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Additional take-home dosages

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Summary

Objectives: The objective of the study was to analyse the practice of giving take-home dosages of opioid medications to patients with reference to the reasons for and the quantity of the medications given as additional or extra take-home dosages. **Methods:** All the patients were checked regarding the kind of medication, urine samples, reasons for extra take-home dosages and their quantity. **Results:** Of the 150 patients selected for the group in the programme, 27 needed one or more extra take-home dosages in 2007. 10 (11*) of those patients had negative urine samples for all illicit drugs and never used alcohol at any stage of the year of the study. 7 patients used marijuana, benzodiazepines or alcohol only once or just occasionally in that year. 10 patients used other illicit drugs or used alcohol and benzodiazepines more often. Among the reasons for extra take-home dosages, hard physical work was listed 7 times, vomiting because of the bad taste of the medication 3 times, difficulties in initiating medical therapy after entering the programme 3 times, vomiting as a part of illness twice and lowering the dosage too quickly twice. Other reasons were listed once each. Altogether, the percentage of the overall quantity of medications received by patients during the year as extra take-home dosages was: 0.47% for methadone, 0.75% for buprenorphine and 0.10% for SR morphine. **Conclusions:** Reviewing the fairly good results of treatment at the centre, therapeutic decisions to give additional take-home dosages to the patients have proved to be reasonable and usually correct. Throughout this study a continual therapeutic wish to achieve a better understanding of opioid addiction as just one among other chronic diseases has been made evident.

Key Words: Opioid treatment; Extra take-home dosages.

1. Introduction

Take-home dosages of opioid medications are a matter of delicate balance in the therapist - client relationship. There are various important reasons for the therapist to worry about the destiny of the medication that has been handed over to the patient. Some medications (methadone, SR morphine) can 'kill' the person who has not adapted to the medication or the dosage.

Treatment education for patients, medical training for prescribers and the right choice of pharmaceutical forms appear to be means that need to be developed simultaneously to optimize treatment [1].

Opioid medications are also present on the Slovenian black market. In 2005, 6 of 45 drug-related death cases involved methadone, usually combined with other drugs

and alcohol [8].

The decision whether to hand the medication over to an opioid-dependent patient is a difficult one, as it involves a risk of misuse. In 2004 there were 2,944 arrests/reports for drug offences (use and/or possession) in Slovenia; 42 of these involved methadone. There was a total of 545 cases of drug-related dealing/trafficking and 20 of those referred to methadone; the numbers recorded for drug-related use and trafficking was 94 in all and 2 of those referred to methadone [9].

In 2005, out of a total of 45 cases of victims of a drug-related death in Slovenia, methadone was involved in 6; in a majority of these cases, methadone overdose was diagnosed as accidental, not as suicide [8]. According to the Slovenian Therapeutic Agreement, in centres for the prevention and treatment of drug addiction (CPTDA) only "trustworthy" patients can get the medication into their own hands. Take-

home dosages are generally a bonus that patients can get by showing good and stable behaviour [10]. In the international inquiry into the quality of work in Slovenian CPTDAs in the year 2007, it was stressed that “leakage is difficult to control, and it is hard to prevent someone from selling his/her medication” [10]. Patients can get their first take-home dosages after 3 to 6 months of negativization of urine samples for illicit drugs – with the debatable exception of marijuana. After 6 to 12 months of negative samples, they can get take-home dosages for the whole week or, in case of holidays, for 10 days. However, the “actual rules” for giving take-home dosages differ from one centre to another, as the inquiry showed [10]. The numbers and the motivation of staff play a role in these decisions [10].

In Slovenia the percentage of the medications used in CPTDAs in 2007 was 81% for methadone, 13% for buprenorphine and 6% for SR morphine [4]. Compared with medications for other chronic diseases, opioid-dependent patients sometimes need additional (extra) dosages of medications even when they are clinically perceived as being stable. According to the National Therapeutic Agreement, they have no right to get extra dosages. This decision was made by the Coordination Committee of CPTDA therapists to prevent misuse of the medication. On the other hand, clinical work showed the need for a better understanding of patients’ problems, and, therefore, the appropriateness of giving extra take-home dosages for a variety of therapeutically sound reasons.

In France, because of positive outcomes maintenance treatments were not officially questioned [2]. A national evaluation of maintenance treatment in France showed that the decrease of 80% in fatal overdoses and of 67% in arrests for heroin use (1994–1999) were directly related to treatment accessibility [2]. Once the authorities decided to implement control measures over patients, the innovations approved might make access to treatment more difficult. The effectiveness of substitution treatment could be affected as a result [2].

One general objective of this study was to provide an important practical tool for improving the quality of the work carried out by the CPTDA in Logatec. The therapists give extra take-home dosages to implement a motivational approach as a powerful resource in enhancing staff-client interactions, quality of services and programme functioning as a whole [7].

The specific aims of this study were:

- to check the topic of so-called »therapeutic reasons« for giving extra take-home dosages;
- to check the therapeutic status of patients at the moment when they receive extra take-home dosage;
- to find out the amount of extra take-home dosages for each medication with reference to the quantity taken over one whole year and the percentage of total medication distributed in this way.

2. Methods

At the centre the data were collected from the protocols on giving medications to patients. The research involved included the collection of the following data:

- dosages given to patients at the centre to be used under close observation by the nurse
- dosages given to patients as their take-home dosages
- dosages given to patients as their extra take-home dosages

The number and proportion of all dosages for each of these three types of medication were calculated from the written dispensary protocols (i.e. the nurse’s book and the computer programme setting out the regime for giving medications).

The reasons for extra take-home dosages were taken from the therapist’s protocol for each patient. For all extra take-home dosages there were two descriptions, of the psychosocial and somatic status of the patient and the »reasons« for prescribing extra take-home dosages. The first was selected by the therapist herself in writing the protocol, and the second was chosen by the patient at home and added to that protocol, together with the patient’s application for extra take-home dosage or dosages.

As one of the measures for discovering the therapeutic stability of the patients, their urine samples were used. The results were taken from the documentation on each patient. In descriptions of the frequency of drug use, the word »occasionally« meant the use of a substance more than once but less than four times during the year.

2.2 Description of the patients

On the question of extra take-home dosages, the population of all 150 opioid-substituted patients attending the centre (29 females and 121 males) in 2007 was checked. 101 patients (19 females and 82 males) were receiving methadone; 32 (7 females and 25 males) were being treated with buprenorphine, and 17 patients (3 females and 14 males) with SR morphine.

At the centre, mean daily dosages were 101.9 mg for methadone, 14.2 mg for buprenorphine and 672.3 mg for SR morphine.

Mean age of patients who got extra take-home dosages was 28.6 years (min. 20 years, max. 39 years) for methadone (3 F and 18 M); the ages of the buprenorphine patients (all men) who got extra take-home dosages were 25, 27 and 31. The one patient (a man) who was given extra take-home dosages of SR morphine was 25.

Mean duration of the opioid treatment of the patients with extra take-home dosages was 5.43 years (min. duration was 1 year and max. was 11 years).

Most of the patients that needed extra take-home dosages were working (17/25): 12 of them had a regular job with a working contract, 3 were working regularly but without a contract, 2 were working without a contract and at the same time going to school, and 4 patients were working occasion-

Table 1. Urine samples of patients with extra take-home (Year 2007)

Urine samples		N patients	%	
All year clean for illicit drugs	All year clean for benzodiazepines	All year clean for alcohol	10	40.0
idem?	idem	idem	1	4.0
Once THC	Occasionally BDZ		4	16.0
Occasionally THC	Occasionally BDZ		1	4.0
Occasionally THC		Occasionally alcohol	1	4.0
	Use of BDZ	Use of alcohol	1	4.0
Use of THC	Use of BDZ	Use of alcohol	1	4.0
Use of cocaine	Use of BDZ	Use of alcohol	1	4.0
Use of Opioid			1	4.0
Use of cocaine	Use of Opioid		1	4.0
Use of cocaine			2	8.0
Use of cocaine?			1	4.0

ally to earn some money. Only 4 patients out of 25 (16%) had no organized work or school.

At the time when they needed extra take-home dosages the patients were coming to the centre at varying frequencies, depending on the therapeutic agreement, the duration of treatment and their therapeutic stability: 2 came once every 2 weeks, 14 once a week, 2 twice a week and 2 three times per week. Two thirds (2/3) of them were travelling to the centre, 20 to 40 km one way. Others were living nearer.

3. Results

In 2007 at least one or sometimes more extra take-home dosages of the medication were given to 27 patients out of 150 (15.3%). Extra methadone was given to 20.7% of the methadone patients, to 12% of buprenorphine patients and to 5.08% of SR morphine-substituted patients.

Regarding urine samples in the year of the research, 10 of the patients (10/27) who got extra take-home dosages (10/27) were negative for all illicit drugs and with complete abstinence from alcohol throughout the year. For 1 patient who needed extra take-home SR morphine, abstinence was very likely but impossible to confirm – because of the cross-reactivity of the tests. 4 patients had once or only occasionally positive THC in urine, 1 had THC and BZO in urine occasionally. 1 had THC occasionally in the urine samples and was drinking alcohol occasionally. Altogether, 17 patients used no other illicit substances or used marijuana, benzodiazepines or alcohol once or only occasionally (table 1).

The most frequent reason for extra take-home dosages

was a heavier physical or sometimes psychological burden at the workplace. The following reasons were cited regarding a) physical status of the patient, b) characteristics of the medication and c) the patient's social environment. (Table 2).

The total quantity of all medications given to the patients attending the centre in 2007 as extra take-home dosages was calculated. The percentages of the medications given to all patients as extra take-home dosages were as follows: 0.49% of the total quantity of methadone taken; 0.75% of the total quantity of buprenorphine; 0.1 % of the total quantity of SR morphine. (Table 3)

4. Discussion

Most patients responded well to methadone maintenance, whereas about one in four tends not to respond well to treatment [6].

From the very start of the programme in the CPTDA in Logatec, in 1995, the therapists at the centre have been trying to get the most complete picture possible of the centre's therapeutic situation. In 2005, when the centre celebrated its 10th anniversary together with its history of using methadone as the only medication for opioid addiction, an overview of the treatment in the centre was published in the Journal of Slovenian Medical Association: "Before starting methadone treatment the detoxification without medical help was accomplished by 37% of the patients, 15% were hospitalized in psychiatric clinics for the purpose of detoxification, 6% were treated in the therapeutic communities, 3.9% in the therapeutic community Project "Človek" (man). 11% of the

Table 2. Reasons for extra take-home

	N patients	%
Patient related		
Working hard (employment-related)	7	25.9
Entering program	3	11.1
Lowering dosage too quickly	2	7.4
Physical comorbidities	2	7.4
Medication related		
Bad taste	3	11.1
Spoiled solution	1	3.7
Theft of the medication	1	3.7
Social environment related		
Aggression by father	1	3.7
Conflict with partner	1	3.7
Small baby	1	3.7
Divorce	1	3.7
Sick mother	1	3.7
Birthday	1	3.7
Laps with cocaine	1	3.7
Laps with cocaine ?	1	3.7

patients spent a part of their youth in juvenile correctional facilities. 13% experienced imprisonment. At the time of their therapy in the centre 79% were working or/and attending school. 30.8% of them had children and they had a partner included in methadone treatment in 23%” [8].

In 2005 a study on one-year abstinence was published: “In the group of 61 patients treated in CPTDA with methadone for at least one year, in the last year of treatment in the centre 67.2% didn’t use heroin, 34.4% didn’t smoke marijuana, 72.1% didn’t use cocaine, 85.2% didn’t use ecstasy and 65.6% didn’t use any medications of benzodiazepines type. Alcohol was not used at all in the last year by 21.3%

of patients. Only 3% of them didn’t smoke tobacco. Chronic infection with hepatitis C viruses was present in 16.4% of patients. None was infected by HIV”[4].

These results give a fairly good overview of the patient population of the centre and the level of treatment success.

Intractable problems in substitution therapy include the distance to be travelled in reaching the centres (18 centres cover an area of 20,256 km²) and their working hours. The CPTDA in Logatec must meet the needs of a region of 13,000 people. Its premises are shared with the primary health centre, and it has the same opening hours as other medical departments, while operating under the same regime; that means

Table 3. Quantity and percentage of medication for extra take-home

Medication	All in 2007 (mg)	Extra dosage (mg)	%
Methadone	3.085.050	14.418	0.47
Buprenorphine	84.938	640	0.75
SR morphine	2.528.530	2720	0.10

it is open every weekday for half the day: Mon Wed Fri 6.30 a.m.-1.30 p.m. and Tue Thu 1 p.m.-8 p.m. The centre can count on contributions from 5 family doctors, 1 paediatrician, 1 school doctor, 5 stomatologists, 1 part-time gynecologist and 1 part-time specialist for occupational medicine. The centre sometimes uses the help of its GPs for exceptional distribution of take-home dosages to patients outside the working hours of the centre (during other weekday hours, plus Saturdays, Sundays and holidays). For patients who are obliged to take their medication daily – including Saturdays and Sundays – and for stabilized patients in situations that prevent their coming to the centre during opening hours, their dosages are left in the refrigerator of the emergency department by the nurse at the centre. She arranges this in agreement with the doctor at the centre, the patient and the staff of the emergency department.

All medications that are given under control at the centre are prepared and delivered by the nurse or by the doctor at the centre. Take-home dosages of buprenorphine and SR morphine are prepared by the nurse for each patient separately at the time of the patient's visit to the centre. Take-home dosages of methadone are prepared by the pharmacy on the basis of a doctor's prescription for all take-home dosages at the centre on Thursday afternoons, applying the Soundex code for each patient. This allows the patient to get his/her own exact take-home dosages for some days or for the whole week ahead. The nurse brings all the take-home dosages of methadone solution mixed with orange juice in 100ml plastic bottles from the pharmacy to the refrigerator at the centre. She gives them to each patient in the centre according to his/her take-home regime as ordered by the doctor.

In the year of the study, a majority of patients who got extra take-home dosages needed only one or few extra dosages. There was an exception: a 26-year-old girl in the year of the study started to encounter difficult family problems caused by her extremely aggressive father. She lived near her primary home with her old and sick grandparents and with her mother, who was seeking this girl patient's help. Before these family troubles reached a climax, this girl was abstinent from all illicit drugs and had drunk no alcohol for three years in our programme. She was working morning, afternoon and night shifts and was living more than 20 km from the centre. Her grandparents and her parents visited the centre at the very beginning of the treatment, but stopped doing so afterwards. During that whole period, she refused to tell them about her taking methadone. She was receiving take-home dosages of methadone to last one week at a time. Apart from the distress experienced at home, she also split with her boyfriend. In those days she started to use cocaine for the first time in her life. Because she was taking extra dosages of methadone and due to her stressful personal situation, her tolerance grew. The therapists slowly raised the daily dosage to 230 mg. She became stable again and stopped using cocaine. She has managed to keep her job,

which is very demanding. Her employer is satisfied with her work. This year she was promoted to a more demanding position. Unfortunately, she got infected by hepatitis C at the time when she was using cocaine. A month ago she started treatment with interferon and ribavirin.

The National Therapeutic Agreement in Slovenia is very demanding. To ensure successful therapy, some therapists decide to provide take-away dosages even before some patients have actually qualified to receive their bonus. Such a decision is always a question of "sailing between Scylla and Charybdis", besides raising the eternal questions of right and wrong.

Doctors have to help people live, and *primum nil nocere* has to be the rule. But there is always the question of how each doctor applies these solutions in treating individual patients. Less frequent visits to the centre may create an opportunity to work better with those who come. In some ways it also prevents patients from grouping around the centre. Unduly strict regulations can be harmful in another way. We can learn this from the German experience, where the official reaction to the troubles emerging in an organization providing ongoing opioid treatment was to tighten the regulations; most of the primary care physicians responded by giving up their work. "When therapy was predominantly offered by special maintenance centres, strong concentration of these specific patients took place." [11]

Having discussed the results of urine testing compared with the patient's real abstinence, we are aware of well-known difficulties. The frequency of urine testing in the centre varies from 2 or 3 times per week for some patients to once in 3 or even 6 months for the few of them who are stable and abstinent in the opinion of the therapist. Besides testing devices for drugs in urine, saliva test devices are sometimes used. For the assessment of drinking habits, a saliva test and quite often the AUDIT and CAGE questionnaires are used. Each year the therapists at the centre carry out some research. Patients are asked to fill in a patient satisfaction questionnaire yearly. The philosophy of the centre aims for an attitude of "listening, understanding and acceptance" towards patients or, as the expression goes, of "dancing with clients".. [1] This attitude of therapists provides an explanation for giving extra take-home dosages, as most patients mostly do not misuse the therapist's trust. Each difficult situation is used as a convenient moment to discuss with a patient his/her decisions in life, his/her feelings and troubles, worries or anger. After such discussions the patients usually feel better.

At the beginning of the study, the therapists were afraid of taking on the task of calculating what had previously been an unknown (potentially large?) quantity of extra take-home medications that had been supplied to their patients. But the top priority of the therapists in carrying out this inquiry was an honest check on the work they were doing. At the end of the study therapists have reached a strong conviction that this has been a positive experience in improving the medical and

social status of their patients, partly through the distribution of additional take-home dosages; this outcome makes it worth discussing the risks involved in not always obeying the rules set by the National Therapeutic Agreement. Not giving extra take-home dosages would mean putting the patient in the position of lacking a required medication. He or she would have to search for the medication on the black market or have to buy a certain amount of heroin. A relapse would be the inevitable result.

The explanations for such therapeutic decisions are easy to understand in diabetes patients, when dietary mistakes have been made or when these patients have an acute illness, or in allergic asthma patients who need more inhaled corticosteroids when an attack of asthma has been exacerbated by visiting an old friend who owns a cat or a rabbit.

5. Conclusion

In reviewing the fairly good results for abstinence and employment in all the years during which the CPTDA in Logatec has provided treatment, and its continual objective of achieving a better understanding of opioid addiction as just one of many chronic diseases, the therapists at the centre view their decisions to give extra take-home dosages to their patients as having been mostly correct.

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