reviews other relevant studies. Related review below. For discussion click and scroll down to highlighted heading.

K Patients who value a 'clear mind' prefer buprenorphine to methadone (2010). The minority of opioid maintenance patients at a clinic in England who chose buprenorphine rather than methadone tended to do so because they wanted to divorce themselves both from illicit and prescribed opioids. Few were successful, and retention was greater on methadone, but those who opted for buprenorphine valued it because it had less intense opiate-type effects (a 'clearer mind') and made them less vulnerable to the charge that they were 'still addicts'. Patient perspectives were similar (2015) in Scotland. Related review below.

R Buprenorphine works but methadone works better (Cochrane review, 2012). High-dose buprenorphine curbs illegal opiate use but when the two were compared in randomised trials, longer retention meant methadone was on average more effective. See also a later US-focused review (2014) commissioned by the US government. Related studies above.

R High-dose methadone most effective (Cochrane review, 2006). Systematic review finds doses averaging across a caseload 60 to 100 mg/day are more effective than lower dosages in retaining patients and reducing heroin and cocaine use during treatment. Related study above. For related discussions click here and here and scroll down to highlighted headings.

R Strategies for incorporating evidence into practice ([Australian] National Centre for Education and Training on Addiction, 2008). Lessons from health promotion and medical care on how to improve addiction treatment practice by introducing research-based innovations, including common medical education and training strategies.

R Trials neither for nor against supervised consumption of methadone and other opioid substitutes (2017). Trials challenge the need for the widely accepted policy of making opioid-dependent patients take their methadone or other opioid substitutes at the clinic or pharmacy, but 'no difference' findings may be due to the limitations of the research. Related studies above (1 2 3 4). For discussion click and scroll down to highlighted heading.

R Worth training clinicians in motivational interviewing (2013). Free source at time of writing. Across medical care clinicians who adopt a motivational interviewing style achieve significantly better outcomes than those who offer usual care, and training clinicians in motivational interviewing improves (2013) motivational skills.

R Prescribing therapy with methadone and counselling does not help (Cochrane review, 2011). Review of rigorous studies found that adding psychosocial therapy to opiate substitute prescribing plus routine counselling has overall made no significant difference to retention or substance use. Similar review (Cochrane review, 2011) of opioid detoxification found little evidence that extra counselling or therapy promoted completion, but more for systematically applied rewards and sanctions. Related studies above (1 2 3 4) and review below. For discussion click and scroll down to highlighted heading.

R G In medication-based programmes focus on generic relationship-forming, not intervention packages (2017). From England a specialist drug dependence psychiatrist and clinical psychologist tease out the practical implications of the evidence on psychosocial adjuncts to opiate substitution treatment, arguing for individualisation rather than blanket application or denial and a focus on "broad, non-specific skills such as therapist empathy and therapeutic alliance, but also tightly controlled interventions to achieve a specific outcome such as reduced symptoms of depression, better parenting or increased levels of employment." Related studies (1 2 3 4) and review above. For discussion click and scroll down to highlighted heading.

G Medication-based treatment as a route to recovery ([UK] National Treatment Agency for Substance Misuse, 2012). UK clinical consensus on how methadone clinics and other medication-based treatment services can be (re)oriented to long-term recovery. See also report ([UK] Advisory Council on the Misuse of Drugs, 2015) on the same issue from official UK government advisers on drug policy. For discussion click and scroll down to highlighted heading.

G K Failings of detoxification procedures in the independent sector ([UK] Care Quality Commission, 2017). Official regulator of health and adult social care in England sums up results of inspections of services offering residential care to people undergoing detoxification from drugs and alcohol, often preparatory to residential rehabilitation. Poor management was a major underlying cause of the failings which risked safety and effectiveness at almost two-thirds of services. Flip side of the failings constitute good practice recommendations.

G Don't set time limits to opioid maintenance ([UK] Advisory Council on the Misuse of Drugs, 2014). Rather than being 'parked' on methadone, generally UK patients leave too soon to fully benefit, argue official UK government advisers on drug policy. Their report countered concerns within the government over long-term methadone

maintenance and rejected the call for time limits, which "may have significant unintended consequences", including increasing more crime, overdose deaths, and blood-borne infections. For related discussions click here and here and scroll down to highlighted headings.

G Pharmacological treatment of opioid dependence (World Health Organization, 2009). Chapter five of the document analysed in this Effectiveness Bank entry offers guidelines for programme managers and clinical leaders. For related discussion click and scroll down to highlighted heading.

G Pharmaceutical services for drug users ([UK] National Treatment Agency for Substance Misuse, 2006). How pharmacies can/should contribute to treating and reducing harm from problem drug use.

G What should managers expect of doctors caring for substance users? ([UK] Royal College of Psychiatrists, Royal College of General Practitioners, 2012). Guidance from UK professional associations for GPs and for psychiatrists on the competencies, training and qualifications expected of doctors involved in caring for substance users, from generalists to addiction specialists. Other UK ([UK] Public Health England, Royal College of Psychiatrists, Royal College of General Practitioners, 2014) and US ([US] American Society of Addiction Medicine, 2014) guides focus on specialists.

G Staff development toolkit ([UK] National Treatment Agency for Substance Misuse, 2003). Workforce development guidance for managers in drug and alcohol services from what was the special health authority responsible for promoting addiction treatment in England.

G How to assess the performance of specialist doctors ([US] American Society of Addiction Medicine, 2014). Indices designed to evaluate an individual doctor's performance against standards of care ([US] American Society of Addiction Medicine, 2014) for specialist addiction physicians.

G Treating substance use service clients with mental health problems ([Australian] National Drug and Alcohol Research Centre, 2016). Funded by the Australian government. Recommends services screen all patients for the full range of mental health problems from mild to severe and that mental illness should not be a barrier to treating substance use problems. Research shows these patients can benefit as much as others from routine treatments for problem substance use. UK guidelines ([UK] National Institute for Health and Care Excellence, 2016) on managing *severe* mental illness and substance use envisage the lead being taken by mental health services.

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What is this cell about? About the treatment of drug dependence in a medical context and/or involving medical care. Medications are the main distinguishing feature, but even when they are prescribed, the clinician-patient relationship influences whether they are taken and may be therapeutic in its own right. The power of being prescribed a medication in a credibly healing context should not be underestimated. Dismissed as a 'placebo effect' merely to be used as a baseline for evaluating active treatments, often it generates most of the overall effects.

This cell focuses on how these processes are affected by the management functions of selecting, training and managing staff, and managing the intervention programme. In highly controlled studies, it may be possible to divorce the impact of interventions from the management of the service delivering them, but in everyday practice, whether interventions (cell A3) get adopted and adequately implemented, and whether practitioners (cell B3) are able to develop and maintain recovery-generating attitudes and knowledge, depend on management and supervision.

Within this remit, the most researched treatments have been opioid substitute prescribing programmes like methadone maintenance, in which management decisions on testing for drug use, supervising the consumption of medications, dosing policy, 'disciplinary' rules, and duration of treatment, are critical to safety and effectiveness.

Where should I start? For UK readers a watershed moment was the release in 2012 of guidance on how methadone maintenance and other medication-based treatments can be (re)oriented to long-term recovery, an attempt to square these treatments with the recovery agenda, despite that agenda's identification in some powerful quarters with abstinence from all drugs, and with leaving rather than being 'maintained' in treatment.

Turn to the Effectiveness Bank analysis of the guidance and click the title to download the original report. Then turn to pages 8 and 9, the "For Services" section of a table on how to recognise whether your service *is* recovery-oriented. Note the advice to assess patients' "recovery capital" – their social network and support, financial resources, education and mental health, and the (sub)cultural norms they have assimilated. Together with the complexity of their problems, the guidance says this assessment should help identify whether long-term treatment is likely to be needed.

Note also the insistence on the roles of mutual aid and other forms of peer support at various stages in treatment, helping to make "pathways through and out of treatment … visible". That relates to the guidance's vision of treatment as a dynamic, goal-orientated movement, ideally towards sustainably drug-free treatment exit – the opposite of the 'parking' jibe then being levelled at methadone maintenance and allied services. The report acknowledges "preservation of benefit" as a reason for continued treatment, but sees coming off opioid substitution treatment and leaving treatment altogether as important indicators of an individual's recovery progress, possibilities never entirely to be abandoned: "It is not acceptable to leave people in [opioid substitution treatment] without actively supporting their recovery and regularly reviewing the benefits of their treatment (as well as checking, responding to, and stimulating their readiness for change)."

> *Must satisfied patients continually be challenged to go further?*

In its attempt to reconcile opposing agendas while sticking to the evidence and maintaining a patient-centred focus, the report leaves important questions not entirely answered. Perhaps, for example, a quietly parked life is what some people want, or can reasonably achieve. Compared to what will often have been a crime-ridden, socially damaging and risky preceding life, 'parking' may be a major and valuable achievement. Is preserving past gains – even if they do not further flourish – justification enough for continuing to prescribe, and how can we tell continued prescribing is needed to sustain those gains? Must satisfied patients continually be challenged to go further towards someone's ideas – even their own ideas – of what recovery ideally entails?

The guidance also wants services to adhere to the evidence, yet this is not always clearly behind its recommendations. Research-based evidence is strongly in favour of indefinite maintenance prescribing, practically silent on mutual aid in the context of methadone and allied programmes, does not suggest

counsellors in recovery are most effective in promoting recovery, is silent on whether recovery capital is indicative of required treatment longevity, and at best equivocal (see *Can we dispense with all but minimal counselling and therapy?* below) about the value of extra psychosocial support.

You could look at each of the recommendations in the "For Services" section of the table on pages 8 and 9 of the report, and ask yourself, is it reasonable, feasible, supported by evidence, and as a whole, would these attributes transform a traditional service into a recovery-oriented service? If needed, check back on what 'recovery' is generally taken to mean.

Highlighted study Dose is certainly not everything in methadone maintenance – relationships and good management count too – but a review and meta-analysis for the Cochrane collaboration (listed above) reveals just how important dose is. The main findings were apparent in the 11 trials which randomly allocated patients to different doses, the best way to eliminate other influences such as which types of patients or services opt for higher doses. According to the authors, the results "support the conclusion that methadone dosages ranging from 60 to 100 mg/day are more effective than lower dosages in retaining patients and in reducing use of heroin and cocaine during treatment". They also warn of some resistance to acting on this finding, "to a certain extent driven by ideological assumptions about the nature of opioid addiction".

Both the recommendation and the resistance are related to the divide between visions of heroin addiction as a long-term condition requiring long-term ameliorative treatment (extended retention is good) versus something more like a bout of illness, first to be stabilised by a short period of maintenance before completing recovery through detoxification (extended retention is bad). Within these opposed treatment philosophies, high doses are either a villain ensnaring patients in treatment due to the difficulty of withdrawal, or a protective shield which keeps them stable, safe from illicit opiate use, and in close contact with treatment and associated medical and psychosocial services.

One flaw in the application of the 'extended retention is good' ideology is that in England, a minority of patients actually do sustain unbroken, long-term treatment, while the 'extended retention is bad' camp must face the fact that it is not unusual for very few patients to complete detoxification and stay abstinent.

Resistance to doses high enough to eliminate illegal opiate use partly derives from fear that these lock patients in to treatment, but it is by no means established that higher doses make methadone maintenance harder to successfully terminate. One study which investigated this found patients randomly allocated to higher doses were actually *more* likely to complete their detoxification after 40 weeks on methadone.

Higher doses on average work better probably because they achieve at least adequate dosing for more patients than lower doses, but adequacy for the individual is the key factor, not the dose per se – an issue explored below.

Issues to consider and discuss

▸ **Can we let the patient choose their dose?** The main studies analysed in the review highlighted above took no account of clinical judgement or the patients' needs or wishes in allocating them to different doses; it was all settled by a virtual roll of the dice. But in real life, dosing is or should be individualised – and who knows better than the patient whether their methadone or buprenorphine is meeting their needs or dousing their craving for illicit heroin without undue sedation?

A change of policy at a US methadone maintenance clinic offered the chance to evaluate this proposition. Preceding the change a doctor's approval was required before methadone doses could be increased to 100 mg or more a day, but the clinic decided to waive this requirement for all existing and new patients, allowing patients themselves to decide to increase (or decrease) their doses with no pre-set limits. Our account of the study is listed above. You will see that among these mainly stable, long-term methadone patients, average doses barely increased, and illicit opiate use became rarer than it had been before the change.

Background notes on the study reveal that this is no isolated finding, and that "When doses are allowed to rise (or fall) to individually appropriate levels, the absolute level of the dose has been found to no longer predict how long individuals stay in treatment or how well they do." It seems that the review highlighted above found higher doses more effective only because its main studies precluded individualised dosing. The background notes also add an important rider: flexible dosing responsive to individual need can transform 'failing' patients into successes, but "Whether the flexibility is nominally in the hands of staff or the patients is

less important."

We suggest you read the background notes on the study, which summarise what at the time were the other relevant studies. As far as we know, no new studies have altered their implications. You might then ask yourself: Would patient self-regulation of dose work at my clinic or the ones I know? What sorts of patients might be offered it; only those already stable and who have showed commitment to curbing heroin use, or (as in study 3 in the notes) all patients starting treatment? Perhaps it is *more* important to offer self-regulation to patients *not* doing well, to give them a chance to do better.

> *The consequences of such a policy are potentially huge*

What are the implications of self-regulation for staff-patient relationships and their respective roles? It should reduce opportunities for friction over dose levels and the time devoted to agreeing these, creating scope for more therapeutic discussions. It empowers the patient and heightens their responsibility for their care. But in the end, can a health professional abrogate responsibility for controlling this core aspect of the patient's care? Is the patient's motivation the key factor? What of those who want to *minimise* their methadone dose so they can continue to 'enjoy' heroin? Should this be allowed with a view to at least keeping them in treatment? Must supervised consumption (discussed below) be strictly imposed to deter patients from raising their doses so they have some spare to sell? The consequences of such a policy are potentially huge. All the more surprising then, that in practice, studies have found it has made so little difference to the impacts of the treatment.

▸ **Can we dispense with all but minimal counselling and therapy?** In many treatment systems this would be virtually a heretical question. Across the world, guidelines insist that "psychosocial interventions are … a crucial part" of opioid substitution treatment, and regular counselling may be required by the regulations governing these programmes. Look for example at the World Health Organization guidelines listed above, which even in their title (*Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence*) integrally partner the medication component of the treatment of opioid dependence with "comprehensive psychosocial support to every patient". The UK's own guidelines (2017) also insist that in opioid substitute prescribing programmes, "optimal behaviour change is unlikely without a good therapeutic alliance and suitable psychosocial interventions" and that "Treatment for drug misuse should always involve a psychosocial component to help support an individual's recovery."

How then can it be that in rigorous studies of opioid maintenance programmes, evidence for the effectiveness of extra psychosocial support is surprisingly thin? After looking at such studies, in 2007 the UK's National Institute for Health and Care Excellence could recommend for medication-based programmes only contingency management procedures – not so much therapies as reward and punishment systems – and certain forms of family or couples therapies typically available and applicable to just a minority of patients dependent on illegal drugs.

Among the most convincing studies to question the need for frequent counselling was a trial (listed above) at two US methadone maintenance clinics in Baltimore. Despite a seemingly unpromising caseload with on average over 20 years of heroin use and over four years in jail behind them, patients who started their first four months of treatment (the 'interim' phase) virtually without counselling did as well as those individually counselled about once a month, and even as well as those counselled fortnightly by a counsellor handpicked for excellence. However, this counsellor's patients achieved these improvements in a different way – on lower doses and with more leaving treatment.

Lest it be thought this finding was due to the distinct caseload and setting, consider the findings of another US study testing the impact of extra therapy in a very different setting and caseload. Listed above, at a primary care clinic treating relatively uncomplicated patients, it found no benefit for randomly selected patients from supplementing buprenorphine maintenance with cognitive-behavioural therapy.

A review (listed above) of such studies found that across trials which randomly allocated patients to opioid substitute prescribing with versus without psychosocial therapy, the therapy made no statistically significant difference to retention or substance use. What these therapies were normally supplementary to may have been important. Rather than being left entirely without psychosocial support, comparison patients usually had access the clinic's routine counselling services. Unfold the supplementary text for more from this review.

Close supplementary text

With therapy, somewhat more patients did manage at least for a time to do without illicit opiate-type drugs. However, this non-statistically significant finding may have been a chance result, and was due to just three studies, none of which trialled what is normally considered psychosocial therapy. In one (1992; free source at time of writing), at issue was the impact of relieving patients of the need to take their methadone under supervision at the clinic if urine tests registered no illicit drug use. A second (1987) tested the subliminal stimulation of "symbiotic fantasies" in the form of fleeting exposure to a card (not consciously readable) on which was written, "MOMMY AND I ARE ONE". Listed above, the third tested drug counselling and 'wrap-around' medical, psychiatric, social work, family therapy and employment services, offering some evidence that when the alternative is virtually no psychosocial support at all, counselling can be beneficial. In the remaining six trials, supplementary psychosocial interventions made virtually no difference.

Close supplementary text

In contrast, a later review (2016) concluded that "In general, the studies reviewed provide support for the use of psychosocial interventions in the context of methadone maintenance treatment," but its conclusions were convincingly contested (2016; free source at time of writing) by the lead author of the study described above. partly on the grounds that the key outcome of illicit opioid use was not explicitly the focus of the review, and that some studies had been misinterpreted.

In 2017 a specialist drug dependence psychiatrist and clinical psychologist who had worked on the UK clinical guidelines referred to above tried to unpick the evidence. They were acutely aware of the contrast between the "equivocal evidence" for psychosocial interventions in opioid substitute prescribing programmes and the commonly unequivocal guidance insisting on their value. Listed above, their commentary argued for individualisation rather than blanket application or denial of these interventions, and a focus on "broad, non-specific skills such as therapist empathy and therapeutic alliance, but also tightly controlled interventions to achieve a specific outcome such as reduced symptoms of depression, better parenting or increased levels of employment". By focusing mainly on identified therapies like cognitive-behavioural therapy, and substance use outcomes overwhelmingly affected by the medication, research had, they thought, missed the target and ended with an unclear scorecard. "Relationship is neglected in favour of technique," while "Outcomes such as compliance (ie, number of psychosocial sessions attended), craving, psychiatric symptoms/psychological distress, quality of life and severity of dependence are given less priority … so the impact of psychosocial interventions may be underplayed."

Their informed plea not to throw the baby out with the bathwater is not devoid of evidence

Their informed plea not to throw the baby out with the bathwater is not devoid of evidence. Even if when averaged across all patients, extra counselling and therapy often makes little difference, there are important exceptions, among whom may be the psychologically unstable patients often excluded from trials and multiply problematic clients who without support suffer repeated crises. It is also possible that while *extra* counselling and psychosocial interventions may not make much of a difference, some counselling is better than none. Three classic US studies support these contentions; unfold supplementary text for more.

Close supplementary text

1 For research purposes commonly studies exclude psychologically unstable patients, the very ones some US studies suggest might have benefited from psychotherapy. One whose early results were published in 1983 found extra benefits from psychotherapy for methadone patients with psychiatric problems, but not for those without (1 2). Benefits were apparent in some ways (but not in substance use) among patients with moderately severe problems, but more clear cut for the high-severity patients, who consistently improved more after being randomly allocated to professional psychotherapy, including a greater reduction in days of opiate use. Without psychotherapy, among these patients opiate use remained virtually unchanged. Clinical records showed that the two groups of patients with appreciable (mid or high) psychiatric severity submitted more drug-positive urines when offered drug counselling alone without psychotherapy, and had required higher doses of methadone, typically a response to continuing problems.

2 The study described above was conducted at university-affiliated methadone programmes. At three more typical programmes, the same lead author broadly replicated (1989) the study among patients selected for severe psychiatric symptoms. In all 123 were sufficiently severe to be randomly allocated to an extra therapy

session a week for 24 weeks of either supportive-expressive psychotherapy or of drug counselling of the kind they were already receiving.

On nearly every measure, by the final follow-up psychotherapy patients were doing better than those given drug counselling, though usually the differences were modest. After the initial impacts of being on methadone had evened out, patients allocated to psychotherapy evidenced somewhat better psychiatric adjustment and a move towards a more conventional and law-abiding lifestyle. However, in some respects the effects were not as substantial as in the previous study and were not seen at the initial follow-up, perhaps partly because both groups of patients were offered an extra weekly session of some kind. This research design was intended to eliminate concerns that the earlier findings might have reflected the *amount* of therapeutic contact rather than its type. Given the relative findings of the two studies, it seems these concerns were at least partly valid – that perhaps amount rather than type was an important active ingredient.

3 Another US trial (1993) listed above provided the strongest evidence that in certain circumstances and for a relatively severe caseload, counselling methadone patients is not a waste of resources. It was analysed in detail in these background notes under the heading, "Are cut-down services a viable alternative to more comprehensive programmes?"

The study involved 92 US military veterans who on starting methadone treatment had been randomly allocated for 24 weeks either to: minimal counselling contact; standard counselling – weekly to begin with, then adjusted to the stability of the patient; or standard counselling enhanced with extra on-site 'wrap-around' services, including regular medical and psychiatric care, social work assistance, family therapy, and employment help. Patients were typical of the area's caseload: black single men with extensive criminal histories and most too, histories of serious psychiatric disorder.

Possibly critical in this trial was how minimal the 'minimal' contact was. It consisted of a monthly meeting lasting about 15 minutes confined to administrative requirements such as those to do with clinic rules and requests to verify to employers and probation officers that the patient was in treatment. In contrast, standard counselling was manualised and systematic, each week monitoring the patient's progress and imposing rewards and sanctions to promote behaviour change. On top of this for some patients were the 'wrap-around' services which patients were required to access at least once.

Each step up from the minimal produced better outcomes over the roughly six months they were operational. The effects were apparent in the proportions of patients who (largely due to regular illicit substance use) met criteria for 'emergency' transfer to usual care: 69% not offered counselling (all in the first 12 weeks of treatment) versus 41% of standard care patients, and just 19% in enhanced care. During the first 12 weeks urinalyses revealed significantly and substantially more illicit opiate and cocaine use in the minimal contact patients than in both the other sets of patients, and specifically more than with standard counselling. When the standard and enhanced groups were compared, improvements were greater in the enhanced group on 14 out of 21 measures and significantly so in respect of employment, drinking, crime, hospitalisation for medical problems, and proportion abstinent from opiates and cocaine, though not in average days of use of these substances or overall drug problems.

Six months after the trial had ended, over which time all patients had reverted to usual care, there remained a statistically significant effect on the proportion abstinent from heroin, contributing to the finding that proportions abstinent from both heroin and cocaine were 29% in the minimal care group but 47–49% in the other two groups.

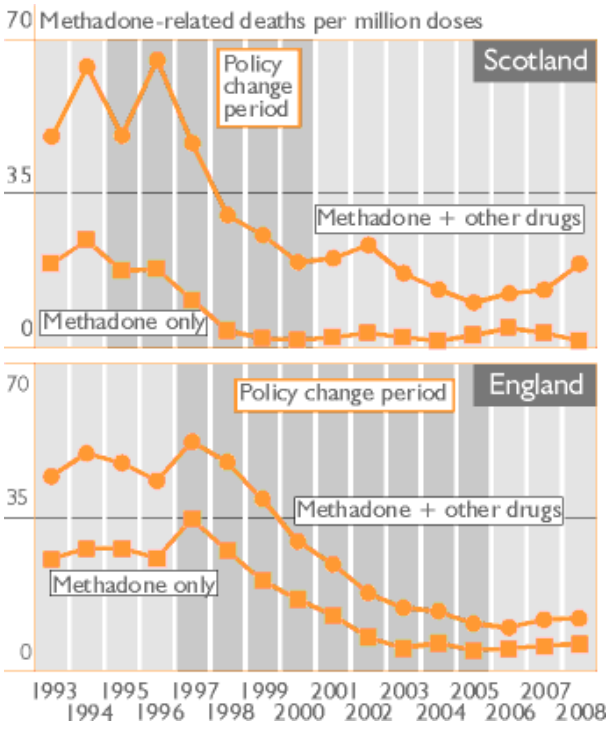
This small study remains the best evidence that supplementing barebones methadone maintenance with counselling further reduces the key outcome for these treatments – illegal opioid use. Whether adding further counselling sessions would make a further difference was doubted by the lead author.

Close supplementary text

Look at our analysis of an important study set in methadone clinics, notes on other similar studies, and the Effectiveness Bank hot topic on counselling in methadone programmes. Consider the implications of taking the big step (for all or selected patients) of doing without anything other than the minimum keyworking required for safety and monitoring. Is this effectively to abandon recovery objectives and accept 'parking' on methadone (see discussion under *Where should I start?*)? Perhaps expert and intensive counselling does not make much difference while patients are in treatment, but enables more to do without illicit drugs and leave

safely? Should counselling be mandatory, or can patients take it or leave it? Is extra counselling worthwhile but not formal psychosocial therapy, or the reverse? Perhaps this depends on the patient? There are caveats and confounds and limitations in the few directly relevant studies – but what there is would seem to contradict assumptions that beyond a minimum, counselling and psychosocial therapy must be mandatory and universal.

▸ **Have we got the balance right on supervised consumption?** Mandatory in US methadone programmes, UK clinics have only relatively recently required patients to consume their medication under the eyes of staff at the clinic or (more usually) at the pharmacy. The aim was primarily to prevent patients diverting their supplies to the illicit market, risking the lives of non-patients, but also to protect patients themselves by ensuring they took their medication, could not 'hoard' supplies, and by closely monitoring the risky initial weeks of prescribing. UK clinical guidance used to recommend supervised consumption for "around three months" or longer if indicated, but in its latest iteration (2017) rejected "arbitrary" rules like set time periods. Instead the advice was that in most cases it will be appropriate for new patients to be required to take their doses under supervision for a "period of time" to allow monitoring of progress and an ongoing risk assessment, the results of which may or may not suggest supervision be extended.



What are the pros and cons? First, findings of a study listed above strongly suggest that in Britain, taking methadone taken under the eyes of treatment or pharmacy staff means that per dose the medication is considerably less likely to be involved in an overdose death – not just of the patients, but anyone. The evidence was the change in the death rate from before to after supervised consumption became routine ▸ chart.

Assuming that is a valid interpretation of the evidence, it is a very important consequence of supervision, but not the whole picture, because it concerns only *methadone*-related deaths. What if due to this unpopular requirement, patients who would have entered or stayed in treatment do not? "Greater flexibility", "Fewer rules" and "Reduced number of months of supervised dosing" were the top regimen changes which opiate-addicted patients being prescribed medications in the UK told researchers would make it easier for them to stay in treatment. In the same study, nearly half the opiate users *not* in treatment said what kept them out was the requirement for daily supervised consumption. As a result, some may never start treatment or drop out and return fully to the illicit market.

Then there is the 'opportunity cost' of supervision – money and time that could have been spent extending the benefits of treatment to more patients. Relaxing this requirement was part of the package which meant (study listed above) a Canadian clinic could treat more patients without any detriment to outcomes. Less stringent or lengthy supervision makes it easier to expand treatment and engage and retain – and thereby protect – a greater proportion of the opioid-dependent population.

Such trade-offs could mean that imposing more stringent or longer supervision results in fewer deaths from diverted methadone, but more from heroin and other illegally-sourced opiate-type drugs among untreated opioid users, or those who leave treatment or are discharged prematurely. Relaxing supervision might lead to the reverse pattern. We have most evidence on the bit of the picture that relates to the impact of supervision on the patients themselves. A key review and the most revealing UK studies suggest (but not very strongly) that if there is to be a blanket policy, it would best be initial supervision only; unfold the supplementary text for details.

Close supplementary text

When a review listed above compared the effectiveness of opioid substitution treatment with versus without supervised consumption, it found no evidence-based reasons to stipulate blanket supervision, but also no conclusive argument *against* supervision. Across the trials there were significant differences in retention in treatment(for maintenance treatments, very important), diversion of medication to other people, adverse effects, or use of non-prescribed opioids.

With its tradition of 'take-home' doses, the UK has contributed several important studies. The largest UK randomised trial (listed above) in effect narrowed down to a trial of post-induction supervised versus unsupervised consumption during the first three months of treatment among the minority of patients who could safely and feasibly be allocated to either, reducing the chances of finding one option preferable to the other. In the event, there were no significant differences in retention in treatment (though this favoured patients allocated to shorter supervision) or in illegal drug use or drinking, nor were there any differences on measures of quality of life. There were, however, significant differences in self-reported crime, which had become less common and less frequent among patients allocated only to initial supervision compared to those allocated three months' supervision. Very few patients (5% supervised, 2% unsupervised) said they had let another person have their medication.

Complicating these findings was the fact that 60 of the 293 patients in the trial had not received their intended supervision regimen. Reanalysing in terms of the regimen patients actually received produced similar findings, but the gap in retention became greater, and supervised patients left significantly sooner. Also, at the 12-week follow-up a significantly higher proportion of patients supervised for three months had used heroin – 73% versus 52%. Suggestive as they are, these findings might have partly been due to the reasons why patients changed from their intended regimens, rather than the regimens themselves.

An earlier pilot study from the same lead author conducted in Scotland had trialled extending supervision after an initial three months when all patients were supervised. Substance use and retention differences were not large and generally not statistically significant, but there was a clear and statistically significant divide in patients' reactions. Two-thirds relieved after three months of the need to take their medication at the pharmacy were happy about their allocation, compared to only 30% subject to continuing twice-weekly supervision and 14% daily.

In England the NTORS study which recruited its patients in 1995 compared (study listed above) GP-led methadone services with hospital clinics. Three-quarters of the clinics required patients to take their methadone under supervision, but just one of the GP programmes. Two years after entering treatment, GP and clinic patients had improved substantially and to roughly the same degree, but what differences there were in drug use, psychological health and retention, favoured the GPs.

Close supplementary text

To further explore this complex issue read these Effectiveness Bank notes and our summary of and commentary on the review listed above. Other analyses related to supervised consumption can be found by running this search. On the basis of what you have read, if you managed a methadone programme, would you opt for discretionary supervision depending on assessments? Can we rely on clinical judgment about when it is right for an individual to change from supervision to less or no supervision or the reverse (a proposition which has never been tested)? Or with the evidence at least not strongly *against* supervision, would you 'play safe' and impose extended and universal supervision? Were we right at one time to standardise the recommended duration at three months? On such decisions could rest thousands of lives just within the UK.

Close Matrix Bite