Opioid substitution treatment in Germany: insights and opportunities

Key findings from the Project IMPROVE study

Draft Report (V4.0)

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Executive summary

Opioid substitution treatment (OST) is recognised internationally as the most effective intervention to reduce the social, health and economic burdens associated with opioid dependence. In Germany, opportunities exist for improving the current OST environment for patients, their families and the wider community. Although in the past 5 years significant progress has been made in scaling up the number of patients in OST (30-50% of the estimated number of opioid dependent persons are in OST; see Michels, Stöver & Gerlach, 2007; Michels, Sander & Stöver, 2009), it is recognised that (i) a significant proportion of the opioid-dependent population either cannot or do not access OST and similarly that (ii) a significant proportion of accredited physicians are not providing OST (see Schulte *et al.*, 2009).

Project IMPROVE was designed to achieve a better understanding of the barriers to OST access, retention and quality amongst both the target patient population and treating physicians. Specifically, an interview- and questionnaire-based methodology was used to assess the attitudes and beliefs of 552 people drawn from the following four target groups:

1. Patients: Opioid-dependent persons currently in treatment (n=200)
2. Users: Opioid-dependent persons not currently in treatment (n=200)
3. Treating physicians: OST-accredited physicians who currently provide treatment (n=101)
4. Non-treating physicians: OST-accredited physicians who do not currently provide treatment (n=51)

Key findings of the survey supported the following conclusions:

1. OST is perceived as valuable and effective by physicians, patients and users

2. OST access and provision are inadequate, especially outside of major cities, due to a worsening imbalance between patient demand for treatment and the supply of available physicians who are accredited to provide it

3. Improvements in the regulatory framework and conditions for OST – which are currently perceived as unclear or unfavourable – would encourage more accredited physicians to actively provide treatment

4. Medication misuse and diversion do occur and are a significant concern for physicians. Many physicians and patients are not aware of, or are not utilising, therapeutic strategies that may help reduce misuse and diversion
5. The opportunity to stabilise the condition of opioid-dependent individuals who cycle in and out of prison, by commencing or continuing treatment during their incarceration, is being lost

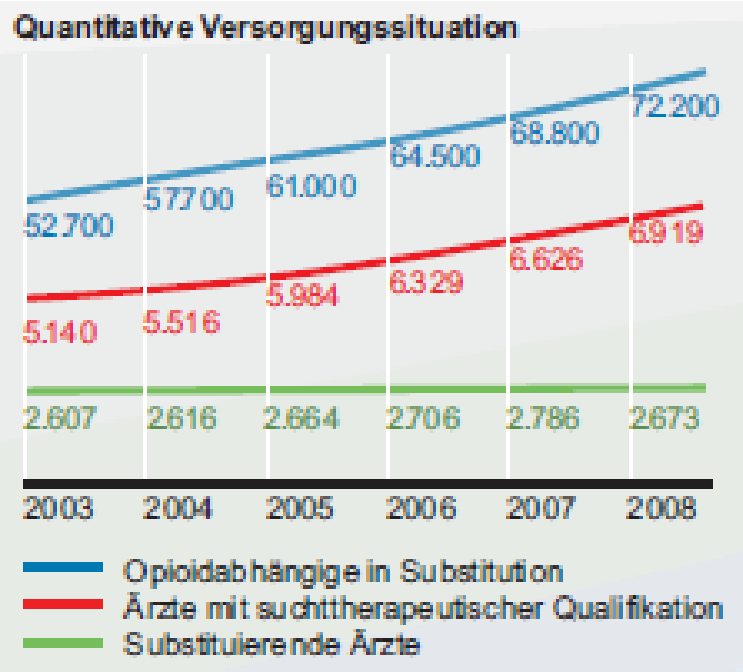
Background

In Germany, like most European countries, opioid dependence presents a major public health challenge. Opioid substitution treatment (OST) is recognised internationally as the most effective intervention for opioid dependence due to its capacity to significantly reduce illicit drug use and associated morbidity, mortality, and criminality. Crucially, the benefits of OST are dependent on patients being able to access and remain in treatment and on the availability of physicians who are legally accredited to prescribe OST medications.

The number of patients receiving OST in Germany has increased from 52,700 in 2003 to 72,200 in 2008 (Figure 1). However, assuming a total opioid-dependent population of between 150,000 - 200,000, treatment coverage is currently between 30-50% (Michels, Stöver & Gerlach, 2007; Michels, Sander & Stöver, 2009) and the majority of dependent opioid users remain out of treatment. This suggests that there is a significant opportunity to increase the utilisation and benefits of OST nationwide.

The number of accredited physicians who are actively prescribing OST treatments has stagnated in recent years (Figure 1), leading to an increasing patient: physician ratio (from 20:1 in 2003 to 27:1 in 2008) and threatening to constrain efforts to increase the availability of OST throughout the country. There is also a significant and widening gap between the number of physicians actively prescribing and those who are accredited to do so. This suggests that more needs to be done to ensure that sufficient numbers of physicians actively participate as providers of OST in order to accommodate the increasing numbers of patients on therapy.

Figure 1. German data on numbers of opioid substitution treatment patients, accredited physicians and actively treating physicians



Quelle: Bundesinstitut für Arzneimittel und Medizinprodukte

A number of aspects are believed to be contributing to the current challenges facing OST in Germany. These include (i) the fragmented and decentralised approach to treatment provision across regions, (ii) the legal and bureaucratic burden imposed on physicians by current regulations, (iii) the lack of national evidence-based guidelines to support quality patient care, (iv) inadequate co-ordination between different services and professional groups, (v) lack of recognition of addiction as a medical speciality, and (vi) stigmatisation and poor understanding of opioid dependence as a chronic, relapsing central nervous system disease.

To inform responses to this challenge on a treatment and policy level, Project IMPROVE was undertaken to better understand the barriers that may currently be preventing the full benefits of OST from being realised. Specifically, this survey was designed to assess the attitudes and beliefs of physicians (treating and non-treating) and opioid-dependent persons (in treatment and out of treatment) regarding the quality and access barriers for OST in Germany.

Methodology

Data were collected between the end of September and the beginning of November 2009 with opioid-dependent persons and physicians, each comprising two subgroups as detailed below.

Opioid-dependent persons: patients and users

Data were collected from two subgroups of opioid-dependent persons:

- Patients: Opioid-dependent persons who are currently in OST
- Users: Opioid-dependent persons who are not currently in OST

The following table summarises the planned and achieved numbers of participants for each group:

	Patients	Users
Total Sample Size: Planned/Achieved	n=200/n=200	n=200/n=200
Sample Source		
• Drug-support centres	n=100/n=101	n=200/n=200
• Physician practices	n=100/n= 99	–
Regions*		
• North (Hamburg, Berlin, Vechta)	n=50/n=50	n=50/n=50
• West (Bochum, Köln, Oberhausen, Dortmund)	n=50/n=50	n=50/n=50
• East (Halle, Leipzig)	n=50/n=50	n=50/n=50
• South (Augsburg, Nürnberg)	n=50/n=50	n=50/n=50

Per region two drug-support centres and two physicians from different cities participated in the research (exception: three physicians in the North). Cities in which drug-support centres were sample points = Hamburg, Berlin, Bochum, Köln, Augsburg and Nürnberg. Cities in which physicians' practices were sample points = Hamburg, Berlin, Vechta, Oberhausen, Dortmund, Halle, Leipzig, Augsburg and Nürnberg. To get a representative sample, regions with cities of different sizes and the rural area have been covered.

Fifty percent of patients in each region were recruited from physicians' practices and 50% from support centres, which were identified from a list provided by a national umbrella organisation (akzept e.V.). One hundred percent of users were

recruited via support centres. Support centres were given donations in recognition of their participation; physicians received an honorarium for each completed patient questionnaire. Patients and users received an incentive for their participation. The methodology used was self-completion questionnaires.

Physicians accredited to provide OST: treating and non-treating

Interviews were conducted with two subgroups of physicians

- Treating physicians: physicians that treat opioid-dependent patients with OST
- Non-treating physicians: physicians that are accredited but do not treat opioid-dependent patients with OST (either have never treated or stopped treating patients)

Akzept e.V. provided an independent market research company with a list of physicians that are accredited to provide OST. In addition, doctors' addresses were identified from regional websites of the 'Kassenärztliche Vereinigung' (SHI Association physicians). In order to raise interest and hence to increase participation rates, a letter of recommendation was sent out to physicians from the Akzept address list before the start of data collection. Physicians received an incentive for their participation. Interviews with physicians were conducted via CATI (Computer Aided Telephone Interviewing).

Copies of the questions used for each group can be obtained on request from akzept e.V.

Key findings

Substitution treatment is effective

Consistent with international experience, physicians, patients and opioid users in Germany recognise the value and benefits of OST. When asked to identify positive aspects of OST, the most commonly highlighted aspects by patients and users were:

- Social aspects (60% patients, 44% users) – including the ability to have a 'normal life', be employed, and have better family relationships
- Addiction aspects (53% patients, 51% users) – including reduced cravings for drugs
- Crime-related aspects (38% patients, 40% users) – including the ability to reduce or cease drug-related crime
- Health-related aspects (24% patients, 13% users) – including improvements in general health and overall well-being

Similarly, patients' most commonly stated reasons for starting treatment included their desire to improve their health (71%), change the circles they were moving in (61%), cease committing crimes for their habit (57%), reduce their drug use (52%), be able to work again (51%), and because financing drug use was too expensive (65%). Importantly, the vast majority (82%) of patients indicated that they were fairly or very satisfied (48% and 35%) with the success of their OST to date.

When treating physicians were asked to rate the importance of several possible goals of OST (1= not important at all, 10 = extremely important), the following were all rated as 8 or higher: social stabilisation of the patient, reducing illegal activities, reintegration of the patient into society, reducing illegal drug use, reducing health risks, reducing physical co-morbidities, reducing mental co-morbidities, and stopping all illegal drug use.

Collectively, these findings suggest that patients and physicians similarly perceive that OST offers a range of different benefits in terms of social rehabilitation, reduced criminality, reduced drug use, and improved health.

Provision of substitution treatment is inadequate

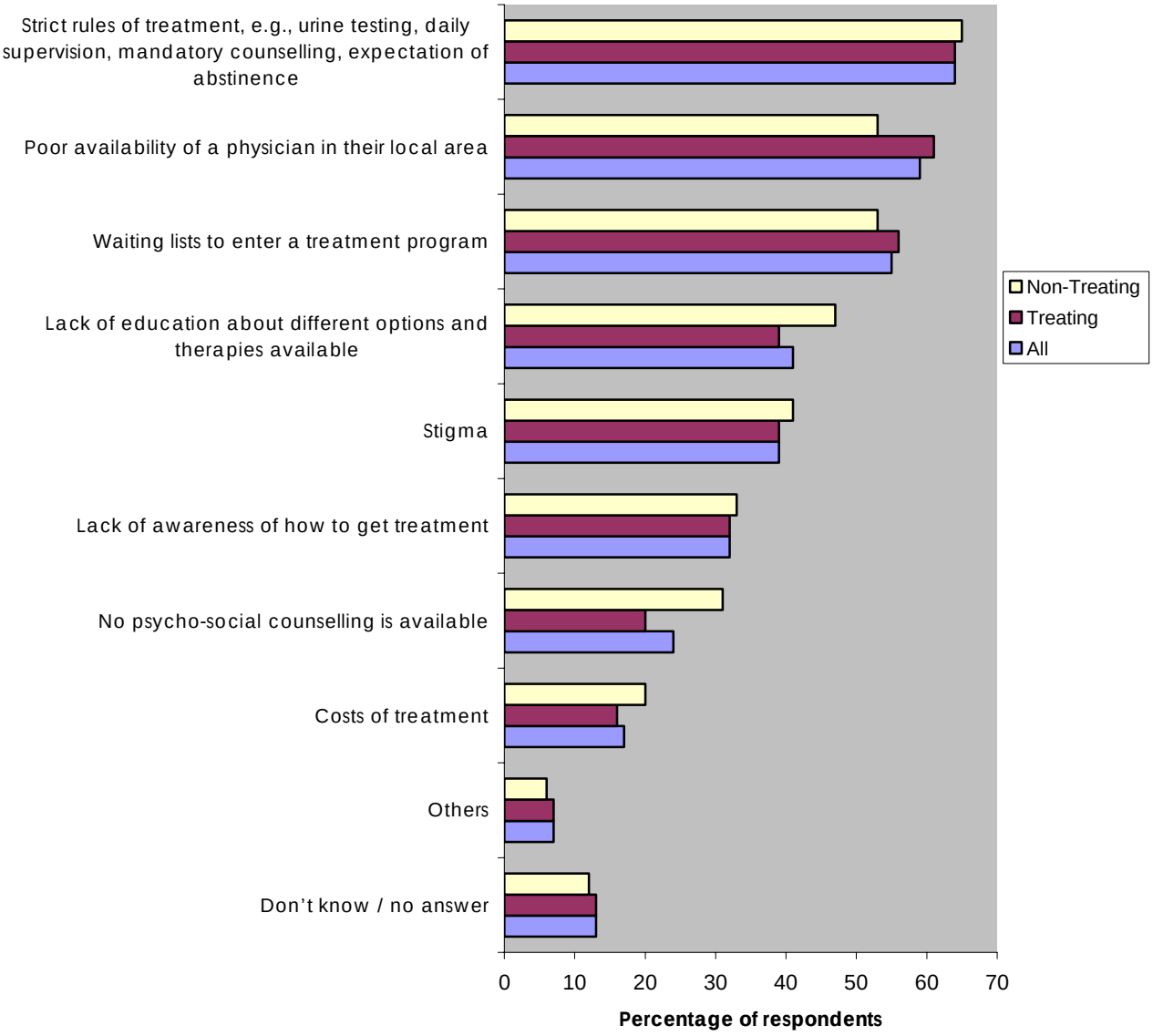
Despite patients' and physicians' positive perceptions of the value and effectiveness of OST, the current availability of OST in Germany is perceived to be inadequate to meet demand, especially outside of larger cities. This suggests that the benefits of OST are not being fully realised.

When treating physicians were asked how easy it is for patients to gain access to OST in their city or region, 45% overall indicated that access to treatment is either difficult or very difficult; the figure was 60% for those based in cities with a population <100,000. Overall, 85% of these physicians indicated that the imbalance between supply and demand was the reason for treatment access being difficult.

Similarly, when patients were asked how easy it was for them to find a physician who could offer treatment, a significant proportion (31% overall) indicated this was difficult or very difficult. These results differed according to region. For example, whereas the majority of patients in the North (78%), West (80%) and East (68%) rated physician availability as easy or very easy, the majority of patients in the South (54%) rated it as difficult or very difficult. Since these ratings are based on patients who did manage to find access to treatment, they may overestimate the ease of access to OST.

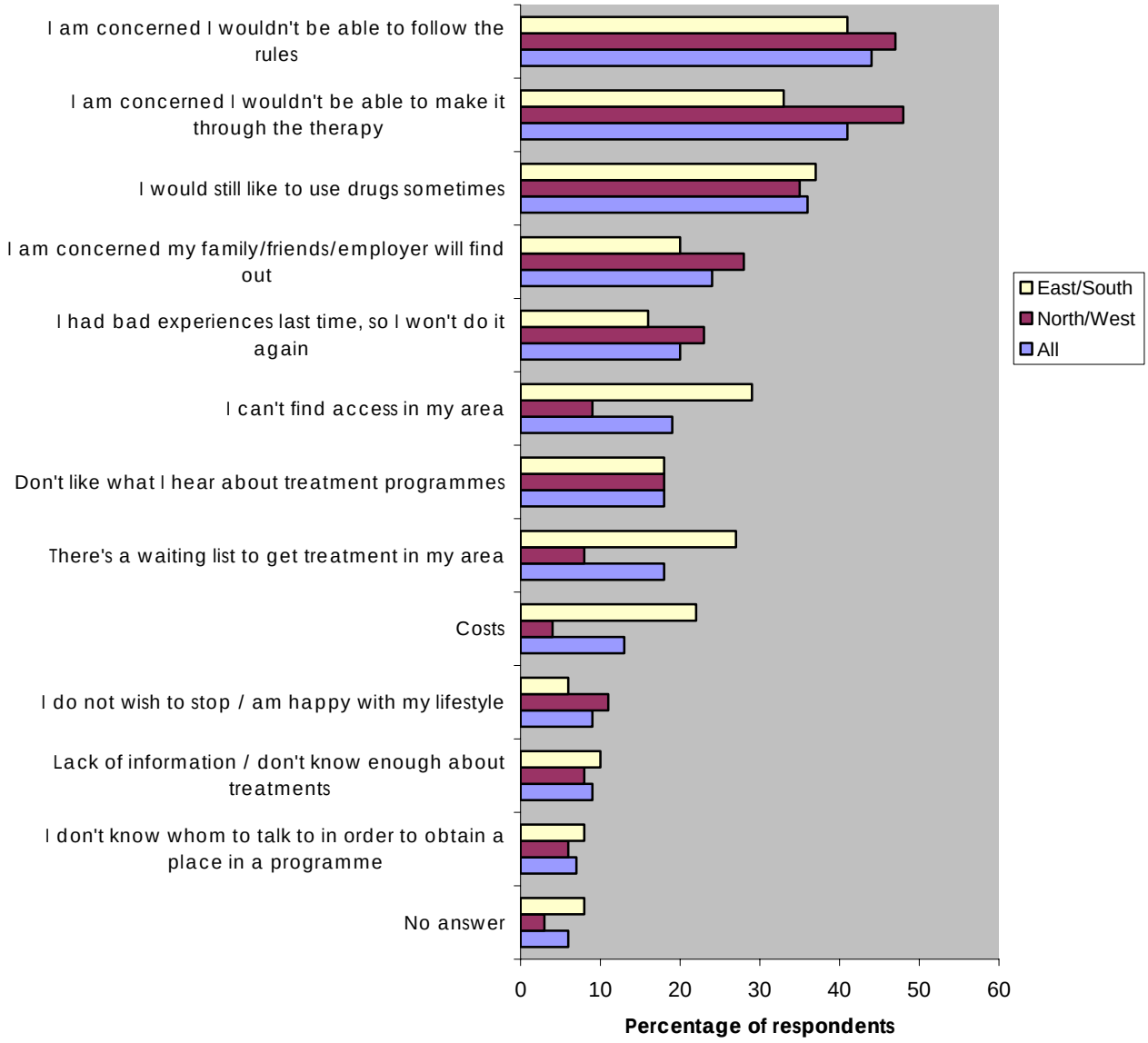
Consistent with the above findings, poor availability of a physician (59%) and waiting lists to enter programmes (55%) featured strongly when physicians were also asked to indicate barriers to patients entering treatment in their state or region (Figure 2). Other barriers included the strict rules of treatment (64%), lack of education about different treatment options available (41%), and stigma (39%).

Figure 2. Physician perceptions of barriers that restrict patients from entering treatment



Opioid users highlighted a range of reasons for staying out of treatment, the most common being concerns about their ability to follow the rules of therapy (44%) and their ability to stay on treatment (41%) (Figure 3); separately, patients indicated that the rules for starting in OST which are hardest to meet included having to completely stop all illegal drug use (41%), having the dose supervised every day (18%), and having to attend all appointments (15%). Users in the South/East (*vs* North/West) were more likely to mention difficulties finding access to treatment (29% *vs* 9%), waiting lists (27% *vs* 8%) and cost (22% *vs* 14%) as reasons for staying out of treatment.

Figure 3. Opioid users' reasons for staying out of treatment



The finding that treatment provision is inadequate in Germany is consistent with national data on the number of patients and physicians (Figure 1). To address the supply/demand imbalance affecting OST access in Germany, it is crucial to understand the reasons why most accredited OST physicians do not provide treatment. Notably, 82% of the non-treating physicians surveyed indicated that they have provided treatment in the past but do not currently do so. Their mains reasons for not currently treating OST patients included:

- Organisational aspects (24%) – such as limited capacity or resources to integrate OST into their practice
- Perceived low need for treatment (24%) – including perceived low demand and the availability of an OST physician in the area already

- Political conditions/framework (14%) – including legal problems of prosecution, bureaucracy and unattractive conditions
- Being a specialist focused in another area of medicine (12%)
- Inadequate financial reward/honoraria (8%)
- Image/society (8%) – including concern about one's reputation or image or perception of opioid dependence as a social problem

Similarly, when non-treating physicians were asked what should change in order for them to restart treating patients, the most common responses included changes to the following aspects of OST:

- Policy/regulatory framework (37%) including reduced legal bureaucracy and clearer structures and conditions
- Organisational aspects (18%) including easier organisation in the office
- Improved payment/honoraria (14%)
- Physician coverage and conditions of provision (14%) including better availability of 'stand in' doctors and having more time or fewer patients

Physicians who *are* currently treating patients also perceive the need for changes to OST addressing similar aspects of therapy:

- Policy/regulatory framework (47%) including less bureaucracy, less restrictive policies, and legal support instead of sanctions
- Physician coverage and conditions (43%), in particular the need for increased numbers of physicians willing to treat; the need for changes in this area were particularly noted by physicians in the East/South regions (59%)
- Accompanying offers and services (19%) including the broader availability of psychosocial support
- Better linkages and co-operation (16%) including between physician colleagues and pharmacists, and the availability of 'stand in' physicians for weekend and vacation cover
- Improved payment/honoraria (9%)

When specifically asked what changes would most help to improve <u>quality</u> of care, policy/regulatory factors (45%) and improving the attractiveness of treating opioid

dependence (37%; e.g., better financial compensation, improved attractiveness of providing or being accredited to provide OST) were the most common answers.

In summary, these findings suggest that the regulations and structures of OST provision in Germany are perceived as unfavourable and unclear by many physicians (treating and non-treating) and are contributing to the growing problem regarding treatment availability. Amendment of these regulations would encourage a greater number of accredited physicians to become involved in OST.

Concern about misuse impacts on treatment access and retention

An important challenge facing OST providers and regulators in Germany is to maximise access to therapy and ensure that the full range of benefits are realised, whilst maintaining the safety and integrity of treatment. The appropriate use of take-home dosing is a particularly important consideration in seeking to maximise treatment access, retention and effectiveness (e.g, in achieving social reintegration), whilst minimising the potential for misuse (e.g., snorting, injecting) and diversion (e.g., medication sold or given away) of prescribed opioids.

Users and patients in this survey indicated that strict take-home policies are a key barrier to accessing treatment. When patients in treatment were asked to indicate which aspect of their treatment they would like to change and why, the most common response (26%) was to make access to take-home dosing easier, including a number who felt it would make it easier to be employed. The second most common response related to the medication dispensing point (14%) and in particular the need for more flexible dosing hours. When asked what would make it easier to stay on therapy, patients' most common responses were greater flexibility (51%), more personal responsibility (32%), and a reduced number of months of supervised dosing (29%).

At the same time, physicians expressed significant concerns about misuse and diversion of OST by patients. For example, two-thirds of treating physicians indicated that drug diversion (to persons other than the intended recipient) is either a significant (49%) or huge (17%) problem, and more than half (53%) of treating physicians also see misuse (injecting/snorting of prescribed medication by patients) as either a significant

(42%) or huge (12%) problem. More than 80% of treating physicians indicated that misuse and diversion of prescribed opioids is either a slight (36%) or great (45%) concern, and more than a quarter (26%) respond by terminating treatment when they become aware of misuse or diversion occurring.

Responses from patients confirm that medication misuse and diversion do occur. Approximately one-quarter of patients (23%) reported having ever previously sold and/ or given away their medication (8% and 20%, respectively); the most common reasons for diversion were to help others treat themselves (54%) and/ or satisfy their cravings (36%). These findings demonstrate the need for more and more adequate treatment offers, as diversion is obviously filling the gap between treatment and demand. Similarly 26% overall reported having injected (19%) and/ or snorted (12%) their medication.

To maintain and optimise the positive benefit:risk profile of OST, take-home regulations and practices should be based on assessment of the safety/risk profile of different therapeutic options. The results of this survey indicated that although safer, less divertible treatments are available, these are not being widely used by physicians. Compared to other treatment options, buprenorphine-naloxone was most frequently identified by treating physicians as the medication which would be most appropriate for take-home dosing in new patients (i.e., if take-home-dosing restrictions were entirely at the discretion of the physician). This option could therefore be useful in seeking to improve access whilst minimising risk.

Lack of comprehensive national guidelines affects quality of care

In addition to highlighting barriers to treatment access, results of the survey provide important insights regarding the factors that affect quality of care across regions and between individual patients.

Among treating physicians, 72% agreed that there are major regional differences in treatment regulations across Germany; only 5% perceived no differences. Hamburg (17%) and Berlin (15%) were the cities most commonly cited as the best when it comes to implementing official regulations/guidelines, followed by Frankfurt (6%). Moreover,

many physicians (59%) also perceived that there are major variations in the quality of patient care across different cities and regions.

At the level of individual patients, the majority of patients surveyed indicated they received the OST they requested (i.e. rather than necessarily the one that may suit them). Almost two-thirds of patients (61%) indicated they requested a specific medication from their physician, which was granted in more than 90% of cases. At present, there are no comprehensive national clinical guidelines to support physicians in the quality care of patients.

Although patient choice appears to have an important effect on the medication they receive, patient awareness of different medication options is variable. Patients were much more likely to report awareness of liquid methadone (87%), levomethadone (81%) and codeine (77%), compared to more recently introduced medications such as buprenorphine (62%) and buprenorphine-naloxone (26%). Amongst patients who informed themselves about OST options prior to starting treatment (79%), the most common sources of information included speaking with people in counselling/drug centres (55%) and other drug users (51%), with 43% saying they obtained information from their substituting physician.

This suggests that physicians are not as influential as other information sources in informing patients about treatment and that the patient-physician relationship does not provide them with individualised treatment. When patients and users were asked what would have helped users stay on therapy (for past treatment episodes that were stopped), the most common responses were physician-related aspects (21% patients, 20% users), including more consideration, understanding and respect of patients' individual situations and acceptance that drug addiction is a disease.

Collectively, these factors suggest that action is needed to support quality of care across different regions and to assist physicians in delivering individualised treatment regimens.

Lack of prison-based treatment is a major missed opportunity

Since a significant proportion of dependent opioid users spent time in prison at some stage, the prison setting provides an excellent opportunity to stabilise these patients during their incarceration and to establish plans for ongoing support or treatment (as required) following their release.

In this survey, only one-third of patients (35%) and users (32%) reported never having been in prison. The average number of prison terms was 2.8 for patients and 4 for users. Of these prison terms, 86% for patients and 70% for users were drug-related. The average total duration of imprisonment was 3.2 and 4.6 years, respectively.

Despite the high level of past drug-related imprisonment in the surveyed population, the proportion of these jail terms during which OST was received was 23% for patients and 35% for users. Among those patients and users who were undergoing OST at the time of their imprisonment, 70% had to stop treatment when they entered prison.

These findings indicate that few patients/users had the opportunity to commence or continue their treatment in prison. The opportunity to stabilise and improve these patients' lives during their incarceration is therefore being lost.

Further information

For further information about Project IMPROVE, please email akzeptbuero@yahoo.de.

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