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Commentary

Opioid Replacement Therapy in Germany – Meeting the Looming Supply Crisis with Structural Changes*

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Summary

This article discusses the structures of opioid replacement therapy (ORT) in Germany and presents alternatives to current care models. The aim is to secure care for patients currently receiving substitution treatment and establish a framework that will enable us to provide a previously unreached group of opioid users with high quality care that takes into account their individual life circumstances.

The Current Situation

The current report by the Federal Institute for Drugs and Medical Devices (BfArM) on the national ORT registry (January 2021) shows a further decline in the number of general practitioners (GPs) providing ORT. The average age of ORT prescribing GPs is almost 60. Since many of them are clearly older, a retirement from professional life is to be expected in the next few years. However, the recorded number of 2,545 prescribing GPs is also deceptive. In reality, every fifth practitioner (563 in total) makes use of the so-called consultation regulation (*Konsiliarregelung*) which allows GPs, who have not completed the mandatory primary addiction care training, to consult ORT patients as long as they liaise with a certified practitioner. They currently treat only 1,5% of patients.

The fact that roughly 14% of practitioners prescribing ORT treat half of all ORT patients (about 41,000 people) shows just how alarming the situation really is. If a number of these GPs retire for age-related or other reasons, some cities and regions could be in danger of developing profound problems in providing care to ORT patients resulting in unforeseeable consequences.

At the same time, the number of ORT patients has risen to 81,700. This means we are currently only reaching about 50% of those eligible for ORT treatment due to their opioid dependence.

We must face reality. The unfortunate truth is that all measures implemented to attract more GPs have had little success in recent years. Over the last 35 years, the structures of ORT have barely changed even though the numerous reforms of the regulations for prescribing narcotics (*BtmVV: Betäubungsmittel-Verschreibungsverordnung*), especially those implemented in 2017, have significantly improved and expanded the scope of treatment and the legal security of GPs. They now allow for a very person-centred approach, adapted to patients' living conditions. Many GPs are not fully aware of these new options and do not take advantage of, for instance, the range of take-home possibilities, local care provision, or the variety in substitute medications available to provide a more person-centred and patient-oriented treatment. We have a shared responsibility to discuss and implement alternative treatment models in the doctor's surgery. If we establish that we will be successful in convincing a large number of GPs to start prescribing ORT in the medium

term. Therefore, we will have to change the existing rigid structures of substitution therapy in doctors' surgeries. The objective is to create time and space for some of the approximately 80,000 opioid users who may decide to undergo substitution treatment in the future.

What Could Alternative Models of Opioid Replacement Therapy Look Like?

There are a variety of alternative models for substitution treatment in doctor's surgeries and many ideas for changes in treatment regimens. Below, some of these alternatives will be presented. It is important to note that many of these models have already been implemented successfully.

Creating Low-Threshold Access

When talking to people who have not tried ORT yet, they often mention uncertainty about whether they can cope with the demands associated with treatment in a doctor's surgery. Many opioid users have had no contact with a GP for years or decades, let alone with a specialist. The 'doctor's surgery' is a foreign concept to them. This influences the factor 'trust', which is highly important to drug users. In the drug scene, word spreads quickly. Particularly when it comes to bad experiences with the healthcare system. This leads to many users being confronted with reports of sanctions due to using drugs on top of an opioid prescription, which makes them even more uncertain of whether they can live up to expectations. Moreover, these sanctions have an extremely deterrent effect, as many users have been confronted with punishments and sanctions throughout their entire lives.

During the corona pandemic, a new model of substitution treatment was set up in Hamburg. There, the *Drob Inn* offered opioid users, many of whom were homeless and uninsured, very low-threshold access to ORT in a familiar environment, in their 'Drobs' (from *Drogenberatungsstelle* meaning local drug counselling services). Located right in the middle of the drug scene where they spend time every day. Within a few months, 300 people were admitted to treatment. Irrespective of the corona pandemic, this demonstrates that although people with particularly complex needs are currently not reached by the conventional system of substitution treatment, there is an identifiable need for alternative services. Such a model could be a great addition to existing structures, especially in a metropolitan context.

Substitution Treatment Outside the Classic Doctor's Surgery

The lack of GP surgeries prescribing ORT has already led some drug support services to establish their own substitution treatment service. For example, the drug support service in Bielefeld has created two options for substitution treatment by reaching a partnership agreement with a prescribing GP. This practitioner offers low-threshold ORT consultation hours outside his surgery, in two clinics operating in two different locations of the Bielefeld drug support service. The concept, in terms of different kinds of settings, is remarkable. One treatment option, for instance, was established in a counselling centre.

Stable patients, often those in employment, who do not want any contact with the drug scene are treated there. Alternatively, the low-threshold centre with an outreach service, drug consumption room, and so on, treats those patients who are there daily or multiple times a week anyway to take advantage of what the drug support service offers. This model demonstrates the major advantages of having medical treatment and psychosocial care under one roof. In addition, patients who occasionally use cocaine or other substances on top of their prescription are offered the possibility to use under controlled and hygienic conditions. In this setting it is important the GP is supported by a team from the counselling service and is to a large extent relieved of any accompanying documentation duties. Thanks to the close cooperation between the outpatient clinic and the drug support service, very flexible dispensing windows and methods can be realised. While prescribing GPs are urgently needed everywhere, Bielefeld has succeeded in recruiting several prescribers who had already retired.

Treatment Close to Home: Increasing Involvement Pharmacies and Care Services

Tens of thousands of patients still have to accept travelling long distances for treatment every day. Narrow dispensing windows lead to crowding in front of and inside surgeries. The majority of patients is of older age, in poor overall physical condition and not very mobile, suffering from for instance COPD, (open) leg

wounds and severe overweight. Therefore, we must ask ourselves why we make thousands of these patients travel to a surgery every day instead of having pharmacies, care services or drug counselling services dispense the medication close to their homes.

Individual Take-Home Dispensing

The corona pandemic shows that for a large number of patients, being responsible for taking their own medication, works much better than previously assumed. The BtmVV regulations for prescribing narcotics together with the current exemptions offer the opportunity to gradually and safely test autonomous use of substitute medications. Going from daily dispensing in the surgery to collection visits three times and then twice a week would also mean a considerable relief for both prescribers and patients. Additionally, take-home dispensing can contribute to an overall improvement in treatment because it facilitates a way for patients to participate in work, social life and family commitments, which in turn will promote their independence.

Alternative Ways of Contact such as Telephone, Skype and Zoom.

The pandemic has clearly changed our methods of communication. Even if face-to-face conversation continues to be the best way to communicate, under current substitute treatment conditions we must establish and use alternative methods of conversation and contact. For example, patients who used to come to the surgery every day and now only twice a week can receive additional support via telephone or Skype. Some surgeries already established this kind of arrangement successfully during the lockdown.

Depot Medication in a Supporting Role

For some time now, prescribers and patients have had access to another alternative treatment method using a depot formulation of buprenorphine. This new treatment option should be examined further to establish whether it can help relieve prescribers and simultaneously treat patients safely and successfully. Every fifth patient is prescribed buprenorphine. If these patients show interest, a switch to a weekly depot formulation should be assessed.

This option would also ease the concerns of those who fear a feeding of the grey market through increased take-home dispensing. The Centre for Interdisciplinary Addiction Research (*Zentrum für Interdisziplinäre Suchtforschung*) report on the evaluation of the reform of BtmVV narcotics regulation, however, actually showed the increased use of take-home prescriptions did not lead to an increased availability of substitute medications on the black market. While prescribing the weekly depot, prescribers could arrange opportunities for contact once or twice a week.

Summary

A closer look at ORT structures in Germany reveals that many sites, even after ten or twenty years of treatment provision, lack the flexibility and the will to get involved in something new and to try alternative treatment methods. This has to change.

Alternatives to rigid treatment models already exist. In the interest of patient satisfaction and the continuous, reliable supply of care, we really need to address these and any other structural changes. Many treatment providers are insufficiently aware of the existing possibilities through the last reform of the BtmVV narcotics regulation and the additional flexibilisation through the SARS-CoV-2 Medicinal Products Supply Ordinance (*Sars-Cov2-Arzneimittelversorgungsverordnung*) and do not put them into practice. If we can convince prescribers in the short term to use the whole range of substitute medications and be flexible with dispensing, then we could succeed in securing our supply chain and increasing the diversity of treatment options. This will enable us to treat opioid users who want to start substitution therapy, even if the number of treatment providers remains the same. Let us not forget that currently only about 50% of the people who are eligible for ORT are in treatment. The corona pandemic has worsened the living conditions of drug users and it is to be expected that more opioid-dependents will opt for substitution therapy, if they can find a treatment place. It is our joint responsibility to facilitate this.

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