This issue examines two developments in drug treatment in the United Kingdom and Australia, respectively, to determine their effects on the public health in general and problem drug users in particular.

The UK has instituted a ‘treatment war on drugs’ that has been in place long enough to provide data for evaluative purposes. The intended and unintended consequences of this approach are debated.

The Sydney Injecting Centre in Australia has provided a hygienic place for injecting illicit drugs since 2001. The authors analyze overdose statistics and discuss the Centre’s effects on both drug use in the surrounding area and on the community itself. Our commentary piece focuses on the thorny issue of chronic pain management and poses valuable questions for practitioners to consider.

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Abstract
From 1998 to 2011 the bulk (some two-thirds) of the UK's drug policy budget was spent on treatment compared with just one third on enforcement and prevention combined. The Labour Government's drug policy priority was to get as many 'problem drug users' (heroin and crack cocaine addicts) into treatment as possible to reduce drug-related crime and other harms associated with their drug use. This was the treatment 'war' on drugs they decided to fight. The assumption was that heroin and crack cocaine alone were problematic and disproportionately damaging in terms of health and crime costs.

Prescribing methadone as a medical substitute would, by retaining these 'high harm causing users' in treatment, eliminate their need to finance drug use through crime, prevent overdose and blood-borne virus transmission, and improve health – the key harms associated with their drug use. But 'universal' access to such treatment has not proved the hoped for panacea or realized its harm reduction objectives. Reductions in drugs-related re-offending have been partial and not sustained. Blood-borne infections have risen sharply; drugs-related mortality is up rather than down with methadone deaths on a fast upward trend. Yet its price is long term dual dependency leaving addicts in the UK on scripts indefinitely with no recovery in sight.

The cost benefit calculations that justified increased treatment investment failed to factor in treatment duration, dependency perpetuation, associated welfare dependency costs, or intergenerational or collateral family damage costs. Today, the problem drug-using treatment bill and associated problem drug user (PDU) welfare claims add up to some £2 and a half billion annually for England alone. With associated child welfare costs the burden to the taxpayer tops three billion - a sum unlikely to decrease without a fall in the number of PDUs. Factoring these costs into the equation exposes the irreconcilable objectives, indeed the policy paradox, that the harm reduction philosophy underlying 'treatment' poses. "It is time for universal access to drug treatment," former UNODC Executive Director Antonio Maria Costa has asserted. But if there is a policy lesson to be learnt from the UK it is that rapid, harm reduction treatment expansion has proved less benign than anticipated, that its gains do not outweigh its costs, and that there is evidence it does more harm than good.

The Coalition's new drugs strategy heralds a change of direction for treatment towards the need for 'recovery.' But achieving 'recovery' for more people may involve an acceptance of treating fewer people more intensively to get them drug free, setting time limits and conditions for harm reduction work, and investing more in supply and use reduction. This may prove a more ethical and cost effective 'harm reduction' strategy.

The Billions Spent on the UK's 'Treatment War on Drugs'
The "growing evidence that treatment works (and) in particular (that) harm reduction work over the last 15 years has had a major impact on the rate of HIV and other drug related infections" determined the direction of Labour's drugs strategy in "Tackling Drugs to Build a Better Britain 1998." As a result, substitute prescribing became drug treatment - the UK's treatment default - while psycho-social treatment was evicted to the margins of provision. Risk aversion rather than any broader consideration of the addicts' (or indeed society's) "own good, either physical or moral" (JS Mill) continues to drive the UK's dominant medico-clinical treatment model.

The conviction that harm reduction treatment is a pragmatic and 'evidence based' public health policy which, while morally neutral, can prioritise goals in relation to a hierarchy of harms - health and crime - that must be extended to the entire 'problem drug-using population' has driven an unprecedented investment into treatment over the last 10 years.

Dedicated drug-related UK annual public expenditure has exceeded the billion pound mark for several years now, dominated by a treatment allocation that jumped from £287 million in 2001/2, to £503 million in 2003/4, and to £573 million in 2004/5 - a period during which the 'control of supply' budget stuck at around £376 million.

By 2009 the English budget alone topped a billion, of which the treatment allocation was £657 million. An even higher total 'local partnership' drug treatment expenditure of £731.85 million, financed by a Department of Health Pooled Treatment budget, local (community care) funds, Ministry of Justice Drugs Intervention Programme funding, and an adolescent treatment funding stream is recorded, the bulk of which is predicated upon harm reduction, in terms of health or crime reduction, as opposed to the holistic treatment of addiction.

Targets and numbers
While treatment expenditure trebled, with numbers accessing treatment rising rapidly in line with government targets
and expenditure from 33,200 drug users in 2001(8) to 202,666 by 2006,(10) investment in abstinence-based rehabilitation programmes fell. With two thirds of the estimated 332,090 problem drug users (heroin and crack cocaine) recruited, (11) numbers accessing state funded rehab fell from 5620 in 2004/5 to 4711 in 2006. (12) Three quarters (153,632) of those reported to be in 'effective' treatment are on a methadone script or another opioid substitute. (13)

Today, two thirds in treatment are over thirty and nearly one third over 40, compared with 10 years ago when the majority were under thirty.

**The Experience of England's Universal Access Treatment System**

"I went to the doctor's and he put me in touch with a drug agency. I went there, and they says, 'well detox you, we'll start cutting you down a couple of mls a month'. I said, 'A month? So, I said, 'I'm on 80mls, so how long is that going to take?' And it worked out it would probably take a couple of years....I actually thought death would be better than what I was going through. I actually said to myself, "I can't do this anymore; I can't live the way I'm living.""(14)

Prescribing is the default response of UK drug 'services' even if the addict also has a cocaine or crack cocaine habit (for which methadone is inappropriate) or if his heroin habit is secondary. For 50.000 of those on prescription, heroin is either not their primary problem or not their only drug problem. A minority are injecting drug users.(15) A further 30,000 present with cocaine, cannabis or amphetamines problems.(16) But with no pharmaceutical agonists available, the National Institute of Clinical Excellence (NICE) has been lost for advice stating: "Very little is known or practiced in relation to managing the misuse of cocaine, amphetamines or cannabis."(17) Abstinence treatment is excluded from national 'models of care' while residential rehabilitation is advised only for those for whom all else has failed, or who are homeless or 'dual diagnosis' cases.

The reality for the thousands of 'service users,' as the National Treatment Agency designates them, is daily or weekly script collections from pharmacies after an initial two or three weeks of supervised consumption. Yet the pharmacies they collect from, like needle exchanges, typically are loci for drug dealers. There are no objective procedures for prescribers (increasingly non-medical prescribers) to assess or review the appropriateness and levels of maintenance dosage - though methadone is not an innocuous treatment.(18) Despite fatal child overdoses, like that reported on June 11th 2010 in The Guardian, prescribing guidance still leaves much open to judgment, and dosages, addicts report, are often a response to their own demands of what they say they need 'to hold' them. (19) A weekly pharmacy 'take away' collection of 500mls at a time is common; so too is the methadone, wine, and welfare profile typical of addicts on prescription.(20) The national prescription of addiction as a 'chronic, relapsing condition' has become "both a mantra and a justification (and has generated) a cycle of ennui and pessimism in treatment, with workers delivering sub-optimal treatment in which the prescription dominates and the requisite psychosocial interventions limp along in the limited time available - around 10 minutes every two weeks.)(21)

Despite low drug worker/client contact, harm reduction treatment services have not come cheap. Annual average client treatment costs for England work out at nearly £4000 a year - a substantial mark up from the basic methadone dispensing and prescribing cost of only £39 million a year (£300 per client per year).(22) A recent Home Office 'bottom up' costing of 'Tier Three' prescribing and 'Tier Four' drug treatment services calculated an annual average treatment cost of £6664. (23)

The 'Treatment Works' Toll

"If there has been one statement that sums up the view of drug abuse treatment over the last 15 years it must surely be that 'treatment works.'(24)

The pressing question given the amount this is costing is, does it? What has universal access to low contact harm reduction treatment services actually achieved? Has it in fact generated more harms than it has solved? These are questions that policy makers can no longer avoid.

Last year England's treatment budget 'bought' 2,476,000 methadone prescriptions(25) compared with just 9,392 inpatient detoxifications and 4,711 residential rehabilitation interventions. It resulted in only 8112 discharges free of drug dependency (only 4 % of the treatment population - arguably no more than would be the case without any treatment intervention at all), though becoming drug free, as treatment outcomes research shows, is associated with access to residential rehabilitation programmes or the achievement of a period of abstinence.(26)

The intention of universal access to treatment, however, was not to buy recovery but to reduce harm. The English experience shows surprisingly little evidence that it has done so, rather it suggests that it may have increased harms.

**Lives Saved or Lost?**

"We are seeing a steady increase in the UK of the numbers of addicts who are dying alongside a massive explosion of the prescribing of methadone - more deaths than in any previous year. More addicts on methadone than in any previous year."(27)

Methadone treatment expansion has proved more risky than anticipated. Drug misuse deaths are up, from 1608 in 2005 to 1876 in 2006. (28) Those deaths involving heroin and morphine are up slightly, but those involving methadone shot up from 220 to 408, by 85 per cent. They now constitute a quarter of all drugs poisoning deaths.(28) To what extent this is attributable to unsupervised consumption and low client contact and whether this is an inevitable outcome of mass long term prescribing is unclear. (30) In mitigation it has been argued that, "...people are much more likely to survive if they're on a methadone treatment programme...we've no idea what would happen to deaths if we stopped prescribing methadone."(31) But were such a rise of deaths found in any other population (other than addicts) as a result of, or relating to, the medical treatment they were receiving, it would, in likelihood, be the subject of a major inquiry.
Public Health or Damaged Health?

Other harm reduction orthodoxies can no longer go unchallenged. "Harm reduction has left us with one of the lowest rates of HIV amongst injecting drug users in Europe," Professor Iversen, the Government's senior drugs policy advisor asserts.(32) But while the incidence of reported HIV infection among injecting drug users has remained low in the UK, as in most European countries,(33) it has risen and has been for a decade. The prevalence of HIV has increased from 0.7% to 1.5%, twice as high as in 2000.(34) Over this period of unprecedented investment in harm reduction drug treatment, 90% plus of Hepatitis C infection is acquired by injecting drug users. 4484 reports in 2000 doubled to 8605 in 2009.(35) This may reflect a poor quality of blood-borne virus testing and vaccination services, more needles being distributed than exchanged, and a total failure in the UK to recruit from needle exchange to treatment as apart from the inherent difficulties of managing an addict population. 40 per cent of these services have no immunisation on site or test for blood-borne viruses when assessing new clients, and one third do not discuss injecting hygiene and safer injecting techniques.(36) The question therefore, for those proposing universal access to treatment services, is at what point do poor quality, unconditional 'public health' needle distribution services do more harm than good – do they increase rather than minimize risk?

A recent economic modeling and evaluation of needle exchange cost effectiveness could not demonstrate this. It points out that needle exchanges could lead to an increase of new injectors; that the duration of an existing intravenous drug user's injecting life may be lengthened (by making injecting safer and more socially acceptable), diluting the benefits of needle exchanges and even reversing them.(37)

Lengthened Dependency and Deteriorating Health?

"(Methadone) sounds good but it keeps people actually where they are. In fact they are worse off because they go back on heroin because they're not holding them", is their phrase. It is harder to come off and it is so sad. It is a very debilitating drug and memory loss is a big thing for the young people coming off it."(38)

Long term script dependence is the treatment norm for both England and Scotland. One quarter of the National Treatment Agency's prescribing clients have been on state sponsored methadone for more than four years, one half of them for more than two years.(39) The sobriquet of being 'parked on methadone' is deserved. There are no guidelines for getting clients off methadone or onto reduction or abstinence treatment plans.

"People can go into chemists, pick up their prescription if they're non-supervised, take it out the chemist, maybe take half it, and sell the other half to somebody that they don't even know. When I was taking heroin on top of my methadone, I was actually cutting down my methadone and selling what I had left. We weren't taking our full prescriptions; we were only taking half of that and still taking heroin at the same time....a lot of drug users see it (methadone) as a back up plan for when you've got no money, you cannot get hold of drugs, and at least you've got something there to hold you."(40)

It is not surprising that problem drug use has barely been dented nor that, despite a drop in the number of heroin users seeking treatment, there is no statistically significant decrease in the most recent estimate made of problem drug user numbers.(41) The argument that 23,500 people exiting the treatment system every year demonstrates treatment success and their overcoming of dependency(42) does not bear scrutiny. Non-return to the 'in treatment' register is all that is demonstrated in the absence of any evidence about these clients' general drug use or health status.(43)

Methadone is viewed by its proponents as a necessary, possibly lifetime, treatment, but many on it say 'it wrecks you physically, mentally and worse spiritually'.(44) Being on methadone prolongs the median duration of addicts drug 'injecting' careers from five to twenty years, a recently published longitudinal cohort study (of 754 addicts followed over a 30 year period) found – along with prolongation of poor health and quality of life and high rates of physical and mental illness. Specifically, the report said, "Exposure to opiate substitution treatment was inversely related to the chances of achieving long term cessation."(45)

The growing evidence that addicts in treatment develop morbid health problems that treatment length exacerbates is something that policy makers need to weigh carefully.

For harm reduction, though driven by the principle of risk aversion, brings new risks and costs. Leakage of prescribed methadone onto the illicit market because pharmacists are not contractually obliged to supervise methadone consumption is one.(46) The fact is that the majority of treatment clients stay street drug dependent is another. The street drug dependency of those in treatment in the UK has been reduced, at best, by only a third. This is what the most recent cohort study of treatment effectiveness reveals.(47) If this is all high investment 'harm reduction' can achieve, is it enough?

Inherent Limitations of the Opiate Harm Reduction Paradigm

The national policy 'obession' with both opiates and its 'evidence base' for substitution prescribing has, in England, distracted from the reality of cross addiction to a range of drugs and alcohol and from the most prevalent drug problems - cannabis and cocaine use. Cocaine, the use of which has more than doubled in ten years, is perceived by Britons to be a very much less harmful drug than heroin or crack.(48) Yet a 129.5% increase in cocaine deaths (a 151.7% increase where cocaine was the only drug mentioned),(49) a 304% rise in poisoning by cocaine (from 188 cases to 760 in 2009/10), and a 132% rise in cocaine-related mental health disorders since 1998 (analysis of HES data reveals) belie this.(50)
Even less 'official' attention has been paid to benzodiazepine dependency and associated deaths, which have risen from 190 in 2005 to 261 in 2009, (including an increase of 13 per cent, in just one year, from 2008). (51) A 252% rise in cannabis-related 'other' mental health and behavioural disorders since 1998(52) has yet to turn cannabis dependency into a treatment priority. Yet as Dr. Stuart Reece has pointed out: "It does not matter whether the various side effects of the addictive drugs are rare or common. If their use increases, both in terms of the numbers of individuals exposed to them, and in terms of the unit exposure per individual, then, since virtually all of these effects are dose-related - that is the larger the dose the more the effects - as the dosing level rises in the community at both the individual and community level, then the drug complications which were once rarer become increasingly common. Furthermore since the drugs are addictive, these complications continue to become ever increasingly common." Harm reduction theory appears insensitive to such an analysis.

Cutting Crime, Reducing Re-Offending?

"Given the public money spent on the strategy and the cost to society, we find it unacceptable that the Department has not carried out sufficient evaluation of the programme of measures in the strategy and does not know if the strategy is directly reducing the overall cost of drug-related crimes ... (that) it could not prove a causal link between the measures in the strategy and the levels of offending by problem drug users." (53)

Last year, the Parliamentary Public Accounts Committee reprimanded both the Home Office (the lead drug policy department) and the National Treatment Agency for not knowing 'the overall effect its expenditure on drugs treatment is having,' specifically with regard to crime. That the Home Office's own Drugs Treatment Outcomes Research Study, (54) commissioned to measure the cost effectiveness of treatment, had failed to keep track of all but 28% of the treatment sample at 11 months also suggested an underlying disarray of the treatment system it had set out to monitor. Earlier Home Office research, notably the Arrestee Surveys, though optimistic, only reported a limited impact of opiate substitution on crime - with only a quarter of those having had treatment reported being no longer heroin dependent. (55)

The problem facing the practice of harm reduction is that the majority (63%) not the minority of those on scripts experience no illicit drug free periods at all, even in the first six months of treatment. (56) The maximum drop in street drug consumption than can be expected as result of treatment is at best one third, the bulk of this drop being in the first 8 months with little thereafter. (57) Whether this level of treatment effectiveness justifies continued methadone maintenance given other downsides is unclear. The science of estimating this remains inexact. Yet, the National Treatment Agency has stated confidently that "all the research evidence states that drug treatment is effective in reducing drug use and cutting crime." (58) But, as has been pointed out, 'insofar as drug treatment is effective in reducing rates of acquisitive crime among recovering drug addicts, it does so, not by altering their criminal activities directly, but by reducing their consumption of illegal drugs and thereby the need for them to engage in crime to sustain their habit.' (59)

The marginal outcomes of the first phase of Drug Treatment and Testing Orders in the UK - a 80% reconviction rate within two years for those who could be traced(50) - suggests this may not be enough. For drug-related re-offending still rises, 2.9% since 2007,(61) with prolific drug-using offenders still committing an average of 2.6 (proven) offences each per year. (62)

Dual Dependency - The Welfare Burden

In all the cost benefits and value for money calculations, little attention has been paid to year on year welfare dependency costs. Most of the treatment population (79%), like most of the problem drug using population (81%), are unemployed and on benefits. (63) Claims made by problem drug users in 2006 for Job Seekers Allowance, Incapacity Benefit, Income Support, and Disability Allowance, calculated at today's prices, using median claims for each category, add up to £1,141,224,400 (£1.14 billion). Including the 10.6% administration cost of government
Hidden Harm Welfare Costs

The overall expenditure estimate for child and family work attributed to drug use has been estimated to be £1.2 billion. (66) This is made up in part by the 'looked after' costs of the children of addict parents - some 12,500 of them. (67) To date, there is no evidence that the introduction of harm reduction treatment services has reduced the numbers of children needing special care or has reduced the risks that parental drug dependency exposes them to. Continuing drug use and dependency, which is the treatment norm, continues to affect conception and pregnancy and the capacity for parenthood as well as the wider family and community. The social and economic cost repercussions of not getting parents to be drug free, sober, and rehabilitated for future generations are yet to be estimated.

Discussion

"For the layman it must seem bizarre in the extreme that a highly addictive drug is being prescribed to people who have a demonstrable capacity to become addicted and that universal access to such substitute drugs is advocated at the highest of levels." (Professor Neil McKeganey, quote permission agreed)

The evidence of the harms of harm reduction can no longer be avoided. For the critical issue is whether, in lengthening drug-using careers, treatment prevents recovery and supports a dual drug and welfare dependency which is more costly (socially and economically) than can be justified by what are 'counter factual' assumptions regarding reductions in drugs-related health and crime that result from treatment (i.e.: without treatment health and crime outcomes would be even worse).

It is time to revisit the conclusion of the National Treatment Outcome Study that, "for every extra £1 spent on drug misuse treatment, there (will be) a return of more than £3 in terms of cost savings associated with victim costs of crime, and reduced demands upon the criminal justice system," that convinced the government of the efficacy of the crime costs benefits approach (68).

Revisiting the Evidence

Given such sizeable public investment, we have to ask whether the present treatment paradigm performs and whether there was ever the evidence for methadone prescribing to justify such a wide and draconian policy application.

The major strength of the recent analysis of the Edinburgh methadone treatment cohort is its highlighting of the fact that information about the relative efficacy opiate treatment is only short term while dependency can be long term - that most of the studies quoted in the present drugs treatment debate are too short term to be helpful. For the 'evidence' of the meta-analyses of randomised control trials for opiate substitution and on which the critical NICE (the National Institute of Clinical Effectiveness) guidance is based refer to trials which had durations of less than a year.

Since then, Professor Sir Michael Rawlins, NICE's Chair, has argued that we need a new approach to analysing clinical evidence and that randomised controlled trials (RCTs), long regarded at the 'gold standard' of evidence, "have been put on an undeserved pedestal." Their appearance at the top of "hierarchies" of evidence he now believes to be inappropriate, and he advocates their replacement by a diversity of approaches that involve analysing the totality of the evidence-base. RCT opiate substitution trials suffer the general limitations he notes:

"RCTs are often carried out on specific types of patients for a relatively short period of time, whereas in clinical practice the treatment will be used on a much greater variety of patients - often suffering from other medical conditions - and for much longer. There is a presumption that, in general, the benefits shown in an RCT can be extrapolated to a wide population; but there is abundant evidence to show that the harmfulness of an intervention is often missed in RCTs."(69)

Observational studies, he acknowledges, can provide an important source of evidence - both about the benefits and harms of therapeutic interventions. Yet, the revelations of two key UK observational studies, NTORS and DORIS, both show (DORIS, startlingly so) that improved recovery outcomes for those assigned to residential rehabilitation have not been given the weight they deserve (70). For decision makers, in the UK, lacked the judgement, taken a narrow focus, and adopted entrenched positions about the very nature of evidence that Sir Michael warns against.

Routine disregarded evidence includes that which shows abstinence to be the best predictor of a range of recovery outcomes and shows that achieving a goal of abstinence for many is challenging without appropriate treatment settings. The UK's new drugs policy strategy has yet to take this on board let alone its implications for the numbers in treatment. Resolving the problem of working out how to deliver intensive, high quality treatment to the very large number of drug users currently 'in treatment' is a question that the UK's Payment by Results treatment pilot plans have yet to face. But if the policy goal of freeing people from dependency remains the key outcome, then the numbers question cannot be indefinitely avoided. For unless there is a reduction, it is difficult to see how resources will stretch to providing the intensive support that addicts require to become drug free.

And if, as Neil Mckeganey suggests, it is "the sheer numbers of drug users in treatment (that have) resulted in a downward pressure on the quality of treatment whether we like it not, the issue of numbers has to be addressed," that challenge is not likely to be successfully met, for "(a) the moment we tend to think that any individual who expresses a wish for treatment should have access to that treatment even if they are in no way committed to the cessation of the
A radical approach of focusing on those that do - treating fewer people properly - while reconfiguring conditional drug support services for those that do not yet do so, may prove the truly pragmatic, cost effective (as well as ethical) way forward. In view of the harms that harm reduction treatment is generating and perpetuating, such an approach warrants urgent and serious policy consideration.

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Kathy Gyngell is a research fellow at the Centre for Policy Studies, a London based independent think tank where she chairs the Prisons and Addictions Policy Forum. She originally studied social anthropology (Cambridge First Class Honours) and sociology (Oxford, M.Phil). She chaired, researched and authored the two Addictions Reports for the Conservative Party's Social Justice Policy Review's Breakdown Britain (December 2006) and Breakthrough Britain (July 2007) to which the Conservative Party's subsequent pledge to overhaul treatment policy are attributed. Her critique of the UK's failed drugs policy, The Phoney War on Drugs, (CPS 2009) was widely covered by the UK press. She has written for The Daily Telegraph, The Times, The Guardian, The Yorkshire Post, the Evening Standard, Drink and Drug News and Addiction Today. She is regularly interviewed for broadcast media and has contributed papers to the Commonwealth Parliamentary Association's International Parliamentary Conference, "Tackling Drugs, Changing Communities - Challenges to Parliamentarians," February 2008, the UKESAD conference, May 2008, the Cumberland Lodge, War on Drugs seminar, April 2010 and WFAD conference, May 2010. She blogs regularly on all aspects of drug research, problems and policy, http://www.cps.org.uk. "Breaking the Habit: De-nationalizing Addiction, Rehabilitating Treatment," her new CPS pamphlet, will be published in April 2011.

Conflict of Interest Statement:
I declare that I have no proprietary, financial, professional or other personal interest of any nature or kind in any product, service and/or company that could be construed as influencing the position presented in, or the review of, the manuscript entitled: The UK's Treatment War on Drugs: A Lesson in Unintended Consequences and Perverse Outcomes

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The Sydney Injecting Centre - Assessing The Evidence-Base
Gary Christian

Abstract
The Sydney Medically Supervised Injecting Centre (MSIC) opened May 6 2001, and a number of government-funded evaluations released between 2003 and 2008 are examined. Findings of this analysis of the data are that the injecting centre, over its initial 18 month evaluation period, failed to statistically save one life and had an overdose rate at least 36 times higher than drug user overdose rates in its immediate vicinity. This and other later evaluations indicate the centre had a very low rate of utilization, had poor referral rates to treatment and detox, did not positively alter behaviour associated with elevated risk of blood-borne diseases and adversely affected the public amenity of the Kings Cross area of Sydney in which the centre is situated. Other data suggests that the injecting centre may increase drug use.

Supervised Injection Facilities are defined as 'legally sanctioned health and social welfare facilities that enable the hygienic injection of pre-obtained drugs under professional supervision.' To date, there are 92 such centres operating in Switzerland, Germany, the Netherlands and Spain, with more recent additions in Australia and Canada.

Evaluation of the European centres has not been extensive to date; however, the Australian and Canadian centres have made concerted efforts to establish a strong evidence-base upon which more meaningful assessments can be founded.

Supervised Injecting Facilities have been established with a number of aims - to reduce the mortality and morbidity associated with illicit drug use, to reduce the nuisance of public injecting, to reduce the number of discarded syringes in public places, to provide improved access to treatment and to reduce the transmission of blood-borne viruses.

Prior to the opening of the Sydney Medically Supervised Injecting Centre (MSIC) on May 6 2001, there were competing predictions regarding what the facility would achieve. The New South Wales Government's Drug Summit of May 1999 approved an 18 month trial on the basis of three projected outcomes: 1. that the proposed MSIC might decrease overdose deaths, 2. that it would provide a gateway to treatment and 3. reduce the problem of discarded needles and users injecting in public places. To this end, the MSIC was placed in the Sydney inner-city suburb of Kings Cross, an area subject to 12% of all heroin overdoses recorded in New South Wales (NSW) between 1996 and 2001 and deemed to have a predominance of problem and open drug use.

Critics of the proposed injecting centre, which included the International Narcotics Control Board (INCB), reasoned that the MSIC would 1. create legitimacy for illicit drug use, 2. lead to elevated levels of drug use and 3. consequently attract drug dealers to the injecting centre's vicinity via what was termed a 'honey-pot' effect.

On July 9 2003, the first of a number of evaluations completed between 2003 and 2007 was published, quite extensively evaluating the performance of the centre during the first 18 month trial period. These evaluations provide a very useful evidence-base for assessing the MSIC against the Drug Summit expectations and equally against the concerns expressed by those who were opposed to the trial.

This article represents the findings of various analyses of the evaluations by the academic Fellows of Drug Free Australia. In 2003 Dr Joe Santamaria, an epidemiologist, Dr Stuart Reece, an addiction medicine practitioner, Dr Lucy Sullivan and Dr Greg Pike, both social researchers, and Gary Christian, a welfare professional, produced an analysis of the first evaluation, and further work has been done by various of these Fellows on the later evaluations.

Impact on Overdose Deaths
The 2003 government-funded evaluation estimated incorrectly, as is demonstrated below, that between 6 and 13 lives had been saved by the MSIC over the 18 month evaluation period. Their upper estimate of 13 lives saved was calculated from the 329 heroin overdose interventions in the MSIC during that period. Noting that the number of opioid-related deaths in the Australian community has a close relationship to the number of ambulance overdose callouts, the evaluation team applied the observation that 8.12% of ambulance heroin overdose callouts resulted in overdose deaths. This percentage was applied by the 2003 evaluators to the 329 overdose interventions within the MSIC but then further corrected for the attendant observation that ambulances attended only 51% of overdoses in the community. Thus,
derivatively, 4.1% of all overdoses in the Australian community were deemed to be fatal. By extrapolation, 4.1% of the 329 overdose interventions in the MSIC might be, on the evaluators’ logic, expected to be fatal, yielding 13.49 deaths averted because there was not one fatality, thus the upper estimate of 13.49 lives saved.

The lower estimate was based on the number of naloxone administrations in the MSIC. Naloxone was administered for 81 of the 329 heroin overdoses. The remaining 248 were managed by other resuscitation techniques. On the rationale that the administration of naloxone was ‘a good clinical marker of serious respiratory depression which left untreated could result in death’, the evaluation team applied the ambulance fatality percentage of 8.12% to the 81 naloxone administrations, deriving the lower estimate of 0.85 lives saved.

The lower estimate was considered by the evaluation team as the more defensible. They significantly noted that:

The lower estimate is the more conservative and plausible, especially as there were only 17 drug-related deaths in the Kings Cross area during the trial period, an average of 11 deaths per annum.

When compared to known Australian mortality rates for dependent heroin users, these estimates of the number of lives saved by the injecting centre are not credible. Rather, statistics indicate that only one life can be saved every two years by the Sydney centre as per the following calculation.

It is well-established in journal studies that one in every 100 dependent heroin users dies in Australia each year from fatal overdose. It is also well established that dependent heroin users inject at least three times a day — this was a stated assumption used by the 2003 evaluators in their calculations. Taking these two together, it is clear not only that 100 heroin users injecting three times daily will cumulatively inject 110,000 times per year but also that only one of these 110,000 injections will and the life of the one in 100 who, on average, will die of fatal overdose annually. Because the injecting centre hosts less than 55,000 opiate injections per year, it will take it two years to accumulate the 110,000 injections for which one fatal overdose is expected. What this means for the Sydney injecting centre is that it takes, on this measure, two years to save just one life, at a cost of $2.7 million per year or $5.4 million for a single life saved.

It is important to recognize that this method of calculating lives is that used by the most comprehensive, and sympathetic, review of injecting rooms worldwide by the European Monitoring Centre for Drugs and Drug Addiction in 2004. It also appears to be the same methodology used by the Canadian government’s Expert Advisory Committee in 2005 which calculated just one life saved for the Vancouver Insite facility which hosts an average of 400 heroin injections per day and where the Committee assumed an average of 4 heroin injections per day per user.

In the 2003 evaluation the injecting centre failed to approach its full capacity, hosting only an average of 65 heroin injections per day, or just 20% of its total capacity. Consequently, in this scenario, it could only have statistically saved the smallest fraction of a life. From this basic and more valid calculation the evaluation team’s estimates on 2003 figures are alarmingly inflated.

High Rates of Overdose

The explanation for the curious overestimation of lives saved becomes evident when the number of overdoses inside the injecting centre is compared with the number of overdoses in its immediate vicinity. This leads to a disturbing outcome for the Sydney facility.

First, it is important to note that the evaluation team’s upper and lower estimates of lives saved were both calculated from the number of overdoses recorded in the injecting centre. Secondly, while there is no evidence within the report that the evaluators pursued any comparative analysis between overdoses in the centre and overdoses in the area, there is nevertheless sufficient data contained within the report that readily allows such a comparison.

In the Kings Cross area during the evaluation period, the MSIC evaluation report notes that there were 431 ambulance callouts for opioid-related overdose which, when corrected for the observation that overdoses are called to 51% of non-fatal overdoses, yields a total of 845 probable non-fatal overdoses for the Kings Cross area. In light of the 3.2 million injections estimated for the whole of Kings Cross over the 18 month evaluation period, the area surrounding the MSIC yields an overdose rate of 0.25 per 1000 injections (845 overdoses: 3,229,030 heroin injections). Yet, the injecting centre compares with an overdose rate of 9.6 per 1000 injections (329 overdoses: 34,869 heroin injections). Remarkably, this is 36 times higher than the overdose rate on the surrounding streets.

Table 1—Comparison of overdose rates for the injecting centre and surrounding Kings Cross:

<table>
<thead>
<tr>
<th>Over 18 month evaluation:</th>
<th>Injecting Centre</th>
<th>Kings Cross/DSH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heroin injections per day</td>
<td>65</td>
<td>6000</td>
</tr>
</tbody>
</table>
The MSIC evaluation report does indeed note that the overdose rate is high, but avoids, with all the data at its disposal, to make the necessary comparison with overdose rates in the immediate vicinity of the MSIC. It is extraordinary that the report failed to do this. It is this extreme rate of overdose in the MSIC which is sufficient explanation for the immense discordance between low heroin-related fatalities outside the MSIC and the report’s excessive estimates of averted mortality inside.

The evaluation report provides other compelling evidence that the overdose rate is unnaturally elevated. On entering the injecting centre for the first time, clients were asked to complete a registration questionnaire which, amongst other things, asked them their previous overdose history. 44% had overdosed a median 3 times in an average 12 year career of illicit drug use. Applying the report’s own estimate of users injecting ‘at least’ three times a day, a rough comparison can be made between overdoses before entering the centre and overdose rates while at the centre.

From the data above, users who are experiencing an overdose on average once every 4 years, injecting at the estimated rate of at least three injections per day, yield 0.23 overdoses for every 1,000 injections before registering at the MSIC.

On this second analysis, MSIC clients are experiencing a rate of overdose around 40 times higher than before entering the MSIC. This is remarkably close to the comparisons in Table 1 and would appear to put the extreme overdose rates inside the MSIC beyond doubt.

Explanations that the centre attracts a higher-risk clientele, thus producing the abnormally high overdose rate, cannot be supported from the evidence-base. Studies reproduced at Table 3 indicate that MSIC clients are the least at-risk when compared to other high-risk users. The most comparable of these studies, the Sydney study of 1996, was a self-volunteered Sydney-wide survey which may well have included lower risk users than those frequenting the Kings Cross area.

It is evident that if there is a dynamic within the injecting centre which increases overdoses by a factor of 36 to 40 above other known rates of overdose, then the ‘lives saved’ estimates for the injecting centre need to be reduced by the same factor of 36-40, yielding a statistical result in agreement with the prior calculation - 0.18 lives saved in 18 months.

Increased drug use
The 2003 report does indeed note the elevated overdose rate (which is correctly recorded as 9.6/1000 on page 24 of the report), despite providing no further commentary, and additionally records the evaluation team’s view concerning the cause of this high overdose rate:

<table>
<thead>
<tr>
<th>Study</th>
<th>Ever Overdosed</th>
<th>Overdosed in Last 12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSIC</td>
<td>44%</td>
<td>12%</td>
</tr>
<tr>
<td>Australian IDRS study</td>
<td>51%</td>
<td>29%</td>
</tr>
<tr>
<td>Sydney study 1996</td>
<td>66%</td>
<td>20%</td>
</tr>
<tr>
<td>British study 1999</td>
<td>58%</td>
<td>30%</td>
</tr>
</tbody>
</table>
In this study of the Sydney MSIC there were 9.2 (sic) heroin overdoses per 1000 heroin injections in the MSIC, and this rate of overdose is likely to be higher than among heroin injectors generally. The MSIC clients seem to have been a high-risk group with a higher rate of heroin injections than heroin injectors who did not use the MSIC, they were often injecting on the streets, and they may have taken more risks and used more heroin in the MSIC. (our emphasis)

Putting aside the explanation of clients being more at-risk, an explanation without support, it is notable that the second explanation confirms the criticism of those opposed to the injecting centre trial – that it would increase illicit drug use. The implications of the statement are of concern, after all, implicit in the explanation of risk-taking is that clients are using the presence of nursing staff as insurance against the risks of experimenting with considerably higher doses of heroin. And such experimentation inevitably entails elevated heroin purchases, increasing trade for criminal drug dealers. The clear conclusion is that the MSIC is enhancing the criminal drug trade.

In 2007, NSW Parliament’s Upper House records the testimony of two ex-clients of the injecting centre who were then in rehabilitation. When asked why the overdose rates were abnormally high in the centre, both gave the same reply, affirming that the centre was used by clients to experiment particularly with dangerous cocktails of drugs. The testimony of one ex-client included the following remark:

“They feel a lot more safer, definitely because they know they can be brought back to life straight away. They know they can, like some people go to the extent of using even more. So in a way they feel it is a comfort zone, and no matter how much they use, if they drop they will be brought back. What users look for is in heroin and pills is to get the most completely out of it as they can, like virtually be asleep. To get that you have to test your limits. And by testing your limits that is how you end up dropping (overdosing).”

Ambulance Callouts for Overdose
The 2003 evaluation examined ambulance overdose callouts in Kings Cross, focusing also on the callouts during the hours the injecting centre was open. The task was difficult because a heroin drought had ensued about 6 months before the centre’s opening on May 6, 2001. After correcting for the reduced demand for heroin, no effect could be discerned for the centre’s expected impact over time or during injecting room hours.

In June 2007 another evaluation was completed by the National Centre in HIV Epidemiology and Clinical Research (NCHECR) which studied the effect of the heroin drought on ambulance overdose callouts for the whole of NSW versus Kings Cross and Darlinghurst, the suburb next to Kings Cross which has historically had a more modest drug scene. Their finding was markedly different to the 2003 evaluation’s – ambulance callouts had reduced by 80% in the Kings Cross postcode over the period 2001-6, while the rest of NSW decreased by 61% as a result of the heroin drought during that same period. Reductions in neighbouring Darlinghurst were a lowly 45%.

However, the conclusion by the 2007 evaluators that the reduced callouts are the result of the injecting centre do not stand up to scrutiny. While Kings Cross reductions are 19% greater than the rest of NSW, Darlinghurst, the suburb next door, is curiously 16% less in terms of reductions against that average. Taking these two against each other indicates a clear displacement effect of heroin users and their street overdoses from Kings Cross to Darlinghurst.

The likely cause for such a displacement effect is also obvious. The most celebrated Australian drug user displacement effect back in 2001 saw heroin users displaced from what was then titled the ‘heroin capital of Australia’, Western Sydney’s Cabramatta, into neighbouring Fairfield. With sniffer dogs trained for the Olympics in 2000 at their disposal and new tougher legislation to back them, police cracked down on drug dealers and users in a New York style zero tolerance operation which yielded an 83% reduction in ambulance overdose callouts.

In November 2001, 5 months after the injecting centre opened, NSW Parliament enacted new laws which would allow use of the Olympics sniffer dogs and tougher policing in other drug hot-spots. On May 18, 2002, ABC News announced the commencement of tougher policing targeting dealers predominantly in Kings Cross which continued throughout the 5 year period covered by the 2007 evaluation. It is clear that tougher law enforcement should have been the first causal explanation considered by the evaluators, whose office is near the boundary between Kings Cross and Darlinghurst, and who undoubtedly would have known of the changes in law enforcement.

Drugs Free Australia calculations give a more realistic estimate of reductions the injecting centre makes to ambulance callouts in Kings Cross. The 2003 injecting room evaluation utilized a study which found that there were 24 non-fatal overdoses for every fatal overdose in Australia. Using this figure against the 110,000 injections per year per fatal overdose, the injecting room consequently saves 12-13 ambulance overdose callouts per year from an annual pre-heroin drought average of 208 in the Kings Cross postcode.

Gateway to Treatment
The injecting centre made little impact in terms of treatment referral outcomes. Despite 66% of injecting centre clients having previously accessed some form of drug treatment, only 11% of clients were referred to maintenance treatment, counselling, detoxification or rehabilitation, with none of the major Sydney-
based rehabilitation centres such as Odyssey House, WHOS or the Salvation Army ever seeing any rehabilitation referrals. While it is recognised that the motivation to access treatment or rehabilitation lies entirely with the client rather than with the referring centre, these results appear poor.

A later evaluation in 2007 found that the injecting room was still referring just 11% of clients to other drug interventions but that the uptake rate to the referred services had moved from 20%, a figure which had received public criticism in 2003, to 84% in 2007. This is a laudable improvement regarding client uptake of referral; however, it leaves the question as to whether clients, many of whom may be only there for the purposes of experimentation, would be motivated while in that frame of mind to consider treatment.

Public Injection and Discarded Needles
The MSIC's 2003 evaluation report provided documentation on detailed counts of discarded syringes and sightings of public injections in the Kings Cross area before and throughout the evaluation period. The evaluation team's analysis was again complicated by the onset of the heroin drought 6 months before the injecting centre opened and which continues with only slightly less severity in 2010.

It would reasonably be predicted that the heroin drought should reduce both of these indicators of public amenity, and the evidence from the report is that the drought did indeed do that. Data within the report shows a decrease in the number of needles distributed by local pharmacies and needle exchanges due to the effect of the heroin drought being 19% between July 2000 and July 2002. Collections by South Sydney Council needle cleanup teams at six Kings Cross drug hotspots in July 2002 recorded no decreases overall for Kings Cross, as might be expected, but 1% more than in July 2000, before the heroin drought began. Major increases in needle counts were on Bayswater Road, 50 metres from the centre (65% greater than 2000), and Kellett Street, onto which the centre's back door opened (24% greater than 2000). Needle counts by cleanup teams from a Kings Cross needle exchange recorded a 9% decrease in counts, still not in line with the reductions in needle distribution.

In June 2007, another evaluation examined needle counts and found a 48% decrease against counts in 2000, before the heroin drought. With the dislocation of drug users from other areas of Kings Cross outside the immediate vicinity of the injecting room, these counts should be expected to have shown a much greater decrease, certainly greater than the 51% decrease in heroin use that is extrapolated from ambulance callout averages for the whole of NSW. Because discarded needles indicate public injection, it is clear that public amenity did not improve in the immediate environs of the injecting centre.

It had been argued by some that crime would increase as a result of the injecting centre. Two studies have focused on crime in the Kings Cross area, finding that crime had indeed decreased, but only in line with the decreases in heroin availability. With increased law enforcement from 2002 on, appreciable decreases in crime should be expected.

Drug Dealers Attracted
It is evident from the 2003 evaluation report that there could be no real opportunity for a marked 'honey-pot effect.' This term was coined to express the criticism that drug dealers would not only be drawn to the vicinity of an injecting facility but would also increase in numbers due to the assured clientele that could be engaged. However, with only an average of 156 opiate injecting episodes monitored per day in the MSIC out of the thousands of injections per day in the area, increased numbers of drug dealers could never have reasonably been expected.

Nevertheless, a geographical attraction of drug dealers did indeed develop. The 2003 evaluation report records repeated complaints about drug-dealing at the Kings Cross railway station, the entrance of which is 25 metres across the street from the MSIC. These same reports confirmed that drug dealing had not been a significant problem at the train station before and that the presence of dealers was related to the hours the MSIC was open. Furthermore, there was a consistent and significant presence of drug dealers at the rear door of the centre, despite security guards being employed throughout the trial period. These security guards were hired specifically to remove dealers and users from the front and rear of the centre.

In regards to drug dealers being attracted to the immediate vicinity of the injecting centre, it can safely be said that there was a defined attraction of drug dealers adequate to the low number of injections in the injecting centre. Drug dealing did indeed increase in the injecting centre's immediate vicinity, creating some predictable degree of negative effect on local business houses.

Injector Safety
In the 2003 evaluation a total of 3,810 clients used the injecting centre over the 18 month trial period for a total of 56,861 injections, representing an average of 15 visits per client (range 1 – 849 visits) against drug use habits estimated by the evaluation team of at least three injections per day. Calculations which take account of client transience still yield utilization rates of one injection in the centre out of every 35 injections for clients. The key rationale for the establishment of the MSIC proposed by lobbyists was the threat of fatal overdose presented to users by their every injection. The assumption was that users would very frequently inject in the premises. But this was the case with very few. A 2007 evaluation showed no changes in client characteristics and utilization.

An implication of this poor rate of utilisation is that the injecting centre clients were largely the very same users who were experiencing the much lower 5.3 opioid-related fatalities per 1,000,000 injections for 99% of their injections in the streets, brothels, public toilets and private homes of Kings Cross. This further magnifies the disparity between the rates of overdose on the streets as compared to within the MSIC.
simply because the widely variant rates of overdose inside and outside the centre were recorded for the very same subjects.

**Blood-Borne Viruses**

Studies in 2003 comparing the risk behaviours of MSIC clients and non-MSIC users from a nearby needle-exchange regarding blood-borne viruses failed to show any significant differences. Both MSIC and non-MSIC users reported similar rates of new needle and syringe use in the month before the survey (79% and 74% respectively), while rates of reuse of someone else’s syringe were the same for both groups. Surveys of MSIC users in 2001 and 2002 showed similar results for sharing of spoons (29% and 32%), filters (11% and 11%), the drug mix solution (10% and 13%) or tourniquets (14% and 16%). Surveys regarding Hepatitis C testing combining MSIC and non-MSIC responses showed no improvement between 2001 and 2002 (60% and 75% for HIV testing, 77% and 77% for HCV testing). Higher rates of HBV vaccination were reported from MSIC than non-MSIC users in 2001 (61% vs 48%) but not in 2002 (63% vs 59%).

**Conclusions**

Data from the MSIC evaluation reports confirm that the predicted positive outcomes for the injecting centre never eventuated. Rather, the very evident outcomes were quite the opposite. There was no discernible decrease in overdose deaths in the Kings Cross area, and the MSIC proved to be an inefficient gateway to treatment. Further, there was no observed reduction in discarded needles or users injecting in public places that could be attributed to the MSIC. Low regard for client safety was apparent, and there was no appreciable improvement in risk behaviours surrounding blood-borne viruses.

The evidence-base does confirm that the pessimistic predictions of those opposed to the injecting centre were fulfilled. Of great concern is the confirmation that the mere availability of injecting facilities encouraged illicit drug use. The verification that the MSIC could not claim to statistically save even one life per annum against an ongoing expenditure of $2.7 million in 2007 reveals that its operation is based on an entirely untenable cost-benefit ratio. And the attraction of drug dealers into the MSIC's immediate vicinity is particularly of concern for local businesses and associated public amenity.

Curiously, the alarming rate of overdose in the Sydney injecting centre, more than 30 times higher than other calculated rates of overdose in the community, is replicated by many other injecting facilities worldwide. The Sydney injecting centre, when overdoses are calculated against all injections in the centre, whether opiate, cocaine or amphetamine, has a rate of 7.2 overdoses per 1,000 injections. While lower rates of overdose have been recorded in Switzerland, at Zurich (0.5 emergencies per 1,000 injections), Biel (0.9 per 1,000) and Geneva (1.3 per 1,000), higher rates of emergencies predominate. The injecting centre in Madrid recorded 1.3 emergencies per 1,000 injections, while the German consumption rooms average 3 overdoses per 1,000 injections, with one service as high as 6.8. As previously noted, these rates of overdose emergency appear extremely high in comparison to known rates of non-fatal overdose outside the facilities, and further inquiry would seem urgent.

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**Conflict of Interest Statement**

I declare that I have no proprietary, financial, professional or other personal interest of any nature or kind in any product, service and/or company that could be construed as influencing the position presented in, or the review of, the manuscript entitled “The Sydney Injecting Centre: Assessing the Evidence-Base” Gary Christian 9 August 2010
Chronic Pain Management Using Buprenorphine: Questions and Considerations
Mel Pohl, M.D., FASAM, Medical Director, Las Vegas Recovery Center, Logan Smith, B.A, Program Develop

More than fifty million Americans currently are living with chronic pain unrelated to cancer. The costs associated with chronic pain are approximately ninety billion dollars annually. During the last two decades of the twentieth century, there has been increased interest in support of fundamentally changing how physicians treat chronic pain conditions (1, 2, 3). Pressure from national agencies and worldwide organizations has led to increased attention to untreated and undertreated pain symptoms (4). At the same time, pharmaceutical companies were marketing new products that were anticipated to be safer and to have lower dependence potential (5). In response, many physicians were enticed to prescribe opioids for chronic noncancer pain. By 2002, prescriptions for OxyContin alone had reached 8.2 million per year (6).

Today, opioid analgesics are the most prescribed medication in the United States, (7) and a clear reliance on prescribing these medications rather than getting to the underlying causes is now part of the standard for "pain management" medical practices (4). Not surprisingly, as rates of prescription opioids increase, so have the negative effects including addiction and unintentional drug poisoning deaths (8). There is a close correlation between death and the amount of opioid medication sold.

A recent study of the Treatment Episode Data Set (TEDS) revealed that admissions to substance abuse treatment programs for abuse of prescription pain relievers increased over 400 percent (9). Prescription opioid abuse in the US has overtaken illicit opioid (heroin) abuse and has grown to epidemic proportions. In spite of rising rates of nonmedical use of opioids (rates of nonmedical use of prescription pain relievers involve 5.2 million Americans), the medical field maintains that the potential for addiction is not sufficient to prohibit the use of narcotic medications (10).

In February 2009, the American Pain Society and the American Academy of Pain Medicine published "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain" (11). The guidelines offer clinical suggestions for appropriately managing pain while accounting for the risk of potential dependence (12). In addition to current prevention and awareness initiatives, national agencies such as the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have also started to investigate the effectiveness of previous measures to curb misuse and abuse of opioid medication (12). Despite these efforts, rates of nonmedical use of prescription pain relievers involve more than 5.2 million Americans (13).

Behavioral abuse and dependence patterns often develop during the course of prescribed treatment. Currently, many rehabilitation centers offer variable durations for detoxification, individual and group therapy, and recommendations for continuing care through such programs as Alcoholics Anonymous (AA) and Narcotics Anonymous (NA) (14). However, with relapse rates so high, many clients have turned to medication-assisted treatment (formerly called maintenance) programs that provide long-lasting opioids such as methadone (Dolophine) or buprenorphine (Suboxone and Subutex). Today, there are currently over 1,000 clinics authorized to dispense methadone (15) and over 1,800 treatment centers authorized to dispense buprenorphine in the US (16). This review will focus on the clinical uses, potential problems, and implications for treatment using buprenorphine.

Science and Pharmacology of Buprenorphine
The US Food and Drug Administration approved buprenorphine in 2002 for the treatment of opioid dependence (17). Under the Drug Addiction Treatment Act of 2000, buprenorphine is available for use through physicians registered with the Substance Abuse and Mental Health Administration (18). There are currently more than 12,000 physicians waivered by the FDA to prescribe buprenorphine in a clinical office setting (15). Buprenorphine's unique pharmacology causes less of the same negative side effects commonly seen with morphine and methadone (e.g., respiratory depression, cognitive impairment, and euphoria more likely to be associated with craving and abuse) and has opened the way for treatment of opioid dependence in new settings. This allows treatment options to reach those who may not have previously had access or don't feel comfortable with other treatment settings such as a methadone clinic (18).

Classified as a Schedule III narcotic, buprenorphine is a semi-synthetic opioid that is an antagonist at kappa opioid receptor sites (19) and a partial agonist of mu-opioid receptors (20). Activation of mu-receptors produces some of the most common effects associated with opioids; i.e., pleasure and pain relief (20). By not fully stimulating mu-receptors, the cognitive and euphorogenic effects of buprenorphine are consequently not as intense as full agonist opioids such as morphine or oxycodone. Buprenorphine does not provide the same levels of pleasure and positive mood elevation, nor does it cause cravings as strong as commonly abused opioids such as heroin, oxycodone, hydrocodone, morphine, and others. Due
to its high affinity for mu-receptors, buprenorphine is not easily displaced and prevents the intense effects of other subsequently used opioids (19). It will also dislodge a previously or presently used opioid from receptor sites (20).

Buprenorphine also has high affinity with kappa receptors as an antagonist (21). Kappa receptors have been shown to play a role in opposing the rewarding effects of drugs of abuse (22). By preventing the dysphoric effects of kappa-receptor stimulation, buprenorphine is able to elevate mood (23) and show antipsychotic properties (24). Blocking kappa receptors may also contribute to buprenorphine's analgesic properties (21).

Buprenorphine has been touted as a safe, low risk option for treatment of opioid dependence (20) because of its mild effects and a ceiling effect at high doses (25). Yet, despite the apparent advantages of buprenorphine over other opioid maintenance medications, an abuse potential remains. Use of buprenorphine for diversion has been reported internationally (26). Also, using buprenorphine illicitly to avoid withdrawal symptoms (called "bridging") until further use of other illicit substances can resume is an alarming trend (27). Furthermore, when combined with benzodiazepines, there is an increased incidence of adverse effects including overdose and death (28). One new and dangerous trend is the rise of "user–how-to" websites touting the effects of "bup" combined with promethazine, temgesic, hydroxyzine, and benzodiazepines as the "new heroin substitute."

Early development of buprenorphine has transferred from liquid injections (because of abuse potential) to sublingual solutions (because of practical limitations and limited oral bioavailability) and is now available in two forms of sublingual tablets (26, 20). Tablets that contain only buprenorphine are marketed as Subutex. The risk potential for diversion remains with Subutex because tablets can easily be broken down, dissolved, and the solution injected. The second tablet form, Suboxone, was developed to incorporate naloxone (Narcan), a mu-opioid receptor competitive antagonist. Naloxone has low bioavailability when taken sublingually, however, when injected it produces a precipitated opioid withdrawal syndrome. The negative effects of the withdrawal syndrome are meant to deter intravenous abuse and have been shown to be effective when compared to Subutex (26).

Clinical Efficacy Studies
Medication-assisted treatment programs that use methadone have been shown to reduce the spread of HIV, decreasing use of illicit opioids, criminal activity, and prolonging average time until next relapse (29). One of the most cited outcomes of buprenorphine maintenance is rates of treatment retention (30). Among combination treatment options, detoxification using buprenorphine and psychosocial treatments is more effective than use of pharmacological treatments alone (31) and reflects established research indicating that the use or abuse of a substance implicates changes to more than just physiological processes.

Does Buprenorphine Cause Hyperalgesia?
Drug use has been positively correlated with pain tolerance and has been shown to vary depending on the type of drug used (32). Pain intolerance due to substance use may even appear to cause hyperalgesia in certain patients (33, 34). Recovering drug addicts have shown higher levels of pain tolerance than their currently using peers, demonstrating that the hyperalgesic effects of opioids are drug and dose specific (32). In other words, opioids may cause more pain. Once the hyperalgesic effects begin to offset the analgesic properties of the prescribed opioid, pain treatment becomes more difficult (34). This inadvertent increase in pain tolerance hinders adequate pain management in patients with comorbid chronic pain conditions. This effect may not be as pronounced with patients receiving buprenorphine maintenance treatment versus treatment with full opioid agonists (35).

Acute pain treatment can be hindered by the use of buprenorphine as well. Due to its pharmacological properties, emergency care centers will find it difficult to control acute pain by administering full agonist opioids because their effects will be blunted by the adherent buprenorphine molecule (36). Opioid tolerance also contributes to diminished pain relief as a result of the chronic use of a long lasting opioid. Special consideration needs to be given to potential circumstances that buprenorphine maintenance treatment patients may encounter during the course of their treatment.

Where does that leave the addiction professional with respect to clients on buprenorphine in your practice setting? Here are several key questions which will challenge each of us as we attempt to assess and treat opioid-dependent clients.

1. Is the brain of the opioid addict more normal with buprenorphine than without, as many medication assistance proponents assert? At least with methadone dependent addicts, it has been shown that the brain dopamine transport system is impaired compared to abstinent opioid addicts (37).

2. Is there a reasonable hope of achieving a buprenorphine-free state once it has been started? If so, when is the logical time to attempt withdrawal? After six weeks, six months, two years? If withdrawal fails, is that because of dependence on buprenorphine, which is extremely difficult to discontinue, or is it relapse inevitable in the absence of some opioids? We all know that discontinuing maintenance doses of opioids is extremely difficult; but is that because of withdrawal (protracted with buprenorphine), or is it because the brain requires a medication like buprenorphine to function and feel normal?

3. There are clinics that have sprung up in some cities that include buprenorphine treatment among a vast "service line" menu including Botox, Restalyne, liposuction, and teeth whitening. Do we truly expect an addict to find recovery in such a setting?
4. How are you to manage these clients as an addiction professional? Is it your task to help clients find quality in their lives. Can you steer them to buprenorphine-friendly meetings? Should the maintained addict go to mainstream meetings and hide the fact that they are on buprenorphine? It is not uncommon for addicts who disclose their status to be ostracized or encouraged to discontinue medications by nonprofessional peers. Can you help clients navigate these difficult waters and develop a supportive community to help them as they live life on life's terms?

5. Some feel that opioid-free is simply not an achievable state; the data appear to suggest low percentages of successful abstinence. Where are all the addicts who are successful? There are thousands of opioid addicts in recovery who have abstained through the help of the twelve step fellowships for decades. We know it can be done, but how can we tell who is likely to be successful?

6. Do we commit everyone to maintenance for life? Is this "harm reduction," or are we actually doing harm by using medications for all without attempting to help clients achieve a drug-free state? Do we try abstinence a time or two or ten? Do we eventually accept buprenorphine maintained recovery as a reasonable alternative? Do we try again for abstinence after a time? If so, when?

These and other questions need to be studied in order for us to develop a rational policy for buprenorphine in opioid dependence and provide the best care for all.

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