Methadon in Nederland: organisatie en uitvoering van de methadonverstrekking, situatie van de methadoncliënten, ontwikkeling van deze situatie gedurende twee jaar en effecten van hoge doses methadon

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METHADONE IN THE NETHERLANDS
Organisation of the dispense of methadone,
The situation of patients on methadone,
The development of this situation within two years and
The effects of high doses of methadone

SUMMARY

In this thesis the following four studies on the dispense of methadone in the Netherlands are brought together:

- An investigation into the organisation of the institutions responsible for dispensing methadone: 66 institutions (100%) filled in a questionnaire in 1990.

- A survey among 631 addicts enrolled in a methadone programme in 1991. They were interviewed on their habits in drug taking and their medical, psychological and social situation.

- A follow-up study among 526 of these addicts after two to three years (1993-1995) to establish progress or deterioration in their situation.

- A long-term multi-centre randomised controlled trial in 1997-2001 among 247 addicts to establish the effects of the use of high doses of methadone (>84 mg) compared to low doses of methadone (<85 mg) during a period of 22 months.

Organisation of the dispense of methadone, 1990

All Dutch institutions dispensing methadone filled in a questionnaire on organisation, dispensing methods, aims, criteria etc.

It turned out that in 1990 these institutions had adjusted their aims. Abstinence was no longer considered a realistic aim, so the emphasis shifted towards harm reduction. Since 1990 this change has gone further. In 1998 only two of the eight methadone programmes in the larger cities of the Netherlands still included "change" (rehabilitation or abstinence) in their aims and in 2002 "palliation" was added on the list of aims by the National Health Council.

In spite of these adjustments in 1990 pressure by the staff on the addicts to become abstinent or to lower the dose of methadone was still widespread. At the moment (2004) this no longer seems to be common practice, although a systematic review is lacking.

In 1990 a large proportion of the heroin-addicted population participated in the methadone programmes (about 75%). In comparison with the US (about 20%) this is a very high percentage. Probably this is a result of the so-called "low-threshold" dispense of methadone in the Netherlands. At the moment (2004) it is estimated that about 50% of the population is reached by the programmes.

It turned out that the staff of the methadone dispensing institutions systematically underestimated the use of drugs and the period of addiction.

In 1990 a number of serious flaws in the organisation of the dispense of methadone were detected, such as the absence of urine tests (11% of the institutions), the absence of a serious intake procedure (17%) and the absence of medical examination on admittance (24%). Although some improvements seem to have been implemented since 1990, in 2004 the organisation of the dispense of methadone still seems to fall short of professional medical standards.

It also turned out that in 1990 big differences in treatment criteria between the institutions were quite normal (dose, acceptance of drug use while on methadone, age on admittance). Research in 1998 and 2004 showed a similar heterogeneity between the institutions. The reasons for these differences are not clear.

The difficult situation of the addiction care in the early nineties (low motivation by adaptation of aims, low societal acceptance) explains the then existing shortcomings in the organisation of the methadone dispense. It is, however, hard to understand why these flaws persisted for such a long period until the present day.

The situation of addicts receiving methadone, 1991

In 1991 interviews were held with a sample of 631 methadone-patients. The four major cities in the Netherlands (Amsterdam, Rotterdam, The Hague and Utrecht) were not included, because in 1991 some research on the
methadone-patients in these four cities had become available.

The mean age of the patients studied is 31 and female addicts form 23% of the population. There is a considerably greater number of younger than older female addicts. This suggests that, in comparison to male addicts, female addicts more often succeed to overcome their addiction. In 1991 overrepresentation of addicts from former colonies of the Netherlands (Surinam and Indonesia) is diminishing, maybe due to an improved assimilation in Dutch society. The situation of these addicts and of the addicts from Morocco and Turkey on the whole is somewhat better than the situation of Dutch addicts.

The majority of the patients use methadone regularly and also for a considerable period of time: on the average eight years. Notwithstanding their regular use, a large proportion of addicts report frequent abstinent intervals. The year before the interview 23% was abstinent for a month or longer, mostly for incidental reasons, such as a holiday, lack of money or being "fed up with it". The mean dose of methadone is very low (32 mg) and doses above 100 mg do not occur in this sample. Nevertheless pressure from the staff to lower the methadone dose is quite common.

About a third of the patients do not seek any counselling or other guidance. To the others, who do take some sort of counselling, guidance is very frequent with 37 contacts each year. The idea that regular use of methadone stimulates regular counselling could not be confirmed.

The use of illicit drugs amongst these addicts on methadone is widespread. The year before the interview 95% used heroin, 75% cocaine, 23% tranquilizers, 26% sleeping pills and 15% amphetamines. Polydrug use is also frequent with 56% taking more than one drug a day during the previous two weeks. In addition, physicians (GP's) prescribe benzodiazepines to these patients and in particular to the patients with heavy illicit drug use. It is possible that these GP's give in to violent threats from the addicts: other research indicates that GP's give in more often than other professionals.

Several indicators suggest that the morbidity rate of these patients is twice the rate of the population in the same age cohort. Most illness is due to infections, (aggressive) accidents and non-fatal overdoses. In 1991 half the patients on methadone were tested on HIV and 6% of those tested HIV-positive. Clean syringes are used by 72% of the injecting patients; condoms are hardly used with the regular partner, but 44% of the patients did use them if they have sex with someone else.

Almost all patients report one or more psychological complaints (82%). Restlessness/tension (65%) and depressive complaints (58%) are the most common. Suicide attempts (4%) and an inclination to commit suicide (19%) are not rare. 50% of the patients report criminal activities with a mean frequency of once each other day. Most delinquency concerns simple theft (33%), dealing (17%) and receiving stolen goods (13%). The educational level of the patients is very low, but, notwithstanding that fact, almost all patients have some experience on the labour market (69% more than two years). The year before the interview 47% had had some work sometimes. There is a negative correlation between the regularity of the use of methadone and participation on the labour market. A possible explanation is that those with earnings from a job can do without methadone, since they can afford to buy heroin. Family turns out to play an important role in the lives of these addicts. The year before the interview 71% had socialised with their family at least five times. Most other social contacts concern other addicts, though a minority reports to have hardly any contact with addicts (28%).

The results suggest that especially non-regulated addicts, with medical, psychological or social problems, use the services of the addiction care (methadone, counselling), while addicts with a job seem to avoid this care system. Generally speaking, in 1991 the addicts on methadone were a very problematic group, while there are no indications that this problematic situation has since improved.

On the basis of this study the institutions for addiction care were advised not to restrict themselves to harm reduction, but to expand their care to services for abstinent addicts (at the moment not or hardly available). Moreover these institutions were advised to develop programmes for the abstinent periods most addicts experience during their career as an addict. The institutions, however, did not follow these recommendations.

The development of the situation of the patients on methadone within two years, 1993-1995

In 1993-1995 91% of the interviewed patients in 1991 was interviewed a second time to establish the development of their situation. One and a half percent of these patients were deceased, 8.4% was abstinent for at least three months and 90.1% used heroin and/or methadone or is abstinent for less than three months. Stated in terms of progress and deterioration during these two years (or two and a half years) the situation of 17% deteriorated, 57% had stabilised their situation and 26% succeeded in improving their situation. This implies that the returns of methadone treatment add up to 9% progress in two years (26% progress minus 17% deterioration).

Although 1.5% died within two (and a half) years, the mortality rate for Dutch methadone patients is estimated to be 1% a year. This is somewhat higher than 0.67% (1.5/2.25), since chronic diseases seem to be underrepresented in the original sample.

As in all other research on this topic, it is hard to explain why some addicts succeed to quit their drug addiction whilst others fail. We found only four small effects. Patients who at the time of the first interview two years earlier, used less regularly used methadone, took more counselling, experienced a radical change in
their lives (positive or negative) and who are of non-Dutch origin have a slightly higher chance to become abstinent.

Three groups were studied in more detail: 39 patients who were abstinent for more than three months, 31 patients who managed to stay abstinent for three months, but who relapsed before the second interview and 487 patients who used methadone and/or heroin in the second interview (including relapsed patients).

Abstinence is clearly the best outcome for the individual patient. The majority of the abstinent patients experiences few problems (87%), 13% has a somewhat problematic situation, while not one abstinent patient has a very problematic situation. 67% of the abstinent patients improved their situation, only the situation of one patient grew worse (2.6%). The remaining problems of those abstinent patients with some problems are linked with heavy alcohol use and psychological complaints.

Relapse into addiction after an interruption of three months of abstinence does not result in a lot of changes in the life of an addict. Only 7% has a very problematic situation, the majority experiences some problems (69%), while 24% has few problems. The percentages progress and deterioration are the same (19%), so relapse is completely neutral in its aggregated consequences.

The vast majority of the patients continued the use of methadone and/or heroin without three months of abstinence. A substantial proportion of the patients who at the time of the second interview used methadone or heroin experiences few problems (33%), the majority (61%) has a somewhat problematic situation and only 7% has a very problematic situation. 22% realised some progress in their situation, 17% saw their situation deteriorate, so the net and aggregated result is 5% progress.

Although it is realistic to moderate the aims of the addiction care system, this study raises the question if this stripping of the aims of the addiction care has not gone too far. On the one hand, abstinence is without any doubt the best outcome of an addiction career. On the other hand, progress while on methadone is very limited (5% net). More efforts to achieve abstinence for some patients, and to prevent relapse thereafter, could certainly improve the rather poor results of the addiction care.

**High doses of methadone**

In the Netherlands the mean dose of the prescribed methadone is very low (46 mg in 1995, 54 in 2002), although the international literature clearly indicates that higher doses of methadone (> 80 mg) are more effective. Since it was not clear if higher doses would also be more effective in the Dutch addiction care system with so-called "low-threshold" prescription of methadone, an experiment was carried out to establish the effectiveness of high doses of methadone.

Within nine methadone posts all over the Netherlands, 247 addicts on methadone were randomised in two groups. The control group received their usual dose of methadone (always less than 85 mg a day), while the experimental group got a prescription between 85 and 160 mg. All other treatment and all data collection (urine tests, interviews) were the same for both groups. The patients were followed for 22 months. Although the physicians of the addiction care agreed with the experimental procedures, it turned out that after 22 months 12% of the low doses group received a dosage above 85 mg and 28% of the high doses group received a dose below 85 mg. Probably professional resistance to high doses played an important role in this prescription policy.

After 22 months the situation of the members of both groups were compared on four points: drug use, medical situation, psychological situation and social situation. Very problematic drug use drops in the high doses group with 28 percent points. In the low doses group it drops with 16 percent points. The percentage of addicts with a very problematic health situation drops in the experimental group with 5 percent points, while this percentage rises in the control group with 4 points. The proportion of patients with many psychological complaints (and/or suicide attempts) drops in the high doses group with 7 percent points, in the low doses group it raises 3 percent points. There is no effect on the social situation of the patients; the progress is in both groups the same.

If these four measurements are brought together in one general index of the total situation of the addicts, it turns out that the percentage of patients with a very problematic general situation drops in the high dose group with 22 percent points from 31% to 9%. In the control group progress is limited to 3 percent points (from 28% to 25%).

Inclusion of deceased and disappeared patients, attributing the most problematic scores to them, does not change these effects. Differences in treatment between the nine methadone posts have no influence on the outcomes. Differences in the situation of the patients at the start of the experiment do not explain the results. Patients in the experimental group rate their well-being higher, but well-being cannot explain the effects if it is controlled for by regression analysis. The measurements of the effects correspond with the opinion of the physicians of the addiction care, with standardised instruments and with urine tests. It can therefore be concluded that the results are not confounded by other factors than the experimental factor.

In comparison with these positive results after 22 months, after 10 months the differences between both groups are small and not significant, so it takes time before high doses of methadone have positive effects.

In addition to the experimental test some exploring analyses were performed. Doses between 134 and 160 mg seem to be more effective. The situation of the patients who got doses below 85 mg in deviation of the randomisation was poor compared to that of the patients who got high doses prescribed during the entire 22 months.

As mentioned, an overall effect of high doses on the social situation was not found. This zero-effect can be
dissected into a positive effect, a zero-effect and a negative effect. Firstly, there exists a strong effect on the composition of the primary group of the addict. Those on high doses meet far less with other addicts than those on low doses. Secondly, the effect of high doses on criminality is nil. Thirdly, high doses negatively affect the participation on the labour market. Maybe this latter finding is caused by the unfamiliarity with high doses in the institutions for addiction care and with an existing difference between the groups at the start of the experiment.

An analysis of the time spending patterns of the patients shows small effects of high doses. Patients in the high doses group participate somewhat more in therapy and sports and see less family and friends. There are indications that the patients on high doses experience some social isolation. They seem to avoid the old social contacts (family, friends), but do not have new social interaction partners.

Although the patients in the high doses group get slightly more therapy, this extra participation does not explain the effects of the high doses methadone. So, counselling and therapy do not intermediate between high doses and the positive outcomes of high doses.

It was expected that 5 patients would die during the 22 months of the experiment, but 2 more died, probably due to selection by the inclusion criteria (heavy problems, no prospect on cure). Two of the deceased patients belonged to the control group, 5 to the experimental group. A serious adverse event (SAE) was reported on 5 patients (1 control group, 4 experimental group). There is no significant difference between the high doses and the low doses group if deaths and SAE’s are taken together. During the first month of the experimental period, when the dose of methadone was raised, and during the two months thereafter no one died.

Thirty percent of the patients reports side effects of the methadone and this percentage is the same in both groups. Other indicators, such as notes by the physician, standardised instruments to measure well-being and time spending pattern, do not show any sedation effect of the high doses. Only obstipation occurs more often in the experimental group.

**Recommendations**

On the basis of these four studies three top priorities for the addiction care in the Netherlands are formulated:

- Development of protocols prescribing high doses of methadone and implementation of these protocols.
- Expansion of aftercare services, which at the moment are hardly available in the Netherlands. Incorporation of relapse prevention in the addiction care.
- Experimentation with programmes to prevent relapse after a spontaneous abstinent period.