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► Impact of supervision of methadone consumption on deaths related to methadone overdose (1993-2008): analyses using OD4 index in England and Scotland.

Strang J., Hall W., Hickman M. et al.

BMJ: 2010, 341, c4851

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Introduced in Scotland and England in the mid-late 1990s to prevent overdose, did supervised consumption of methadone really make methadone maintenance safer? After accounting for increased prescribing, this analysis concludes that it did curb methadone-related deaths.

Summary Concern over overdose deaths in which methadone was implicated led in the mid-late 1990s to tighter controls on methadone maintenance in both Scotland and England. These were intended 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 greater supervision over the relatively risky initial weeks of prescribing. Instead of several doses being dispensed at once, clinics more often arranged for only one dose a day to be dispensed, and instead of patients taking these away to consume at home, doses were more often consumed at the clinic or (more usually) at the pharmacy where staff could supervise the process. This study aimed to assess whether these changes really did prevent methadone overdose deaths. Its innovation was to account for the tendency for deaths to rise simply because more methadone was being prescribed to more patients by calculating an index of the number of deaths per million doses. In other words, it was interested in whether on average *each dose* of methadone was less likely to result in a death after controls were tightened.

Separately for Scotland and England, over the period from 1993 to 2008 the study obtained coroners' records of the numbers of drug-related deaths in which methadone was implicated. Over the same period, records were obtained of the **quantity of methadone** prescribed for the treatment of substance dependence by the NHS in the two countries. From this could be estimated the number of doses prescribed **on the assumption** that each dose averaged 60mg, the minimum recommended for maintenance prescribing. The next step was to combine deaths and doses to calculate for each year the number of deaths per million doses. This was done separately for deaths in respect of which methadone was the only drug recorded by the coroner, and those in which it was one of several.

Deaths per dose fell as controls were tightened

The key issue was whether these indices of deaths per million doses dipped after controls were tightened. If they did, this would at least be consistent with the argument that, as intended, daily dispensing and **especially** supervised consumption saved lives. In both countries this was the case; the index dipped substantially over the period when controls were being tightened and then remained at a historically low level.

Supervised consumption began in Scotland in 1992. It became the norm in Glasgow, the major conurbation, by 1995, and nationally by the year 2000. Before widespread adoption of the practice, each million doses of methadone was associated with about 19 methadone-only deaths a year. By the time it had become the national norm in 2000, the death rate had fallen to about 2 per million doses and then remained in low single figures for the rest of the study period. A similar though less pronounced trend was seen with methadone-plus-other-drugs deaths [► chart](#).

England introduced supervised consumption in 1996. In 1999 national guidance recommended it during the first months of treatment, and it spread slowly to account for 36% of all pharmacy dispensing by 2005. Before the issuing of national guidance, each million doses was associated with over 25 methadone-only deaths a year. This index then fell steadily to plateau at between 5 and 7 per million from 2003 until the end of the study period. As in Scotland, a similar trend was seen with methadone-plus-other-drugs deaths [► chart](#).

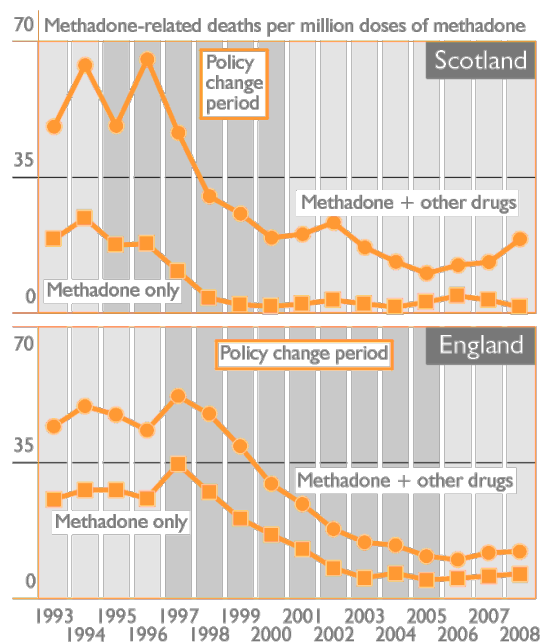
In both countries, when the 16 years of the study were split in to four-year blocks, all but two of the changes in the methadone-only index and all those in the methadone-plus-other-drugs index were statistically significant. The net result of safer per dose dispensing was that though in both countries the amount of methadone in circulation rose steadily and substantially, associated deaths did not. In Scotland they peaked in 1996-1997 then fell; in England, the peaks were a year later, after which the number of deaths fell for six years, rising again later but still not to peak levels.

The authors' conclusions

Given the coincidence in death trends and policy changes, and the absence of any convincing alternative explanations, the authors cautiously accepted the inference that the decline in the per-dose rate of deaths due to methadone overdose was the result of the spread of supervised consumption, and that this was the main reason for a remarkable improvement in the safety of methadone prescribing, particularly over the period from 1995 to 2004.

FINDINGS Later the authors **calculated** that had the earlier unsupervised regimens continued, another 2600 people would have died from methadone overdose (counting only deaths where this was the sole drug noted) in Scotland and England between 2001 and 2008.

The key to this study is its attempt to account for the 'natural' inflation in methadone-related deaths due to increased prescribing. Its conclusion that per dose methadone prescribing has become safer seems (as the authors suggest) a testament to the impact of the major anti-diversion measure – supervising the consumption of methadone to ensure that it does not leak in to the illicit market. To show that the most serious 'side effect' of a medical treatment has been controlled is important to its clinical justification, but from society's point of view, this is only part of the story. The more pertinent issue is not whether each dose of methadone has become safer, but whether each opiate user in or out of treatment has become more likely to survive. This is not an inevitable consequence of the anti-diversion measures highlighted by the study; in some ways, supervised consumption and other anti-diversion measures might save lives overall, but in other



ways, they might have the reverse impact. Summary below. For details see [these fully referenced notes](#).

On the plus side is the fact that most forms of diversion undermine treatment because the patient is not taking their medication as intended in their care plan. Some forms also threaten patient welfare through the injection of unsuitable preparations such as oral methadone with potentially contaminated injecting equipment, by creating a breach in the medication 'shield' which helps block a return to illegal opioid use, and through overdoses. Diversion also risks the lives of other people who acquire the medication, particularly those not as tolerant to opioids as the patient. Especially when illicitly manufactured supplies are scarce, diverted medications can fuel the spread of dependent opioid use. In a climate of antipathy to agonist maintenance, the consequences of poorly controlled diversion can threaten a particular service or the modality as a whole; effective anti-diversion measures may be essential simply to keep the service running so patients can benefit from its life-saving potential.

On the minus side, too restrictive a regimen can reduce the extent to which opiate addicts access the treatment, costing lives which might otherwise have been saved. Even when controls are relatively lax, making maintenance treatment widely available can save more lives than it costs. Patients generally dislike supervised consumption and the need for frequent pharmacy or clinic visits. As a result, some will be deterred from entering treatment or leave prematurely. Anti-diversion controls are cumbersome and costly, using up resources which could have been used to extend the treatment to more patients. Diverted medications are often taken by people already dependent on opioids who would otherwise be using illicitly produced drugs. Many take this medication for purposes similar to those promoted by treatment services – to maintain stability, prevent or manage withdrawal, and reduce use of illegal substances. These consumers risk death due to overdose and other causes, but perhaps less so than if they had used only illicit products. Successful anti-diversion measures also rob them of the wherewithal to self-manage their dependence. Patients who hoard doses or inject non-injectable preparations are arguably better off retained in imperfect treatment than deterred from treatment to avoid diversion. Where illicitly manufactured supplies are plentiful, a small amount of leakage from treatment services will have little impact on the extent of opioid addiction. Given these conditions, supervised consumption might reduce methadone-related deaths, but only at the expense of increasing deaths due to illicit opiates.

The inference that supervised consumption actually caused per dose death rates to fall rests on several assumptions which somewhat reduce confidence in its validity without fatally undermining it. Most serious is the implicit assumption that the vulnerability of the addict population, and in particular the methadone caseload, remained unchanged over the 16 years analysed by the study. Yet the early years of this period saw a [considerable expansion](#) in injecting drug use in England, and across Britain the methadone caseload [expanded dramatically](#). It seems possible that this expansion was accompanied by a trend for the average patient to become less atypical, less disturbed and damaged, and to retain more of the supports in life which aid survival. If so, this trend to the 'normalisation' of opiate use across a less risk-prone population could account for part of the improved per-dose safety of methadone prescribing.

Other minor concerns include the fact that the average dose of methadone [was higher](#) in the later years of the study period; the assumption of a fixed dose throughout would have slightly lowered the per dose death rate during those years relative to the earlier years. Also the fuzzy timeline of the spread of supervised consumption complicates the attempt to attribute changes in the per dose death rate to changes in the extent of the practice.

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