CHAPTER 11: History, methods, and implementation of national treatment guidelines

Compilation from National Reports 2010

National Reports 2010........................................................................................................................................................................2

BELGIUM .......................................................................................................................... 2
BULGARIA.................................................................................................................. 9
CEZCH REPUBLIC........................................................................................................ 11
DENMARK ..................................................................................................................... 22
GERMANY .................................................................................................................... 25
ESTONIA ..................................................................................................................... 45
IRELAND ..................................................................................................................... 49
GREECE ....................................................................................................................... 59
SPAIN ......................................................................................................................... 73
FRANCE ....................................................................................................................... 77
ITALY ......................................................................................................................... 102
CYPRUS ...................................................................................................................... 106
LATVIA ....................................................................................................................... 110
LITHUANIA ................................................................................................................. 119
LUXEMBOURG ......................................................................................................... 124
HUNGARY .................................................................................................................. 130
MALTA ......................................................................................................................... 138
NETHERLANDS ........................................................................................................ 139
AUSTRIA .................................................................................................................... 161
POLAND ..................................................................................................................... 167
PORTUGAL ............................................................................................................... 168
ROMANIA .................................................................................................................. 179
SLOVENIA .................................................................................................................. 192
SLOVAKIA ................................................................................................................... 202
FINLAND .................................................................................................................... 205
SWEDEN .................................................................................................................... 207
UNITED KINGDOM .................................................................................................... 223
CROATIA .................................................................................................................... 249
TURKEY ..................................................................................................................... 257
NORWAY .................................................................................................................... 260
11.1 History and overall framework

In Belgium, the implementation of evidence-based practice and guidelines is becoming an important issue for policy makers, researchers and practitioners in substance abuse treatment (Pieters, 1999; Broekaert et al., 2001; Broekaert et al., 2002; Henneman et al., 2004; Autrique et al., 2007, 2009; Pham et al., 2010). Never before, so many efforts have been made for the observation, registration and systematisation of daily practice in substance abuse treatment (Pham et al., 2010). Despite this rising interest, almost no guidelines for substance abuse treatment have been developed at a national level and working with evidence-based guidelines is not imposed by the government.

This situation makes it particularly interesting to study the implementation of evidence-based guidelines in Belgian substance abuse treatment, which would be mainly a bottom-up movement. Moreover, the Belgian situation may also be regarded as illustrative for other European countries, since the Flemish Community is more closely connected with the Anglo-Saxon tradition and the mid- and northern European countries, while the French Community is more closely oriented to the Latin tradition and southern European countries (Autrique et al., 2009).

By the Flemish Community we mean the Flemish provinces and the Dutch-speaking part of Brussels and by the French Community we mean the Walloon provinces and the French-speaking part of Brussels. In this text, we will talk about Dutch-speaking substance abuse treatment services, which are situated within the Flemish Community and about French-speaking substance abuse treatment services, which are situated within the French Community.

Two studies have recently been conducted on evidence-based guidelines in substance abuse treatment, of which one in Belgium and one in the Flemish Community, both funded by the Federal Government (respectively Belgian Science Policy and Federaal Fonds ter Bestrijding van de Verslavingen).

The Belgian study was carried out by the University of Ghent (department of orthopedagogics), the University of Antwerp (CAPRI - Collaborative Antwerp Psychiatric Research Institute) and the Centre de Recherche en Défense Sociale (Tournai)1. In the first part of this study, an overview has been made of international effectiveness research on and evidence-based guidelines for substance abuse treatment. The second part focuses on practitioners’ attitudes towards and readiness for the implementation of evidence-based guidelines in Belgian substance abuse treatment, and identifies potential barriers and strategies concerning the implementation of such guidelines (Autrique et al., 2007, 2009). For the latter part of this study, a stratified and representative sample of 60 substance abuse treatment services providing specialized substance abuse treatment was selected out of all 176 such services in Belgium, including psychiatric hospitals; crisis intervention centres, psychiatric emergency wards, and psychiatric wards of general hospitals (short-term residential treatment);

specialized residential treatment services (long-term residential treatment); and specialized outpatient services.

Thirty-two services are situated in the Flemish Community and 28 services are situated in the French Community. In the selected services, the person responsible for the therapeutic programme was interviewed. Most of these services (n = 47) provide detoxification, 31 substitution treatment, 39 drug-free treatment and 31 also offer aftercare. The most commonly applied interventions are individual counselling, family-oriented interventions, pharmaco-therapeutic interventions, psychoeducation and brief interventions. In Dutch-speaking services, gradual reduction schemes, behavioural and cognitive interventions, coping skills training, psychoeducation and aftercare are applied significantly more often as compared to French-speaking services. In French-speaking services, the psychodynamic approach is used significantly more often (Autrique et al., 2007, 2009).

The Flemish study is part of a pilot project on the implementation of evidence-based guidelines and outcome management currently running in 5 substance abuse treatment services in the Flemish Community. This project is called ‘Quality improvement in substance abuse treatment’ and is coordinated by the Flemish Association for Alcohol and other Drug problems (VAD). It is mainly focusing on ways to support the implementation process of evidence-based guidelines and outcome management. Within the project, a needs assessment was carried out in Dutch-speaking substance abuse treatment services concerning the implementation of evidence-based guidelines and outcome instruments (VAD, 2009a), the overview of evidence-based guidelines of the above mentioned study was updated and the quality of these guidelines was appraised (VAD, 2009b). The results of these studies will be discussed further on in this chapter.

11.2 Existing guidelines

For substance abuse treatment, not many evidence-based guidelines have been developed yet in Belgium (VAD, 2009b). However, some treatment services are making use of international guidelines, adapting them to their specific context. This is congruent with the suggestion of some authors that investing in the adaptation of existing evidence-based guidelines and even the development of shareable guidelines at a European level might be preferable over the development of guidelines at a national level, since the evidence underlying guideline recommendations is usually of an international nature (Stiegler et al., 2005). So far, in Belgium no international evidence-based guidelines for substance abuse treatment have been adapted at a national level.

Description of national substance abuse treatment guidelines

This guideline provides recommendations on prescription of benzodiazepines to illegal drug users (adults). Target users are general practitioners and medical doctors / psychiatrists working in substance abuse treatment.

Methodology
These guidelines were developed by means of a systematic literature review and expert consensus, following the methodology of the Scottish Intercollegiate Guidelines Network (SIGN - http://www.sign.ac.uk). All relevant stakeholders were represented in the expert group: general practitioners, psychiatrists and medical doctors working in outpatients and residential substance abuse treatment. Methods used to formulate recommendations are clearly described in the guideline, as well as how final decisions are arrived at. There is an explicit link between the recommendations and the supporting evidence.

Clarity and presentation
All recommendations are summed up in a separate chapter. Key recommendations are easily identifiable as they are summarised in a box. Recommendations are specific and unambiguous.

**Applicability**
The guideline is supported with tools for application, such as the Bendep-SRQ questionnaire and a conversion table. The potential cost implications of applying the guideline and potential organisational barriers in applying the recommendations are not discussed. No review criteria for monitoring and/or audit purposes are available.

**Flexibility**
Clients' views and preferences are not explicitly taken into account. Client features that demand an adaptation of the guideline are discussed by means of a specification of different client groups. Comorbidity is taken into account.

**Editorial independence**
All members of the development group are mentioned in the guideline. Conflicts of interest have not been reported explicitly.


This guideline provides recommendations for the use of buprenorphine – high dosage – in the treatment of opiate dependency. Target users are medical doctors and general practitioners.

**Methodology**
These guidelines were developed by means of a systematic literature review and expert consensus. The methods used for formulating recommendations are clearly described. For most recommendations, there is an explicit link with the supporting evidence. No levels of evidence were assigned to the recommendations.

**Clarity and presentation**
The different recommendations are clearly presented and the guideline is well structured. Key recommendations are easily identifiable as they are summarised in boxes.

**Applicability**
The guideline is supported with an objective and subjective scoring list for opiate detoxification. The potential cost implications of applying the guideline and potential organisational barriers in applying the recommendations are not discussed. No review criteria for monitoring and/or audit purposes are available.

**Flexibility**
Clients' views and preferences are taken into account, for example in choosing for methadone or buprenorphine. Client features that demand an adaptation of the guideline are not specified. Comorbidity is taken into account to a certain extent.

**Editorial independence**
There are no conflicts of interest of guideline development members.

**Ongoing guideline development**

At this moment, guidelines for ADHD and addiction are being developed by VAD and the Flemish Forum for Addiction Medicine. Domus Medica, the Flemish association for general practitioners ([www.domusmedica.be](http://www.domusmedica.be)), is developing guidelines on alcohol problems for general practitioners.

**Need for evidence-based guidelines**
In a needs assessment in Dutch-speaking substance abuse treatment services (VAD, 2009a), many substance abuse treatment services indicated the need for specific evidence-based guidelines, adapted to their context. Most cited are guidelines on motivational interviewing, guidelines on family therapy and guidelines on comorbidity and other substance abuse related problems such as sexual abuse, ADHD, automutilation and eating disorders. There also appears to be a need for guidelines on drama, creative therapy and non-verbal methods, group therapy, cannabis, gambling and aftercare and reintegration. The need for guidelines on methadone substitution treatment and cognitive-behavioural treatment was also mentioned.

11.3 Implementation process

Adoption of evidence-based guidelines

In the Belgian study, 40 out of 60 substance abuse treatment services mentioned the availability at their service of some kinds of guidelines for the treatment of substance abusers (Autrique et al., 2007, 2009). This is significantly more often the case in Dutch-speaking than in French-speaking services. Most guidelines appear to be self-developed and are based on scientific literature, clinical experience and team consultation. All respondents say to have confidence in the guidelines at their service because they have participated in the development of the guidelines, the application turns out to be successful, the guidelines are based on scientific research and they have been adapted based on experience from daily practice. They state that there is a high degree of implementation of these guidelines at their agency, which is being monitored and coached.

In a recent needs analysis in Dutch-speaking substance abuse treatment services (VAD, 2009a), 18 of 28 services mentioned the use of evidence-based guidelines. It concerns mostly pharmacological guidelines, used by medical doctors. In other services and by other disciplines, no or self-developed guidelines are used.

These self-developed guidelines can however not be called ‘evidence-based’ as defined by the AGREE criteria and the GLIA criteria, both indicators of the quality of guidelines (The AGREE Collaboration, 2001; Shiffman et al., 2005). On guideline implementation or adherence, no conclusions can be drawn either. This would require evidence-based guidelines adapted to the Belgian situation, specific implementation strategies and indicators for guideline adherence (Grol, 2001). In the Flemish project coordinated by VAD, it will be possible to draw conclusions on this matter. Five pilot services in substance abuse treatment have selected an international evidence-based guideline and have chosen some key recommendations from this guideline for implementation at their service. They have adapted these recommendations to the specific context of their service and will monitor the implementation process by means of criteria for a clinical audit in the period of September 2010 until June 2011.

Attitudes towards evidence-based practice and evidence-based guidelines

In the Belgian study, most respondents report a positive attitude towards the current tendency of more evidence-based practice and consider results of scientific research and evidence-based guidelines as useful (Pham et al., 2010).

They think evidence-based practice can guarantee the quality of treatment, provides objective information about treatment interventions and offers a clear framework to start from (Autrique et al., 2009). Critical remarks are related to concerns that the individual patient is not sufficiently taken into account and the possible loss of therapeutic freedom, and to doubts about the value of addiction research for daily practice.

Thirty-seven practitioners report no differences in attitude towards evidence-based practice between various disciplines and professions in the service, while 21 persons do perceive such differences
due to personal disparities as well as divergences in professional position. According to these respondents, physicians and nurses have a more positive attitude towards evidence-based guidelines while psychologists – especially those with a psychodynamic background or orientation – are less in favour of this tendency. They think the attitude of the directors and responsible persons in the selected services is also mainly positive, although in the Flemish Community they seem to be more positive about this tendency than in the French Community.

Most practitioners agree that evidence-based guidelines are a means to learn something about intervention methods, are a useful source of advice, can be implemented in existing programmes and ameliorate the quality of care. Fewer French-speaking respondents than Dutch-speaking respondents think such guidelines are useful. The main reasons for a positive attitude towards guidelines are that they provide a framework and guarantee the quality of treatment. Guidelines are perceived as not being of much use because they might ignore individual differences, could take away therapeutic freedom and were developed in a research context which differs significantly from practice (Autrique et al., 2009; Pham et al., 2010).

Clinical experience and scientific research are considered equally important in daily practice by most respondents. More than one-third think clinical experience is more important since experience is needed to be able to take into account individual differences. Again a significant difference was found between the perspectives of practitioners from Dutch-speaking and French-speaking services as the latter consider clinical experience more important than scientific research (Autrique et al., 2009).

Some respondents are concerned that the implementation of evidence-based guidelines would lead to a uniformisation of substance abuse treatment. They are also worried that it would be difficult to implement these guidelines because of the incompatibility of their treatment context and treatment philosophy with the evidence-based paradigm (Pham et al., 2010). Still, more than one-third reject the expression that the philosophy of their treatment programme is more important than evidence-based guidelines. The latter view is more predominant among Dutch-speaking practitioners.

It is remarkable that some differences in attitude can be observed between practitioners in the Flemish Community and the French Community, mainly concerning the perception of the usefulness of guidelines and the perceived attitudes at management level towards evidence-based practice. This could possibly be explained as being part of a more global anti-American tendency (l’anti-américanisme) in the French Community (Roger, 2002). Another possible explanation is that in the Flemish Community the Anglo-Saxon, empirical-analytical orientation is more commonly accepted, while the Latin-French tradition and the application of the psychodynamic theory is more widespread in the French Community (Autrique et al., 2007, 2009). Related to this is the fact that there is not much ‘hard’ evidence yet for the effectiveness of the psychodynamic approach in treating substance abuse problems. Still, no firm conclusions can be drawn, since no significant differences were found between the Flemish Community and the French Community in the attitude of respondents towards evidence-based practice in general and no possible causal relations were assessed between for example therapeutic approaches and attitudes.

Barriers concerning the implementation of evidence-based guidelines

In the Belgian study on evidence-based practice in substance abuse treatment, some barriers were identified concerning the implementation of evidence-based guidelines (Autrique et al., 2007, 2009; Pham et al., 2010). These barriers are mainly hypothetical, since in most services, no evidence-based guidelines are applied yet. Besides concerns on the implications of the implementation of evidence-based guidelines for daily practice such as the loss of therapeutic freedom and the compatibility with the treatment philosophy and ideas, many respondents say the implementation of evidence-based guidelines would require advice or training by an expert. They also regard lack of time and resources as an important barrier for implementation of evidence-based guidelines as well
as lack of coaching and training. They are not eager to implement guidelines when they are imposed top-down by policy makers.

Within the project ‘Quality improvement in substance abuse treatment’, in September 2010 focus groups will be held in 5 different Dutch-speaking substance abuse treatment services on barriers and facilitating factors in the implementation of evidence-based guidelines. The results of these focus groups will be analysed, and the treatment services will use these data to develop specific actions for the improvement of the implementation of the evidence-based guidelines they have selected.

Strategies for the implementation of evidence-based guidelines

In the Belgian study, respondents have identified various strategies to facilitate the implementation of evidence-based guidelines, particularly easy access to guidelines, good communication on evidence-based guidelines, staff training and provision of manuals (Autrique et al., 2009; Pham et al., 2010). It is further mentioned that guidelines have to be implemented gradually and that (imposed) top-down implementation should be avoided. During the implementation process, which is not a linear process, practitioners have to be involved and consulted, and regular evaluation and feedback moments are needed (Pham et al., 2010). Financial resources and time is needed as well as support from at policy and management level. The use of experts as well as opinion leaders is recommended.

In a needs assessment in the Flemish Community (VAD, 2009a), it was found that substance abuse treatment services need information on existing evidence-based guidelines. They asked for an easily accessible and up-to-date overview of evidence-based guidelines for substance abuse treatment and a quality assessment of these guidelines. For the implementation, they prefer a bottom-up strategy, and would like to get coaching in the implementation of evidence-based guidelines, by means of education, peer review and tailor-made advice.

In 2009, different initiatives were taken within the project ‘Quality improvement in substance abuse treatment’ to inform and sensitize substance abuse treatment practitioners in the Flemish Community concerning the importance of evidence-based guidelines, and to increase the expertise of professionals in substance abuse treatment. An overview of existing evidence-based guidelines was developed and disclosed; it concerns general guidelines for substance related problems, as well as guidelines for specific interventions in substance abuse treatment. Dual diagnosis and HIV related to substance abuse are also included. The quality of the guidelines has been assessed by means of indicators derived from the AGREE instrument (the AGREE Collaboration, 2001) and the GLIA instrument (Shiffman et al., 2005). Based on the results of the needs assessment, one international evidence-based guideline is translated each year. All this information can be found on the VAD website: [http://www.vad.be/evidence-based-werken/kwaliteitsbevordering.aspx](http://www.vad.be/evidence-based-werken/kwaliteitsbevordering.aspx). Training was developed on evidence-based practice / evidence-based guidelines and is organised annually. By means of a digital newsletter, substance abuse treatment services are informed of interesting weblinks, new initiatives, evidence-based guidelines.

In 2010, a manual for quality improvement in substance abuse treatment will be developed, focusing on the implementation of evidence-based guidelines and outcome management. Target users of this manual are therapeutic coordinators, quality coordinators and other persons that are mandated to coach an implementation process of evidence-based guidelines. To develop this manual, monitoring results of the pilot stage with five substance abuse treatment services will be used. As mentioned before, this pilot project is currently running. Each involved service has selected and will implement one international evidence-based guideline as well as one outcome instrument.

The treatment services are each represented by two staff members working in daily practice, who are considered as ‘clinical leaders’ and are attending 10 training / peer review days on evidence-
based practice and evidence-based guidelines, clinical leadership and clinical audit, change management and implementation strategies and Project Cycle Management (PCM).

Clinical leadership is a main focus of this project, as the core recommendations and outcome instruments are implemented bottom-up by the staff members working in daily practice (Ham, 2003). Through a digital platform the clinical leaders can exchange experiences and discuss barriers. VAD is providing ad hoc support, with possible involvement of external expertise. On peer review days, experiences are exchanged with attention for the implementation process as well as for the outcomes of the implementation. The university of Ghent, department of orthopedagogics, is providing support in monitoring and evaluating the implementation process.

11.4 Comparison with the WHO guidelines

Neither Belgian evidence-based guidelines on methadone treatment for substitution or withdrawal purpose in opioid dependence, nor guidelines on closed settings are available.
BULGARIA

WHO guidelines coherence: only to be applied to guidelines on methadone treatment for substitution or withdrawal purpose in opioid dependence

<table>
<thead>
<tr>
<th>Name of Assessors:</th>
<th>Tsveta Raycheva MD</th>
</tr>
</thead>
</table>

### 1. Choice of treatment

1.2 For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment. Do the present guidelines include this recommendation?

1.3 For opioid-dependent patients not commencing opioid agonist maintenance treatment, consider antagonist pharmacotherapy using naltrexone following the completion of opioid withdrawal. Do the present guidelines include this recommendation?

### 2. Opioid agonist maintenance treatment

2.1 For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine. Do the present guidelines include this recommendation?

2.2 During methadone induction, the initial daily dose should depend on the level of neuroadaptation; it should generally not be more than 20 mg, and certainly not more than 30mg. Do the present guidelines include this recommendation?

2.3 On average, methadone maintenance doses should be in the range of 60–120 mg per day. Do the present guidelines include this recommendation?

2.4 Average buprenorphine maintenance doses should be at least 8 mg per day. Do the present guidelines include this recommendation?

2.5 Methadone and buprenorphine doses should be directly supervised in the early phase of treatment. Do the present guidelines include this recommendation?

2.6 Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review. Do the present guidelines include this recommendation?

2.7 Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence. Do the present guidelines include this recommendation?

### 3. Management of opioid withdrawal

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 choice of treatment</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2 opioid agonist maintenance treatment</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3 opioid antagonist treatment</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4 management of opioid withdrawal</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.1 For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used. Do the present guidelines include this recommendation? X □ □ □

3.2 Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation? □ □ □ X

3.3 Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation? □ □ □ X

3.4 Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal. Do the present guidelines include this recommendation? X □ □ □

4 Pregnancy

4.1 Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy. Do the present guidelines include this recommendation? □ □ □ X □ □

4.2 Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered. Do the present guidelines include this recommendation? □ □ □ □ X

**WHO guidelines coherence: only to be applied to guidelines applied for guidelines on closed settings**

In case your guidelines are about closed settings (“closed settings” refers to prisons, work camps, compulsory drug treatment centres and any other institution in which people are detained), state whether they agrees with the “Clinical guidelines for withdrawal management and treatment of drug dependence in closed settings” freely downloadable at: [http://www.who.int/hiv/pub/idu/wpro_withdrawl/en/index.html](http://www.who.int/hiv/pub/idu/wpro_withdrawl/en/index.html).

For each recommendation, please state whether your guidelines include them (even if not with exactly the same wording). Please select only one answer.

<table>
<thead>
<tr>
<th>1. Do the present guidelines agree with the “Clinical guidelines for withdrawal management and treatment of drug dependence in closed settings”?</th>
<th>□ Yes □ No □ Not applicable □ Specify</th>
<th>□</th>
</tr>
</thead>
</table>

**BACK TO TOP**
This chapter deals with the treatment guidelines applicable to drug users in the Czech Republic. The EMCDDA lists the Czech Republic as a Member State which has implemented and applied treatment guidelines in the area of drug use. However, a closer examination of the documents that have been implemented and their use reveals that this is not entirely certain. It will therefore be useful to begin with a brief excursion into the general topic of guidelines and their typology, purpose, logic, and mutual links.

**History and Overall Framework**

**Definitions and Typology**

Guidelines are instruments used for quality maintenance and assurance. The term “guideline” refers to a set of criteria applied in order to assess whether and to what extent the service in question is provided in a quality manner. However, the view of “quality” is rather broad and, in addition to comprising the correct execution of certain measures whose effectiveness has been verified, it also includes management and organisational support for the service, its availability, client-friendliness, and involvement in a network of other services.

These multidimensional criteria are usually not compiled into a single code. In addition, there are multiple approaches to “quality”. The WHO (WHO, 1997; Kalina, 2001) distinguishes the following guidelines:

1. training guidelines;
2. guidelines for centres, facilities, and programmes;
3. case or diagnosis-based procedural guidelines;
4. guidelines for methods, and
5. ethical guidelines.

Types 3 and 4 are sometimes referred to as “good practices”. They are a valuable link between research and practice. Their main objective is to assist professionals, as well as patients, in their decision making about the appropriate interventions under specific circumstances, e.g. in case of a certain health-related event or its complications. In addition, they also help public officials, administrators, and clinical managers plan the services and create the environment of good practice. Last but not least, teaching materials are also involved because well-prepared guidelines support the training of students, as well as of the more advanced practitioners aspiring for greater expertise. The main requirements for sound good practice guidelines include a broad expert base and scientific evidence (Kalina, 2010).

The “mechanisms” applied to verify the compliance with the criteria represent the second component of quality assurance. These mechanisms include, for example, comprehensive workplace quality management, internal and external supervision, peer reviewing, and formal and “official” mechanisms such as inspection, accreditation, certification, licensing, etc.

---

2 Termination note: The term standard rather than guideline is more commonly used in the Czech Republic and, as such, is interchangeable with the term guideline for the purposes of this document. In accordance with the EMCDDA, the term treatment is understood as professional care provided to patients or clients, and goes beyond the term of “treatment” in the medical sense.

3 The references to the selected sources are provided in the text of the chapter. In addition, this selected issue chapter has been prepared using the following literature: Kalina and Jaroš, 1998; Kalina K. et al., 2001; Kalina, 2000; Kalina, 2003; Kalina, 2007a; Kalina, 2009b; Miovský, 2008; WHO, 2000.
Purpose of Guidelines
This section covers the questions regarding whom the standards serve, who needs them, and who uses them and for what purpose.

Expert Communities
Historically, guidelines were created in professional communities, in particular the medical ones, which sought to strengthen the quality performance of the profession and achieve external recognition. This is where the terms “good practice” or “lege artis procedure” originated from. Specialised publications, lectures, seminars, and other components of the life of professional communities have spread and introduced good practices into the training of those who wish to pursue the profession. The formalisation of good practices, i.e. guidelines as we understand them today, occurred in medicine in the second half of the 20th century, and even earlier in the USA. In the 1950s and 1960s, this model was adopted by the newly formed non-medical profession of social workers, especially in English-speaking countries. It was also during that period that communities of institutions appeared, such as associations of hospitals, adding organisational aspects to the criteria of good practices. Mechanisms such as peer review and supervision began to spread. A number of communities of care providers sought to achieve a status where the very membership of such communities would indicate and guarantee quality. The so-called accreditation communities subjected the candidates (individuals or institutions) to demanding examinations prior to their acceptance as members. The prestigious Royal College in the countries of the British Crown is an example of such an institution.
In the late 20th century, quality assurance ceased to be the exclusive domain of the providers and, instead, the state took on the important role, often to their displeasure. However, the direct providers of services continue to be interested in developing quality, and professional communities are still an irreplaceable source of the professional parameters of good practices.

Government and Public Administration
The state interventions in the area of the quality of health and social services arise from the fact that the state guarantees the availability of these services for its citizens in terms of accessibility and affordability. It performs its guarantee by funding these services, whether by redistributing general taxes or using dedicated “taxes” such as public health insurance. In order to ensure the proper use of these financial resources following the “value for money” principle, it also takes charge of quality control, and guarantees quality to its citizens. Especially in the Member States of the EU, the extent of these guarantees is enormous.
However, this triple guarantee also represents a trap for the state. Public financial resources are always limited and, as has been shown by social economists, so are private resources. On the other hand, the needs increase without any limit, pushed by the demands of the citizens (with the legitimate demands including, for example, the ageing of the population) and pulled by the professional development of services (the providers continuously improve their quality potential). We can imagine the resulting difficulties for politicians and administrators when assigning the state-guaranteed values of quality, availability, and costs to the apexes of a triangle, which, however, cannot stand on all three apexes at one time. If the base is “quality care – expensive care”, it is not likely to be widely available. If the base is “quality care – widely available care”, the costs increase. If the “widely available care – cheap care” base is selected, it will be difficult to maintain its quality. Public policies must always balance between the availability, quality, and cost of care but, at the same time, they rely on the saying “We can never have everything at the same time but we always want it” (Acheson, 1994), cited in Kalina (2001).
The state and the providers thus find themselves in a conflicting position. The state promotes the value-for-money principle, requiring quality and availability at the lowest cost possible, while the providers promote the money-for-value principle, requiring the level achieved to be adequately paid for and development to be supported. The current situation in the Czech Republic in the area of services for drug users and persons with an addiction proves that this is not only a textbook description (see also the information on the We Have Had Enough of This).
International and Intergovernmental Organisations

On the global scene, it is mainly the WHO that promotes guidelines in order to transfer good practices from the developed countries to the less developed ones to contribute to an improvement in the health of their population. Together with the Council of Europe, it operates in the "European" region of the two organisations, which also covers the entire post-Soviet bloc, including the former Soviet republics in Central Asia. The less developed countries, however, often choose the “available care – cheap care” formula and lack the funding for quality improvement.

The interventions of the European Union in the area of service quality are derived from the central principles of the EU: the free movement of services and people. The objective is to ensure a comparable and optimum level of services for the citizens of the EU in all Member States. As far as the quality of the services for drug users and persons with an addiction is concerned, it is the topic of several measures in the current Action Plan of the EU. The current EMCDDA initiative is aimed at their implementation.

Users of Services

It is again the WHO that promotes “user reviews”, which should be carried out by the users of the services, their families and friends, and, in the broader sense, the public stakeholders. This is an important trend in developed Europe, which is supported by the WHO Regional Office for Europe. It represents the principle of a patient/client focus of services and a belief that the “user’s voice and choice” are as crucial for service provision as the professional and economic aspects. The public administration in most EU Member States usually considers the opinions of the users a necessary addition to expert and administrative evaluations. However, service providers, especially those on the European continent, have not been open to the increased influence of non-professionals until recently.

The participation of the users in quality assurance can be valuable and does not have to impair the professional aspects. In any case, understandable guidelines can contribute to overcoming the information imbalance between the service provider and the service user, even though the resulting deeper insights and their demanding and critical nature may be unusual for the provider.

Internal Correlates of Guidelines

Good practices, in particular type 3 – case or diagnosis-based procedural guidelines – form the core of the guidelines. When designed optimally, they should clearly formulate what needs to be done with an individual – the problem bearer – from their entry into professional care to their exit from it in order to maintain and improve the quality of their life. The type 3 guideline refers to the detailed description of the individual verified references (type 4). It can be used to derive the parameters of facilities competent to perform the good practices (type 2) and the qualifications of the staff capable of such performance (type 1). In addition, it also provides the service user with an understandable idea of their demand and is the basis of the “invoice” vis-à-vis public financial resources.

Even though (or perhaps because) the type 3 guidelines are crucial, their design is often not optimal: for example, they may not encompass the entire continuum of the resolution of the problem but instead only concern a certain segment thereof (such as the current status) or they may only consist of a set of methods and interventions that may be considered problematic. Previous attempts show that there are certain concerns, on the part of the providers as well as the public payers, regarding the excessive accuracy (and the resulting excessively binding nature) of such procedures.

---

4 These shortcomings also apply to the recently prepared Recommended Procedures for Psychiatry, the section of which on addictive disorders is discussed in detail in Section 0 (page 15).
5 The DRG (Diagnosis-Related Groups) scheme, applied mainly in the USA for payments to health facilities, is an example of type 3 guidelines. Efforts to introduce a DRG equivalent have been made in the Czech Republic since the 1990s with significant public financial backing but they have not been implemented into practice. A body that is active in the area of the implementation of DRG in the Czech Republic is the National Reference Centre (“Národní referenční centrum”) (http://www.nrc.cz), an interest group of legal entities, which also administers the National Sets of Health Service Standards register (https://kvalita.nrc.cz).
Existing Guidelines

This section will attempt to clearly outline the existing guidelines in the Czech Republic, in particular those pertaining to services for drug users and persons with an addiction.

Training Guidelines

As mentioned above, the guidelines of this type specify what qualifications, knowledge, and skills a person competent to perform “good practices” should possess. The standardisation of education and training has been achieved in the greatest detail in medicine through the system of university curricula and the content of the postgraduate specialisations, subspecialisations, and microspecialisations, a system which is embedded in health care legislation. The Czech Republic does not differ from other developed countries in this respect. Where it differs in a positive manner is the inclusion of addiction disorders and their treatment in the curriculum for students of medicine and for beginning physicians. The mandatory content of the graduate and postgraduate studies, which is generally considered insufficient in the Czech Republic, is well above the European average (Vermeulen et al. 2003). The Czech Republic is also one of the few countries in Europe where a medical specialisation in the field of addictive diseases exists, which has been the case since as early as 1980 (for additional information see the 2008 Annual Report). However, the interest in the specialisation is not great, and it is also impossible to guarantee that the specialised physician will master the psychosocial interventions required in practice.

The above-mentioned shortage of specialists should be compensated for by the new profession of an addiction specialist – addictologist (a Bachelor’s study programme at the First Faculty of Medicine of Charles University in Prague since 2005; a follow-up Master’s programme is being prepared from 2010). The curriculum of this major is based on the “bio-psycho-social” concept of the WHO and on the integrated interdisciplinary model of training promoted by the Council of Europe at the turn of the century. In this form, i.e. as a non-medical specialisation in health care, addictology is most probably unparalleled anywhere in Europe. The addictologist-physician and the addictologist-non-physician are foreseen as constituting two of the professional pillars of the addiction treatment services in the Czech Republic in the future.

Another profession applicable to services for drug users and persons with an addiction (specifically those falling within the sector of social services) is that of the social worker (for details see the 2008 Annual Report), whose official definition is vague and broad, though. We have no knowledge of any training guidelines qualifying a “social worker” to perform good practices in facilities for drug users.

Guidelines for Centres, Facilities, and Programmes

These types of guidelines are well-developed in the Czech Republic but their direct impact on good practices in services for drug users and persons with an addiction is difficult to assess because this is where the departmental and interdepartmental approaches meet (and collide).

The Ministry of Health formulates the basic requirements for different forms of health care facilities through legal standards, and its extensive programme for quality and safety in health care also specifies the quality standards for hospitals and treatment facilities, which are assessed by the Joint Accreditation Commission, a public service organisation, under the accreditation process (accreditation standards for hospitals, for long-term care, etc.). These quality standards correspond with the internationally recognised accreditation standards for health care quality and safety and with the requirements of the EU. They focus on the quality and safety of care in the broader sense. They undoubtedly stimulate quality in departments or separate facilities for addiction treatment. The Ministry of Labour and Social Affairs has prepared its Standards for Quality in Social Services, which are binding for most non-health services for drug users and persons with an addiction, which,

---

6 European Drug Abuse Treatment Training Programme, Drug Demand Reduction Staff Training Programme. See also Miovský et al., 2009.
7 Procedures in the area of care and care quality management, in particular care availability and continuity; organisation of patient examinations and treatment; operational rules; qualified staffing; lifelong education; record keeping and other administrative, management, and organisational parameters; sanitary and epidemiological aspects; the security, rights, and safety of patients, etc.
according to the law\textsuperscript{9}, fall into the category of social services. However, their impact on quality is not very stimulating because they do not greatly respect the specific professional focus. Nevertheless, the fulfilment of the standards, verified by the audit process, is a prerequisite for funding from the subsidies of the Ministry of Labour and Social Affairs (see below).

The Government Council for Drug Policy Coordination has introduced the Standards of Professional Competency for Facilities and Programmes Providing Professional Services to Problem Substance Users and Persons with a Substance Addiction, the so-called Certification Standards (Kalina K. et al., 2003). The standards are verified through a certification process. They are of an interdepartmental nature, spanning a wide range of health, social health, and social services, and their original ambition was to bridge the interdepartmental interfaces. Even though the Certification Standards reflect the professional specifics, as well as the more general areas of quality, they have failed in the competition with the departmental policies and their fulfilment is only a requirement for entry into the grant systems of the Government Council for Drug Policy Coordination and of certain regions. The Certification Standards are discussed in detail in Section 0 (p. 18). However, their justified inclusion in guidelines of this type also indicates that they are not typical treatment guidelines as understood by the EMCDDA.

It needs to be stated in this category that the Ministry of Education, Youth, and Sports has prepared guidelines for drug use/abuse primary prevention programmes (Ministerstvo školství, mládeže a tělovýchovy, 2005). These guidelines are formally inspired by the Certification Standards of the Government Council for Drug Policy Coordination, and the certification process is also similar. Certification is a precondition (although not the only one) for obtaining a subsidy from the departmental budget.

Case or Diagnosis-Based Treatment Guidelines

As stated above, this is a crucial issue, and therefore a vexed one, in the entire circle of quality assurance. There are not many optimum models. From the professional perspective, the basic requirements for the drafting of the guidelines include: (1) an evidence-based approach; (2) the broad involvement of professionals, and (3) the consensus of the relevant professional community. In the area of addictions, the guidelines from the United Kingdom or the proposals of the Hamburg team of Professor Haasen drafted for the European Commission can be considered examples of achievable guidelines (Department of Health (England) and the devolved administrations, 2007; Haasen et al., 2008).

The development of these guidelines for professional treatment in the Czech Republic is a long-term process, which requires the necessary active participation of all the institutions involved. The responsibility for these guidelines in the individual areas lies with the professional communities who are members of the J. E. Purkyně Czech Medical Association. In order to ensure that a consistent methodology is applied in the preparation of the national guidelines, the Ministry of Health has established the Professional Forum for the Preparation of Treatment Guidelines and the Concentration of Selected Highly Specialised Care\textsuperscript{10}. Over 300 so-called diagnostic and treatment standards have been prepared, covering various acute and sub-acute conditions, in particular those in somatic medicine. As part of these initiatives, the Psychiatric Association of the J. E. Purkyně Czech Medical Association has formulated a set of the so-called “recommended procedures” for various diagnostic areas in psychiatry.

The Recommended Treatment Procedures for Addiction Disorders and Pathological Gambling (Nešpor, 2010), which follow up on the similar recommended procedures of the Psychiatric Association from 2006, form a component of the set (Popov and Nešpor, 2006). The new version of the Recommended Procedures was prepared without the knowledge and participation of the Society for Addictive Diseases of the J. E. Purkyně Czech Medical Association. Certain members of the Committee of the Society for Addictive Diseases have expressed their significant reservations.

\textsuperscript{9} Act No. 108/2006 Coll. on social services.

regarding the *Recommended Procedures* (Jeřábek, 2010; Kalina, 2010). The *Society for Addictive Diseases* is preparing its own guidelines based on the prior activities in this field\(^\text{11}\).

**Guidelines for Methods**

An evidence-based approach and the consensus of the professional community again represent the basic requirements. In the area of addiction treatment, good examples include the British set of guidelines for psychosocial interventions or the guidelines for substitution procedures published by the *WHO* (NICE, 2008; WHO, 2009).

In essence, the only guidelines of this type in the area of addictology also concern substitution. The first version of the Substitution Treatment Standard (Ministerstvo zdravotnictví ČR, 2008) of 2001 was prepared at the dawn of the development of substitution programmes in the Czech Republic. A major amendment to the Standard is currently being considered in order to sufficiently reflect upon the current developments in substitution programmes, as well as the “sample” substitution treatment guidelines of the *WHO* (2009). A comparison of the Substitution Treatment Standard with the criteria of the *WHO* guidelines is provided in Table 0-1. However, no matter how good the guidelines, they cannot ensure good practices if there is an absence of control, which is the case in the area of substitution in the Czech Republic.

**Ethical Guidelines**

The “good practices” must necessarily include ethics, which, however, appears to be the Cinderella in quality assurance. The guidelines for centres, facilities, and programmes always discuss the rights of the patients in detail but often overlook the fact that each such right must also be based on an ethical obligation on the part of the provider. Ethical issues are often neglected, even in the specific professional guidelines. The codes of ethics of different professions and professional communities and their own control mechanisms (ethics committees etc.) seem to be put aside. Even though ethical standards of various professions and specialisations operating in the drug services do exist in the Czech Republic, the level of ethical awareness is rather low and sensitivity to ethical problems is increasing only slowly. It is therefore interesting that, as early as in the mid-1990s, a code of ethics was implemented in the Czech Republic in the therapeutic communities for addicts\(^\text{12}\) and has spread, with certain modifications, into other services. Even the *Certification Standards* make reference to this code of ethics and require the certified facility to ensure awareness of the code and adherence to it\(^\text{13}\) (the Standards classify this item as “required”).

---

\(^{11}\) For example, the area of dealing with acute conditions has been previously addressed (Dvořáček, 2003), and there is publication and research support available for the area of therapeutic communities for addiction treatment.

\(^{12}\) It originated from the World Federation of Therapeutic Communities (WFTC).

\(^{13}\) A-General, Section 5.11.
Table 0-1: The comparison of the Substitution Treatment Standard with the criteria of the WHO guidelines.

<table>
<thead>
<tr>
<th>WHO guideline recommendation</th>
<th>Included in the Czech guidelines?</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Choice of treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most opiate/opioid-dependent patients should be advised to use opioid agonist maintenance treatment as the pharmacological method of choice.</td>
<td>No</td>
<td>Substitution therapy is specified as the method of second choice for patients who are objectively or subjectively incapable of undergoing treatment without opioid agonists.</td>
</tr>
<tr>
<td>For patients not commencing opioid agonist maintenance treatment, antagonist pharmacotherapy following the completion of opioid withdrawal should be considered.</td>
<td>No</td>
<td>The Czech guidelines do not address any other types of therapy, i.e. also no opioid antagonist pharmacotherapy.</td>
</tr>
<tr>
<td><strong>Opioid agonist maintenance treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine.</td>
<td>No</td>
<td>The Czech guidelines do not address this issue.</td>
</tr>
<tr>
<td>During methadone induction, the initial daily dose should generally not be more than 20 mg, and certainly not more than 30 mg.</td>
<td>No</td>
<td>The initial daily dose is set at 5-10 mg for patients with a lower tolerance and 20-40 mg for patients with a higher tolerance.</td>
</tr>
<tr>
<td>On average, methadone maintenance doses should be in the range of 60-120 mg per day.</td>
<td>n. a.</td>
<td>The average dose is not specified. It is determined on an individual basis. The usual dose is 60 to 100 mg per day but the necessity of administering a multiple of the recommended dose has been reported in individual cases or under specific circumstances (e.g. in the case of a concurrent antiretroviral therapy).</td>
</tr>
<tr>
<td>Average buprenorphine maintenance doses should be at least 8 mg per day.</td>
<td>No</td>
<td>The lowest therapeutic dose is set at 4 mg per day or 8 mg every other day, respectively.</td>
</tr>
<tr>
<td>Methadone and buprenorphine doses should be directly supervised in the early phase of treatment.</td>
<td>Yes</td>
<td>Supervision for at least 2 hours following the administration is required.</td>
</tr>
<tr>
<td>Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review.</td>
<td>No</td>
<td>The continuous review of the patient does not expressly mention this specific aspect.</td>
</tr>
<tr>
<td>Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence.</td>
<td>Yes</td>
<td>Four types of substitution therapy are defined, three of which include psychosocial or social support/counselling as standard. Such support is not included only in the short-term emergency administration (hospitalisation for other illnesses, etc.).</td>
</tr>
<tr>
<td><strong>Management of opioid withdrawal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used.</td>
<td>Yes</td>
<td>Opioid withdrawal schemes using opioid agonists are specified as the method of first choice; alpha-2 adrenergic agonists are not mentioned in the guidelines.</td>
</tr>
<tr>
<td>Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal.</td>
<td>n. a.</td>
<td>The Czech guidelines only provide the withdrawal (detoxification) schemes and are not specifically a guideline for opioid withdrawal using substitution preparations. They specify the general interactions between the substitution substances and other pharmacological groups, including sedatives.</td>
</tr>
<tr>
<td>Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal.</td>
<td>n. a.</td>
<td>The Czech guidelines do not address this issue.</td>
</tr>
<tr>
<td>Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal.</td>
<td>n. a.</td>
<td>The Czech guidelines do not address this issue.</td>
</tr>
<tr>
<td><strong>Pregnancy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy.</td>
<td>Yes</td>
<td>Pregnancy is specified as a factor supporting entry into the treatment.</td>
</tr>
<tr>
<td>Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered.</td>
<td>No</td>
<td>The Czech guidelines do not address this issue (the authors do not consider such a recommendation appropriate/generalisable/evidence-based).</td>
</tr>
</tbody>
</table>
Development and Implementation Process

The Standards of Professional Competency for Facilities and Programmes Providing Professional Services to Problem Substance Users and Persons with a Substance Addiction (Certification Standards) were created in the period 1998-2003 on the basis of a previous document, the Minimum Standards issued and recommended by the then-existing interdepartmental National Drug Commission in 1995. The Minimum Standards were prepared by Pavel Bém, who was the Secretary-General of the National Drug Commission at the time, on the basis of documents from the WHO. They were accepted quite positively by the provider community, and the Association of Non-Governmental Organisations (A.N.O.), which was then established, adopted them with a view to becoming the accrediting association to guarantee the quality of the services of providers who are its members. This plan was never fulfilled because the opinion prevailed that it should be the state that should take over the process of standard certification, and that the verified quality of the service should be considered in the distribution of state grants. Despite many obstacles, the A.N.O. and the Secretariat of the National Drug Commission/Government Council for Drug Policy Coordination continued to work for a number of years on implementing the plan.

The project regarding the certification system was implemented under the alternating competence of the National Drug Commission/Government Council for Drug Policy Coordination and of the Ministry of Health, but always by a relatively coherent group of external experts led by Kamil Kalina. The guidelines prepared by this group were tested in pilot studies and discussed by the professional community in order to achieve a clear and widespread consensus and unquestionable compatibility between the certification standards and the simultaneously pursued efforts of the individual ministries, in particular the Ministry of Health and the Ministry of Labour and Social Affairs. In the last stage, the process for the verification of the standards, i.e. the certification of professional competency, was designed and established. The documents produced included the Certification Rules, accompanying manuals, a scoring system, and a set of templates for the standards. The first seminar was organised for the future certifying officers – practitioners. In 2005 the Government approved the entire certification system and authorised the Government Council for Drug Policy Coordination to award the certificates. The certification programme was launched in 2005. In terms of organisation, the certifications are supported by a third party (an NGO), the so-called certification agency. The on-site audits are conducted by a team of three trained certifiers, and the outcomes are discussed by the Certification Committee of the Government Council for Drug Policy Coordination, whose recommendations are used by the Government Council for Drug Policy Coordination to grant the certification. In 2005-2009, the certification was awarded for a maximum of 3 years.

An evaluation of the first stage of the evaluation process (2005-2006) was conducted and resulted in a number of suggestions for the modification of the process, standards, and scoring system. These suggestions were partially used in the amendment to the Certification Rules and to other documents applicable to the certification process. The desired innovation of the standards themselves and of the scoring scheme has not taken place. Neither has the specialised section been extended by additional types (suggestions for the dedicated standards

---

14 Now the Government Council for Drug Policy Coordination (GCDPC).
15 The terms “accreditation” and “accreditation standards” were used during the initial years.
16 At the time, they concerned the ISQua/JCIA criteria (Kalina K. et al., 2002).
17 As part of the PHARE Twinning CZ 2000/IB/H/03 Strengthening National Drug Policy project between the Czech Republic and Austria.
18 The rather complex scoring system was based on the then-existing accreditation scoring sheet of the Joint Accreditation Commission of the Czech Republic (for hospital accreditation).
19 Government Resolution No. 300 of 16 March 2005 regarding the proposed changes in drug policy funding.
20 The Centre for Quality and Standards in Social Services (CEKAS) of the National Training Fund performs the role of the certification agency under a contract with the Office of the Government of the Czech Republic; for additional information see http://www.cekas.cz/.
for drug services in prisons and for multipurpose outpatient facilities, respectively, have been considered for many years).

The current version of the standards is described in Table 0-2. Their general part (Part A) provides a comprehensive and detailed idea of “quality”. It consists of 12 sections and a total of 136 items, 42 of which are classified as “required”. The special standards for the 9 basic types of services, described in Part B, consist of 18-25 items, with 3-8 of them always classified as “required”\(^\text{21}\).

According to the scoring system, a facility must score at least 635 out of the available 815 points (80%) in the general part, of which 176 points must be obtained for the “required” items (28% of the minimum score). In the special part, a facility should score at least 125 out of the available 165 points (76%) on average for all the types of services, of which 25 points must be obtained for the “required” items (20% of the minimum score). The required items in the general part include, for example, staff training, independent supervision, and the evaluation of service efficiency.

<table>
<thead>
<tr>
<th>A – General</th>
<th>B – Special (“type” standards)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Availability of professional services</td>
<td>1. Detoxification</td>
</tr>
<tr>
<td>2. Patient/client rights</td>
<td>2. Outreach programmes (including syringe and needle exchange programmes)</td>
</tr>
<tr>
<td>3. Admission and initial assessment</td>
<td>3. Low-threshold and counselling services (including syringe and needle exchange programmes)</td>
</tr>
<tr>
<td>4. Range of services and principles of their provision</td>
<td>4. Outpatient treatment</td>
</tr>
<tr>
<td>5. Human resources</td>
<td>5. Day care programmes</td>
</tr>
<tr>
<td>6. Professional leadership and development of staff and teams</td>
<td>6. Short-term and medium-term institutional treatment</td>
</tr>
<tr>
<td>7. Accessibility, external relations</td>
<td>7. Residential care in therapeutic communities</td>
</tr>
<tr>
<td>8. Organisational aspects</td>
<td>8. Outpatient aftercare programmes (including sheltered housing and protected employment programmes)</td>
</tr>
<tr>
<td>10. Environment and physical resources</td>
<td></td>
</tr>
<tr>
<td>11. Minimum safety</td>
<td></td>
</tr>
<tr>
<td>12. Service quality and efficiency evaluation</td>
<td></td>
</tr>
</tbody>
</table>

Even though the dedicated standards in Part B specify in quite considerable detail what the relevant facility should do to meet the standard (including the application of the required or desired approaches), they cannot be considered “treatment guidelines” as understood by the EMCDDA. It was not the objective in the preparation of this set of standards to specify the procedures, and hence this dimension is completely absent. The inadequacy in this respect was shown by a study aimed at Standard B7 – Therapeutic communities (Kalina, 2007b). The study confirmed the pre-existing concern that facilities certified according to Standard B7 may not even be a therapeutic community within the meaning of internationally recognised criteria for a therapeutic community as an evidence-based treatment method. Therefore, an additional standard for B7 has been drafted, verified in a pilot project, and published, but has never seen use in the certification practice (Kalina, 2006). The same may apply to other dedicated standards in the certification dossier.

The original ambition of the certification standards was high: they were to become the actual “national guidelines” for the area of drug services, and meeting them was to be the prerequisite for access to any public funding (i.e. to subsidies from the state or the regions, as well as to payments from health insurance companies). However, their importance and value have been reduced in recent years because the departmental approaches have prevailed over the interdepartmental one. The certification is currently not recognised even by the Ministry of Health (it has its own criteria and mechanisms to evaluate quality in the health care sector) or the Ministry of Labour and Social Affairs (which has its own standards for quality in social services and for their verification as part of the inspection process). The certification is now only one of the requirements for access to subsidies from the Government Council for Drug Policy Coordination. In the distribution of subsidies, it is taken into consideration by Prague and by certain other regions. In the years 2009-2010, the

\(^{21}\) As far as aftercare programmes are concerned, additional partial standards and scoring systems are also provided for sheltered housing and protected employment, if applicable.
The certification system has struggled with a lack of funding and the certification audit process has already been suspended twice for that reason.

The Standards for Quality in Social Services and Their Relevance for Addiction Treatment Services

The Standards for Quality in Social Services of the Ministry of Labour and Social Affairs were drafted almost simultaneously with the Certification Standards of the Government Council for Drug Policy Coordination, with certain experts working in both teams. There was an effort on the part of the creators of the Certification Standards to achieve “tight compatibility”, which means that the Certification Standards contain all the fundamental components of the quality standards of the Ministry of Labour and Social Affairs. The opposite, however, does not, and perhaps even cannot apply because the ministry and its working groups prepared the standards for all the social services ranging from conventional homes for senior citizens and institutions for persons with physical or mental disabilities or those with sensory impairments to small non-governmental initiatives such as early intervention or crisis centres for children. The ministry made no secret of the fact that it was mainly seeking to improve the quality of the care provided in large institutions, where the quality level was often critical.

In comparison with the Certification Standards, the standards of the Ministry of Labour and Social Affairs are professionally less sophisticated, and they are also “only social”, which interferes with the required comprehensive and bio-psycho-social approach to services for drug users. A comparison of these two sets of standards using 13 aspects is shown in Table 0-3 (Kalina K. et al., 2002). As far as the dedicated standards for the individual types of social services are concerned, the Ministry of Labour and Social Affairs launched its activities in this field but eventually abandoned this large-scale project; the individual types are therefore briefly described in social legislation.

Table 0-3: Comparison of the Certification Standards and the Standards for Quality in Social Services (Kalina K. et al., 2002)

<table>
<thead>
<tr>
<th>Aspect of the Certification Standards of the Government Council for Drug Policy Coordination</th>
<th>Standards for Quality in Social Services of the Ministry of Labour and Social Affairs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Quality facility</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Comprehensive assessment of the client upon admission</td>
<td>Yes – differently</td>
</tr>
<tr>
<td>3. Evaluated and documented process of care</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Bio-psycho-social approach</td>
<td>No</td>
</tr>
<tr>
<td>5. Comprehensiveness of care</td>
<td>No</td>
</tr>
<tr>
<td>6. Continuity of care</td>
<td>Yes</td>
</tr>
<tr>
<td>7. Confidentiality of information</td>
<td>Yes</td>
</tr>
<tr>
<td>8. Minimum safety requirements</td>
<td>Partially</td>
</tr>
<tr>
<td>9. Client rights</td>
<td>Yes</td>
</tr>
<tr>
<td>10. Adequate team composition</td>
<td>Yes – differently</td>
</tr>
<tr>
<td>11. Staff training</td>
<td>Yes</td>
</tr>
<tr>
<td>12. Evaluation of efficiency</td>
<td>Partially</td>
</tr>
<tr>
<td>13. Mandatory content and scope of care depending on type</td>
<td>No</td>
</tr>
</tbody>
</table>

The standards of the Government Council for Drug Policy Coordination were endorsed only by a Government resolution, i.e. in the lowest and least binding legal norm, while the standards for social services are backed by a specific legal regulation\(^\text{22}\). The law also specifies the mechanism for their verification – through the inspection of social services, which is usually conducted by regional officials under the State Audit Act. The providers of services for drug users and the experts in the field have varying views of the impact of the social standards and inspection on the addiction treatment policy and specialisation previously implemented and achieved, respectively, in the area of drug services. Attempts by the Government Council for Drug Policy Coordination to achieve

\(^{22}\) Act No. 108/2006 Coll. on social services.
interdepartmental harmonisation of the standards have failed as the Ministry of Labour and Social Affairs continues to refer to the act on social services.

Summary of the Development of Certification Standards in the Czech Republic

The development of a series of guidelines and standards for agencies and programmes in the Czech Republic during almost the past 15 years, from the issue of the first Minimum Standards to the Certification Standards, can be seen as highly valuable for both the services and the professionals. The integrated and detailed description of the services has raised and unified the standard of services, made its way into publications, as well as the curricula of the discipline of addictology, inspired primary prevention standards, and initiated professional activities regarding other types of evaluation criteria, which should introduce additional aspects to the criteria\textsuperscript{23}, thus encouraging more publication, research, and training efforts.

On the other hand, it is apparent that there are significant gaps and excessive blank spaces in the Czech Republic in the core areas of treatment guidelines, diagnostic and treatment procedures, recommended evidence-based procedures, etc. With regard to the data provided in the preceding sections of this selected issue, there is a risk that even the Certification Standards, which are, quite rightly, considered the “family silver” of addictology, will lose their place and importance in the system of drug services.

Table 0-4 attempts to briefly analyse the current status in the area of quality assurance in services for drug users and addicts in the Czech Republic.

Table 0-4: Attempted SWOT analysis of the current status in the area of quality assurance in services for drug users and addicts in the Czech Republic.

<table>
<thead>
<tr>
<th><strong>Strengths</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Both medical and non-medical professional qualifications in the field exist</td>
<td></td>
</tr>
<tr>
<td>15 years of the stimulating impact of the Minimum/Certification Standards</td>
<td></td>
</tr>
<tr>
<td>Introduction of a professional certification process</td>
<td></td>
</tr>
<tr>
<td>Capability and willingness of the professional community to address quality and pursue professional development</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Weaknesses</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence-based diagnostic and treatment guidelines are absent or inadequate</td>
<td></td>
</tr>
<tr>
<td>Uncoordinated initiatives, many existing methodologies and evaluation tools are not utilised</td>
<td></td>
</tr>
<tr>
<td>Insufficient funding of research and development</td>
<td></td>
</tr>
<tr>
<td>Poor assurance and insufficient control of adherence to procedures, e.g. in substitution</td>
<td></td>
</tr>
<tr>
<td>Fragmentation of interdepartmental and departmental approaches; certification standards are pushed aside by departmental schemes</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Opportunities</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The new Action Plan of the Czech Republic includes the creation of diagnostic and treatment guidelines and other innovative measures</td>
<td></td>
</tr>
<tr>
<td>Increasing opportunities for the involvement of addictology students and graduates in projects concerning quality</td>
<td></td>
</tr>
<tr>
<td>A programme is being formulated to link research and practice in addictology</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Threats</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient funding may reduce service quality</td>
<td></td>
</tr>
<tr>
<td>The certification system of the Government Council for Drug Policy Coordination may cease to exist</td>
<td></td>
</tr>
<tr>
<td>The specific (drug) specialisation may be weakened in services falling within the social sector</td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{23} E.g. the list and definitions of the interventions pursued in addictology, the so-called Minimum Evaluation Set (Národní monitorovací středisko pro drogy a drogové závislosti, 2006); the above-mentioned standard for a therapeutic community as a method; the drafting of the main performance indicators (Russel, Hrdina, Kalina, and Kuda, incomplete and unpublished); the cost-effectiveness criteria for the grant procedures of the Government Council for Drug Policy Coordination, etc.
DENMARK

National guidelines for the treatment of drug use

In recent years, focus has been on quality development of drug use treatment in Denmark. The reason has been a wish to develop effective treatment methods and secure treatment quality. In this connection, there has been increasing focus on requirements governing documentation and quality provided to citizens, administrators and politicians. This theme chapter provides a description of the development of national guidelines in drug use treatment in Denmark as part of this quality development.

From disagreement to agreement

Throughout the years, the drug use area has been characterized by very diverging ideas of treatment interventions and thus also lacking consensus on goals for treatment effect. The lack of defined treatment services and references has contributed to difficulties in defining the professional understanding of treatment effect. In spite of a large volume of scientific literature within drug use, practice has often been far away from scientific evidence. Useless and varying recording methods in terms of treatment interventions have also made everything more complicated.

Therefore, there is an increasing need for establishing an overall content description of the various treatment interventions, for consensus on quality goals of treatment and for uniform recording principles in order to perform a qualified assessment of practice.

The medical treatment of opioid addicts is primarily made in the municipal drug use treatment systems and is assumed to be an integral part of each municipality’s overall treatment and care services provided to drug users. Medical treatment of drug users is carried out in general practice, in hospitals and within the Danish Prison and Probation Service. The medical treatment of drug use has been characterised by much variation, one of the reasons being the different backgrounds of the doctors and the different organisational structures involved.

Also substitution treatment of opioid addicts in Denmark has been characterised by the same variation, in clinical practice as well as in treatment results. The Government’s drug action plan from 2003 “The Fight against Drugs” thus stipulated the importance of strengthening medical treatment intervention in drug use treatment. In order to retain and expand the existing treatment intervention, an amount of DKK 3 mill (EUR 0.4 million) was set aside under the social reserve agreement for 2004 for the completion of quality assurance and development of substitution treatment. Following this, the National Board of Health launched a proactive investigation of the overall medical treatment of drug users in substitution treatment. The outcome was new professional guidelines for medical treatment of drug users in substitution treatment.

The purpose of the guideline is to contribute to reducing morbidity and mortality among drug users and improve the drug user’s quality of life as well as reduce the use of illicit drugs. Another purpose of the guideline is thus to support and strengthen overall intervention using guidelines for the substitution treatment itself and a description of the medical core services related to the treatment. The contents of the guideline are described below.

As regards national guidelines and guidance for the social element of drug use treatment, guideline 4 on the Act on Social Services (VEJ #95 of 5 Dec 2006) describes the type of treatments that should be included in the municipal intervention for drug users, ie inpatient and outpatient services, and that the planning of treatment services should provide services to all drug users. Furthermore, the guideline also includes provisions and objectives for re-integration and after-treatment as well as drug relapse treatment.
Furthermore, the National Board of Social Services has prepared a methodology book for professionals working with drug users, "Stofmisbrug i socialfagligt perspektiv" (Drug Use in a Social Perspective) and the pamphlet "God sagsbehandling på stofmisbrugsområdet" (Good case handling within drug use) which addresses case handlers. The main objective is to ensure correct case handling and legal safety for the citizens. The aim of the pamphlet is also to act as a daily working tool to brush up applicable rules and good practice in specific situations within municipal administration or at the drug use centre. The Danish National Centre for Social Research (SFI) has described the social treatment of drug use in the report "Den sociale stofmisbrugsbehandling i Danmark" (Social Treatment of Drug Users in Denmark).

Guideline in medical treatment of drug use

According to the Danish Authorization Act (Ministeriet for Sundhed og Forebyggelse [the Ministry for Health and Prevention] 2006), a doctor must practice medicine carefully and conscientiously. The purpose of the guideline is to specify the National Board of Health's requirements for medical diligence and conscientiousness in connection with the medical treatment of opioid addicts in substitution treatment.

The guideline is a specification of the rules already in force for the medical treatment of drug use. Although the same, the professional guidelines provide for the medical substitution treatment with buprenorphine and methadone. As a new feature of the guideline, the professional guidelines are described in more detail in terms of diagnostic assessment and treatment of drug use, including polydrug use, diagnostics and treatment of somatic comorbidity resulting from drug use, including HIV and hepatitis, assessment of and general principles the treatment of mental comorbidity, principles governing prevention of unwanted pregnancy and handling of pregnant drug users as well as the use of urine sampling when treating drug users. Also, the guideline contains a section about the regulatory and organisational framework for treatment as well as a section on patients' rights.

The target group and contents of the guideline

The guideline aims primarily at doctors who are responsible for substitution treatment of opioid addicts in the municipalities. The medical treatment of drug use comprises, apart from specific diagnostics and treatment, also diagnostics and treatment of comorbidity which involves many specialities, such as psychiatry, infectious medicine, traumatology, obstetrics/gynaecology, etc. The guideline describes the medical tasks in the municipalities in relation to handling of the often multifaceted comorbidity resulting from drug use which comprises general diagnostics and treatment of the above disease areas, including coordination of the necessary treatment in general practice and on a specialist level.

The guideline also addresses any doctor treating a drug user as a patient and other health care professionals as well as municipal and institutional administrators who are engaged in treatment of drug users.

The background and follow-up of the guideline

The guideline was prepared by the National Board of Health during the period 2005-2008. It was prepared on the basis of the current international and national scientific evidence and best knowledge within the area. During the process, core areas were defined, existing knowledge and experience was obtained, structure and content, etc was drawn up.

The provisions of the guideline include the overall general practice for the medical treatment of drug users in substitution treatment. If a doctor assesses that in this specific case there is a need for treating a patient outside the framework of the guideline, this must be explained in detail and documented in the patient's medical chart.
The National Board of Health has distributed the guideline to all municipalities in Denmark, the regions, hospital managements, the Danish Prison and Probation Service, etc and has asked the receivers to make sure that all relevant doctors in treatment institutions, departments, etc are informed about the guideline. The guideline has been printed in a hardback version and distributed to all municipalities, municipal drug use institutions, regions, the Danish Prison and Probation Service, etc. Furthermore, the guideline is presented and discussed in meetings held at treatment facilities and presented at conferences dealing with drug use.

Documentation and follow-up on the guideline
As a follow up on the guideline no. 42 on the medical treatment of drug users in substitution treatment of 1 July 2008, it was imposed on the National Board of Health to establish a quality assurance tool in the form of a recording and reporting scheme. Based on the 10 indicators of medical core services, the National Board of Health will establish a quality assurance tool by the end of 2010, when the municipalities in the form of annual electronic reporting to the National Board of Health will record activities on a local basis. By using this reporting system, the municipalities as well as the National Board of Health will gain an overview of the medical treatment within the area, and furthermore generate a possibility for proactive quality assurance of health care intervention targeted at drug users. The National Board of Health will annually give feedback on the reported data, hold an audit meeting with a view to discussing data, and the municipalities will be given access to data with a view to ongoing benchmarking.
GERMANY

History, methods and implementation of national treatment guidelines

In Germany there are guidelines from various institutions, organisations and scientific medical societies. Problems in demarcating the borderlines between terms such as standards, guidelines and regulations/rules, overlapping of the actual content and differences in bindingness and relevance to the field of practice all combine to produce a very heterogeneous overall picture when it comes to “guidelines”.

The guidelines examined in this chapter can be broken down into three types. (I) guidelines are developed by scientific medical societies in accordance with the definition of treatment guidelines which is also used by the EMCBDDA. Work began on the preparation of treatment guidelines for substance-related disorders in 2000 under the umbrella of the Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften - AWMF). The treatment guidelines of the Association of Scientific Medical Societies in Germany are developed in a standardised procedure based on the scientific state of knowledge. (II) In addition to these treatment guidelines, there have been regulations and rules on substitution treatment from the German Medical Association (BAEK) since 2001. Among other things, these are intended for the purpose of helping achieve a manageable implementation of different legal prerequisites (from the Narcotics Act, the Amending Regulation on the Prescription of Narcotic Drugs und the Medical Products Act). As regulations and rules these have a greater binding effect and are of considerable relevance to the field of practice in Germany. In terms of their actual content, they overlap with the treatment guidelines of the Association of the Scientific Medical Societies in Germany. (III) The German Statutory Pension Service (DRV) developed “Guidelines on Rehabilitation Needs in Cases of Dependency-Related Illnesses” (Leitlinien zur Rehabilitationsbedürftigkeit bei Abhängigkeitserkrankungen) for the first time in 2003. They are highly relevant to the field of practice in terms of quality assurance for rehabilitation services which are financed by Statutory Pension Insurance.

The three types are first of all presented in this chapter. In the institutional background to the respective histories of guidelines past and present are discussed. The discussion within the community of informed persons and specialists who have supported the development of guidelines is also briefly outlined. A description of the guidelines themselves is provided in along with several comments on the further development of existing guidelines. Finally, addresses implementation, implementation strategies and impediments. By the same token, it will be taken into account in what contexts the respective guidelines bear relevance to areas of actual practice.

History and overall framework

Guidelines of the Association of the Scientific Medical Societies in Germany (AWMF)

The Association of the Scientific Medical Societies in Germany (AWMF) was founded as a non-profit association in 1962 by 16 societies at the time. The area of tasks of the Association of the Scientific Medical Societies in Germany, which has 153 scientific societies as members at present, includes tasks such as quality assurance the profession of physician or the electronic publication of scientific literature. Upon the instigation of the “Sachverstaendigenrats fuer die Konzertierte Aktion im Gesundheitswesen” (“Council of Experts for Concerted Action in the Health Sector”), the Association of the Scientific Medical Societies in Germany has been coordinating the guidelines for diagnostics and therapy through the individual scientific medical societies since 1995.

Guidelines are understood to mean “systematically developed statements to support decision-making by physicians and if need be by other health professions and patients to promote an appropriate approach to existing health problems” (AWMF & AEZQ 2008). Together with the

---

24 See AWMF Online: http://www.awmf-online.de/
AErztliche Zentralstelle fuer Qualitaetssicherung (AEZQ – “Physicians’ Central Office for Quality Assurance”), the Association of the Scientific Medical Societies in Germany has developed the “German Instrument for Methodical Assessment of guidelines (DELBI)”, which was published for the first time in 2005 and replaced the checklist “Methodical Quality of Guidelines (“Methodische Qualitaet von guidelines”) from 2000. On top of additional manuals of the Association of the Scientific Medical Societies in Germany for the development of guidelines, the instrument is intended to support quality assurance in the development of guidelines (AWMF & AEZQ 2008; AWMF Online: http://www.awmf-online.de/).

Under the umbrella of the Association of the Scientific Medical Societies in Germany, treatment guidelines for substance-related problems have been developed since September 2000, with the two scientific medical societies “The German Society for Research on Addictions” (DG-Sucht) and “Deutsche Gesellschaft fuer Psychiatrie, Psychotherapie und Nervenheilkunde e.V. (DGPPN – “The German Society for Psychiatry, Psychotherapy and Neuropsychiatry”) in charge. Depending on the subject of the guidelines, additional scientific societies and experts are included in the development process.

Guidelines of the Association of the Scientific Medical Societies in Germany are developed in a 3-stage procedure in accordance with “methodical standards for the development of evidence-based guidelines in Germany”. Guidelines based on an informal consensus of an expert group are described as development level S1 guidelines. Non-systematic summarisation work which is based on a formal consensus procedure and which members of several groups are involved in are described as development level S2 guidelines. A systematic research of evidence is labelled development level S3 (Helou et al. 2000; Schmidt & Gastpar 2006).

The current status of substance-related treatment was published in 2006 (Schmidt & Gastpar 2006). The guidelines have the development status of level 2 (on the further development of the guidelines at present, see chapter 0). In addition to the substance-related treatment guidelines on “Cannabis-related disorders”, “opioid-related disorders” (acute treatment and post-acute treatment), “physical and behavioural disorders due to cocaine, amphetamine, ecstasy and hallucinogens” and “medication dependency (sedatives, hypnotics, analgesics and psycho-stimulants)”, the publications also contain treatment guidelines on the substances of alcohol and tobacco.

The guidelines of the Association of the Scientific Medical Societies in Germany have a limited period of validity. The applicability of the Guidelines on the Treatment of Substance-Related Disorders expired at the beginning of 2010. The revision of the guidelines had not yet been completed at the time when this report was compiled. No point in time has been set for their completion (on the further development of the guidelines see chapter 0). In this special chapter, the most recent guidelines of the scientific medical societies, which were valid until the beginning of the year, are nevertheless taken into account in the national reporting to the EMCDDA.

Substitution regulations and rules of the German Medical Association

In its capacity as peak organisation of the system of physicians’ self-administration, the German Medical Association (BAEK) represents the professional interests of physicians in the Federal Republic of Germany. A majority of substitution treatments in Germany are performed by physicians in private practice.

The German Medical Association was assigned by lawmakers the task of drafting rules and regulations for substitution treatment in accordance with the generally recognised state of medical knowledge for the first time in 2001 through the 15th Amending Regulation on Narcotic Law (Betaeubungsmittelrechtsaenderungsverordnung, BtMAEndV). The “Rules and Regulations on the Performance of Substitution-Supported Treatment of Opiate Addicts” was submitted for the first time in 2002. The latest revision from 2010 takes into account the statutory foundations, which changed

25 Under statutory provisions, substitution treatment can only be performed by physicians who comply with the minimum requirements applying to addiction therapy qualifications, see chapter 0.
in 2009 as a result of the 23rd BtMAEndV) and the Act on Diamorphine-Supported Substitution Treatment (BAEK 2010).

In this case, the guidelines are not treatment guidelines, but rather rules and regulations of the German Medical Association. Because these are of tremendous importance to the treatments in the field of practice, however, they are nevertheless examined in this special chapter.

**History of the guidelines of German Statutory Pension Insurance (DRV)**

Under German social security law, German Statutory Pension Insurance (DRV) finances rehabilitation measures for people suffering from substance abuse disorders. The reason for the responsibility of Statutory Pension Insurance is that rehabilitation measures help enable people to return to work and thus aim to return people insured under statutory pension schemes to employment. Because this insurance is mandatory, every employee has pension insurance. The rehabilitation measures carried out for addicts, in particular alcoholics, accounted for 6% (56,393 rehabilitations for people with addiction illnesses) of all payments for medical rehabilitation (903,257) by Statutory Pension Insurance in 2007, while costs related to rehabilitation of addicts accounted for 18% (EUR 469 m. out of EUR 2,675 m.) of total costs of medical benefits from Statutory Pension Insurance (Beckmann et al. 2009b).

Statutory Pension Insurance commenced projects to develop rehabilitation process guidelines in 1998. In this context guidelines are understood as “systematically developed decision-making aids for care providers and patients on the proper procedure in the case of special health problems” (Brueggemann et al. 2004; Brueggemann & Klosterhuis 2005).

Guidelines were developed in four phases, beginning with an analysis of the literature. This was followed by a comparison of the actual with the current situation in order to determine needs (the so-called “KTL-Analyse”), the development of process guidelines and implementation. The first version of the “guidelines on the need for rehabilitation in the case of persons suffering from addiction illnesses” was developed in 2003. The current version was issued in 2005 (on the current further development of the rehabilitation guidelines of German Statutory Pension Insurance see 0).

As process guidelines, the rehabilitation guidelines are of major importance to the field of practice. In spite of the same term – “guidelines” – being used, a distinction needs to be made between these process guidelines and the treatment guidelines of the Association of the Scientific Medical Societies in Germany (Koch 2006). The guidelines are orientated towards rehabilitation clinics and treatment facilities, setting out the framework conditions for them. Actors involved in treatment (for example, medical personnel, therapists and social workers) are thus the target group/users of these guidelines. The guidelines stipulate what elements of treatment are to be granted in what scope to what percentage of patients. This thus places the focus on adherence to minimum standards at institutions.

**Discussion on the development of guidelines**

The development of guidelines which relate to the treatment of substance-abuse illnesses in Germany is accompanied by discussions by the informed public and experts over aspects such as the demarcation between the terms “guidelines”, “standards” and “rules and regulations” (Flenker &

---

26 The Pensions Regulatory Authority is responsible for substance abuse treatment if the prerequisites for §§ 9 – 11 Social Code VI have been met. If the requirements set out in §§ 27 and 40 Social Code V have been met, the health insurance schemes are responsible for substance abuse treatment (DRV 2005).

27 The Federal Pension System for Employees (Bundesversicherungsanstalt fuer Angestellte - BfA), which started up the guidelines programme in 1997, was merged with the Verband Deutscher Rentenversicherungsträger (VDR) in 2005 to form German National Statutory Pension Insurance (Deutsche Rentenversicherung Bund - DRV).

28 KTL-Analyse: The classification of therapeutic services is a directory of therapeutic services compiled by the BfA (now the German National Statutory Pension Insurance - DRV) which can be performed in medical rehabilitation. The results of literature research, formulated as an evidence-based therapy module, are compared as treatment target with the actual condition (illustrated in the approval reports which have been submitted to the Bundesversicherungsanstalt fuer Angestellte (now German Statutory Pension Insurance)).
Bredehoeft 2002), methods for developing guidelines, the applicability of guidelines and generally speaking quality assurance in the area of treatment of substance abuse disorders (see Kuhlmann 2006; Schmidt & Gastpar 2002; Weissinger & Schneider 2006). The limits of application possibilities for evidence-based medicine for everyday practice, the degree to which studies conducted in countries with different health-care structures can be applied to Germany, the degree to which findings from selected populations in studies and studies settings can be applied to patients in everyday practice and the advantages of guidelines as systematically developed aids in decision-making for care providers with regard to an appropriate mode of procedure with the given problems are topics which are discussed. In this context it is frequently pointed out that the development of guidelines also has to involve a consensus among experts, at least as a low level of evidence (Schmidt et al. 2006; Fleischmann 2006; Koch 2006; Kuhlmann 2006; see. Lindenmeyer 2006; Weissinger & Schneider 2006).

The relevance of guidelines to the field of practice will probably become a subject of discussion once again as a result of the further development29 of the guidelines of the Association of the Scientific Medical Societies in Germany at the development level with the highest degree of evidence “S3”. It would thus appear, for example, that certain criteria for excluding study populations in clinical studies (for example comorbidity) are more the rule than they are the exception in the field of practice. On the other hand, these study results are a basic prerequisite for basing guidelines on a high level of evidence (German Centre for Addiction Issues (DHS), personal communication 2010).

**Existing guidelines: narrative description of existing guidelines**

**Opioid-related disorders: acute treatment**

The latest guidelines of the Association of the Scientific Medical Societies in Germany on acute treatment in cases involving opioid-related disorders were published in 2006 in “Evidenzbasierte Suchtmedizin” (“Evidence-Based Addiction Medicine”) (Reymann & Gastpar 2006). These guidelines were first published in 2002 in the journal “Sucht” (Reymann et al. 2002).

**Definition and aims**

The objective in the treatment of treating opioid-related disorders is to ensure survival, the prevention of long-term damage to health, permanent abstinence from the use of illegal opioids and overcoming possible disorders which the addiction might be based on.

The acute treatment of opioid problems ranges over the following medical measures: the treatment of acute intoxication (detoxification), the treatment of physical withdrawal symptoms (withdrawal treatment) in reducing or discontinuing the substance, the encouragement of motivation to become abstinent, support of the motivation to make use of post-acute treatments, the termination of other possible dependencies, including medication or alcohol and the diagnostics and treatment of secondary psychiatric and somatic illnesses and the containment of negative social effects as a result of the addiction. The guidelines lay down an 8-week period of treatment.

**Diagnostics**

With regard to diagnostics, the guidelines contain recommendations for the case history (for example the recording of the history and pattern of consumption as well as consumption of other substances and concomitant illnesses), psychiatric examinations (in particular a record of symptoms from intoxication, withdrawal and delirium), the physical examination (e.g. examination for injection track marks, abscesses and dermatological infections), the diagnosis of withdrawal syndrome and for laboratory examinations (a comprehensive drug screening is recommended as well as testing for hepatitis viruses and HIV).

---

29 See chapter 0.
The treatment setting

Acute treatment can be provided on an outpatient basis or in day clinic addiction medicine settings. Reasons against an outpatient treatment include, for example, complications in withdrawal, suicidal tendencies, polytoxicomania as well as reasons relating to the social environment or the prior addiction history of the patient. If such reasons are present, fully inpatient treatment is performed.

Need for and planning of treatment

In the case of an acute, severe opiate intoxication, emergency medical measures should be taken. It is recommended that naloxone be used to antagonise a respiratory depression. In addition to the diagnosis of somatic and psychiatric comorbidity, collateral social damage and legal aspects should be included in the treatment planning. This necessitates a setting with support from social workers. In order to ensure the success of treatment, the motivation and in some circumstances the motivation of the patient is important. Post-acute treatment should follow upon acute treatment directly.

Pharmacotherapy of the withdrawal syndrome

Withdrawal without the administration of medication is only appropriate if the patient himself desires this. Treatment with the support of medication is generally administered with an µ-opiate receptor antagonists, with dosages then being reduced gradually. Generally speaking it is recommended that D,L methadone by taken orally. If there is evidence that the patient does not tolerate this, levomethadone can be used. Buprenorphine can also be used to treat opioid withdrawal syndrome and is superior to methadone in cases involving severe depression. Clonidine can be used in Germany in inpatient treatment of withdrawal. If it is administered in combination with methadone, treatment is only supposed to occur after withdrawal from methadone. Deepen can also be used, but has considerable side-effects. It cannot be used at the same time with Clonidine.

The treatment of withdrawal symptoms with opiate antagonists (naloxone and naltrexone) is only recommended if the patient is under general anaesthesia or deep sedation or this treatment is expressly desired or several conventional attempts at withdrawal have failed. This treatment should generally speaking not be used, as withdrawal symptoms and problems with the general well-being can be long-lasting and low compliance for a follow-up treatment is to be expected.

Dosage and period of application

The guidelines contain recommendations on the dosage and how long it is to be applied. With opioid-supported withdrawal using methadone or buprenorphine, the initial dosage is first determined. The dosage is reduced step by step or digressively in the course of the withdrawal treatment. The treatment of the withdrawal syndrome with medication being gradually reduced can last several weeks in an outpatient setting, while in an inpatient setting only 10 days can already be sufficient.

Withdrawal with the support of Clonidine can be used after the opiate effect tapers off or following methadone substitution in order to treat withdrawal symptoms. Following the withdrawal phase, a naltrexone treatment can be used in order to support the abstinence of the patient.

Information of patients and psychotherapy

It is recommended that patients be informed about risks and dangers during the treatment. Patients should be informed that a loss of opiate tolerance increases the risk of overdose if they consume opiates again. Patients should be informed about health and infection risks associated with intravenous consumption, as they should about possible vaccinations against hepatitis B and the treatment of hepatitis C. The patients should be encouraged to avoid consumption of alcohol or taking benzodiazepines prior to an injection and the reasons for this communicated. Self-help groups

30 The statutory framework conditions are set out in the Narcotics Act and the Narcotics Prescription Regulation (see chapter Error! Reference source not found.).
are also recommended. Psychotherapy in acute treatment *inter alia* helps reinforce or encourage motivation to undergo treatment and spell out treatment goals which are addressed in the post-acute treatment. Other forms of psychotherapy (e.g. cognitive therapy, behavioural theory and others) are generally considered to be helpful.

**Sociotherapy**

Sociotherapy is an indispensable part of the overall treatment. It helps patients reduce the negative effects of a financial and legal nature and eases their social situation. Often sociotherapy makes treatment for addiction possible in the first place, putting patients in a position to make use of longer-term treatment. If the patient agrees, the social environment of the patient should also be included in the sociotherapy.

Movement therapy procedures, which can benefit patients especially when performed in a group, are also recommended. Ergotherapy and art therapy can also be commenced during the acute treatment.

In an inpatient setting, nursing care is assigned the tasks of establishing a continuous professional relationship between the providers of treatment and care to the patient and creating a drug-free environment as the foundation for the treatment. A comprehensive assessment of the course of the treatment is performed, covering not only vital parameters and withdrawal symptoms, but also behaviour, affect and motivation.

**Comorbidity**

To treat hepatitis B, C and HIV, the authors cite international and national regulations and guidelines addressing this topic. Because opiate addicts frequently consume additional psychotropic substances, it is recommended that the degree of consumption be determined in the screening and the patient motivated to avoid consumption of other drugs. In particular, the (gradual) elimination of alcohol and benzodiazepine consumption should take place prior to opioid withdrawal.

**Neonatal withdrawal syndrome**

In Germany, neonatal withdrawal syndrome is usually treated with trinctura opil or phenobarbital. The authors point out that there is a need for additional research with regard to neonatal opioid withdrawal syndrome.

**Opioid-related disorders: post-acute treatment**

The most current guidelines of the Association of the Scientific Medical Societies in Germany on post-acute treatment in the case of opioid-related disorders were published in 2006 (Havemann-Reinicke et al. 2006). These guidelines were first published in 2004 (Havemann-Reinicke et al. 2004).

**Objective in post-acute treatment**

Acute treatment is followed by post-acute treatment. The target groups are primarily opioid addicts (ICD 10: F11.2, F11.5-9) and persons with multiple addictions with clinical addiction to opioids predominating. Post-acute treatment aims at helping patients stop using addictive substances and minimising negative effects in all areas of life. If it is not possible for patients to completely discontinue use of addictive substances, the focal point is on minimising the negative effects (e.g. ensuring survival, partial withdrawal from other addictive substances, reduction in the risk of

---

31 See Reymann & Gastpar, 2006: pp. 184 et seq. In this connection the guidelines “Therapy for chronic hepatitis C in the case of intravenous drug users” (Backmund et al. 2006) and the consensus text “HIV infection in the case of intravenous drug addicts (IVDA)” (Deutsche Gesellschaft fuer Suchtmedizin (DGS e.V.) et al. 2008), which have been issued in the meantime, should also be cited. Both documents are available at the Internet site of the Deutsche Gesellschaft fuer Suchtmedizin (German Society for Addiction Medicine): http://www.dgsu christmedizin.de/ueber uns/leitlinien/
infection with HIV and HCV, stabilisation of health and the psychosocial situation, occupational rehabilitation and social reintegration).

**Forms of treatment, indication and diagnostics**

Post-acute treatment can be abstinence-orientated or substitution-supported. There are outpatient, day hospital care and inpatient forms of treatment with and without medication (e.g. psychopharmaceuticals). Psychosocial counselling and treatment definitely plays an important role here.32

Comprehensive diagnostics are part of the post-acute treatment. These include among other things a physical examination, clinical-chemical laboratory examinations, drug screening, psychiatric, neuropsychological and psychosocial diagnostics. The aim is to achieve an overall picture of the physical and psychological condition of the patient by means of the various examinations in order to be able to create as broad a foundation as possible for fine-tuned treatment decisions (and forms of treatment).

**Therapies: abstinence treatment**

The indication for the selection of the form of treatment and the selection of the setting is determined by the individual situation of the patient at the outset. Abstinence therapy is for patients with a high level of motivation and willingness to abstain from drug consumption, for patients with shorter periods of addiction (less than 2 years) and for younger patients (under 18). The decision of the patient determines whether an abstinence-orientated therapy is performed in an outpatient, day hospital or inpatient setting. There are no empirically validated indication criteria, but experience shows, for example, that inpatient treatment should be recommended for patients with additional psychological or psychiatric disorders.

Individual therapies are recommended at first in the case of outpatient therapy. Group therapies are only advisable after patients have achieved a certain stability, as possible relapses could jeopardise other members of the group. Group settings are fixed elements of the treatment, on the other hand, in the case of inpatient forms of treatment.

Abstinence-orientated outpatient care usually lasts one year, with less intensity in the second half of the year. Inpatient post-acute treatment generally lasts six to nine months, with a regular termination after this time producing the highest abstinence rates following treatment.

Medication therapy is used as a supportive measure within the framework of abstinence-oriented post-acute treatment in order to maintain abstinence which has already been achieved and avoid relapses.

To prevent relapses, opiate antagonists, which achieve their prophylactic effect through the blockage of opiate receptors, can be used. Naltrexon (Nemexin) is used in Germany to support withdrawal treatment following detoxification. The guidelines recommend that treatment be commenced at the end of the inpatient acute treatment and that it also be continued in outpatient post-acute treatment. A high willingness to become abstinent and compliance are needed for treatment with Naltrexon. Patients should have discontinued consumption of opioids before the mediation is administered (the length of time of the interval depends on the type of opioid used). The guidelines contain recommendations on the dosage of the medication. Severe liver insufficiency is considered to be a contraindication for the administration of Naltrexon as well as is acute hepatitis, the use of opioids, withdrawal reactions to Naloxon, unsuccessful withdrawal, acute Opioid withdrawal symptoms and if patients are under 18 years of age. The administration of Naltrexon is also contraindicated for older drug addicts.

32 For additional information on the treatment system, see chapter Error! Reference source not found..
Therapies: substitution treatment

Substitution-supported treatments are indicated as part of a comprehensive therapy strategy if the aim of discontinuing consumption of substances appears unattainable over the short or medium term in cases of lengthy addictions, attempts to achieve abstinence under the supervision of a physician have not been successful, a substitution-supported therapy has greater prospects of success or is to be used a transition to an abstinence-orientated treatment. It can be performed in an outpatient, day hospital or inpatient setting. The overwhelming number of substitution treatments in Germany are carried out in an outpatient setting. Drug counselling and therapy facilities, physicians at private practices, psychiatric and other clinics and in some cases chemists as well refer patients to substitution treatments.

In addition to substitution in the narrower sense of the word, general medicine, psychiatric, psychotherapeutic and psychosocial treatment measures are part of the overall strategy for a substitution treatment. The overall treatment plan must be coordinated with all the actors providing treatment (e.g. the substituting physician, therapist and social worker).

The substitution treatment can take place over a longer period of time, frequently several years. If a patient achieves a certain stability (e.g. one year without any consumption of other substances) and shows motivation towards abstinence, a phase-out of the substitution should be reviewed and planned.

In Germany substances admitted for oral substitution are levomethadone (e.g. L-Polamidone), methadone (D,L methadone), buprenorphine and in justified cases of exception codein/dihydrocodein (if there is a demonstrated incompatibility of methadone and buprenorphine). The synthetic opioid LAAM was licensed for substitution in Germany in 1998, but is no longer licensed as a result of massive side effects. For parenteral substitution of severe opioid addicts a diamorphine-containing commercial pharmaceutical product is licensed since October 2009.

An initial dosage is determined in a search-and-find phase in order establish a suitable dosage for the substituted patients; the so-called maintenance dosage is given during the substitution phase. The medication – apart from diamorphine- is administered orally as a preparation (e.g. dissolved in orange juice) and cannot be injected.

A substitution can also take place during pregnancy if drug consumption which has been substituted in some other manner or withdrawal would pose a health risk to mother and child. An improved health condition of mother and child and a stable pregnancy can be achieved through methadone treatment with low dosages. Psychiatric treatment of the mother is urgently recommended.

Buprenorphine (Subutex®) was licensed for substitution treatment in Germany at the beginning of 2000. Buprenorphine is suited for an initial substitution therapy over a brief period of time if the addiction illness is not yet that severe. Two metaanalyses (highest degree of evidence) describe a slight tendency towards a greater effectiveness of methadone compared to buprenorphine (see Havemann-Reinicke et al. 2006, p. 216).

A legal arrangement in the Amending Regulation on the Prescription of Narcotic Drugs (§ 5 para. 8, “Take home”) stipulates that the physician providing the substitution can prescribe the required quantity of the substitute (methadone, levomethadone or buprenorphine) for 7 days and the patient can take this under his own responsibility.

Psychotherapy and psychosocial therapy

Psychotherapy and psychosocial therapy have high priority in the overall treatment strategy. In post-acute therapy, psychosocial therapy has proven to be effective as an abstinence therapy. It should also be part of the treatment strategy in any substitution treatment and support it. A discontinuation of therapy is generally considered to be a negative predictor of treatment success.

---

33 Diamorphine was not yet licensed at the point in time these guidelines were issued. See chapter 0. Combination preparations of buprenorphine and Naloxon (suboxone) have also been licensed in Germany (since 2006).

34 For the prerequisites and underlying conditions under which this “take-home substitute” is possible, see chapter 0.
Different psychotherapy procedures (e.g. behavioural analysis and cognitive intervention or activity, social, communications and relapse prevention training) seek to prepare patients for a drug-free situation after the therapy as do psychosocial therapy (e.g. work and ergotherapy, occupational therapy, leisure time/experience pedagogic, sports and movement therapy, creative therapy and sociotherapy).

The guidelines stipulate that “standard psychosocial treatment” should take place during substitution on a weekly basis during the first 6 to 12 months and thereafter every 14 days. The key elements are motivating discussions and case management (coordination and referral to other psychosocial helpers), furthermore social security (dwelling, financial support), crisis intervention, drug self-management, motivation development, the solution of interpersonal problems and leisure programmes helping participants structure their everyday lives and occupational rehabilitation in the form of counselling and work projects.

It is possible to provide intensive psychosocial treatment and this should be taken advantage of if standard treatment does not suffice (any longer). The crucial parameters are comorbid disorders and pronounced problems in various areas of life. In the case of intensive psychosocial therapies, two appointments per week are offered – one individual and one in a group setting. Especially interventions and prevention of relapse are important components in intensive treatment. Psychological reference persons and family members should be involved in efforts to cope with interpersonal problems.\(^{35}\)

**Sociotherapy**

Sociotherapy is an integral and indispensable component in abstinence and substitution treatments. Both the degree of success and the maintenance rate are increased by it. Special attention should in particular be devoted to occupational reintegration, as stable employment is a predictor of the success of a therapy.

The aim of psychotherapy is the social reintegration and the establishment of functional relationships. The patient should be prepared for a life without drugs and, to achieve this, also receive comprehensive help and support in everyday life involving the social environment. The general objectives must be spelled out in detail individually in accordance with the living situation.

Measures to solidify daily structures are a boon particularly for unemployed persons. Ergotherapy and work therapy can help integrate people in gainful employment, while work and training programmes help restore, maintain and improve employability (“occupational rehabilitation” under Social Code IX: benefits to help participate in working life). This includes, for example, counselling, job placement, initial and continuous training programmes or internships.

The strategy of assisting living helps secure the living situation and make it possible to run one’s own household. Social isolation can be countered through assisted living.

Patients should be offered counselling and support in various areas of life. These may be everyday chores which are related to filling out forms for government authorities (e.g. in the case of claims to unemployment benefits, housing subsidies, sickness allowances, but also criminal and civil law procedures such as the termination of an apartment lease or job, issues involving child custody or debt-handling advice).

\(^{35}\) As a result of different financing models and funding agencies for treatment in the 16 German Laender, the performance of the treatment varies in practice.
Comorbid disorders

With drug addicts, frequently occurring comorbid disorders require consistent psychiatric-psychotherapeutic co-treatment. For treatment purposes, the use of psychopharmaceuticals are recommended as well as psychotherapeutic procedures. The guidelines contain a translation of the basic treatment principles for treating comorbid disorders of the American Society of Addiction Medicine in the annex.

The treatment of depressive disorders, psychotic disorders and personality disorders should also be handled within the framework of integrative overall treatment. This also goes for the treatment of general medical comorbid disorders, in particular types of hepatitis and HIV infections.

Incarceration and hospital treatment order

Under German law, incarcerated persons and as a rule persons undergoing hospital treatment by court order (in accordance with § 64 of the Criminal Code) are treated in an abstinence-orientated manner. The authors of the guidelines state that a substitution treatment can also be successful at these facilities if the patients meet the prerequisites for such.

After-care

Follow-up care following an abstinence or substitution treatment helps stabilise the continued motivation for abstinence, social and occupational integration, psychological stability and prevention of relapse. After-care is carried out under supervision within the framework of self-help or professionally (for example, assisted living after treatment).

Rules and regulations of the German Medical Association on the performance of substitution-supported treatment of opiate addicts

As a result of the revision of the Amending Regulation on the Prescription of Narcotic Drugs in 2001, § 5, section 11 assigns the German Medical Association the task of setting out the generally recognised state of medical knowledge pursuant to compliance with the prerequisites for the licensing of substitution treatment under § 5, section 2, nos. 1, 2, 4 letter c. The German Medical Association appointed a joint experts commission with the Association of Statutory Health Care Physicians (Kassenärztliche Bundesvereinigung) in the autumn of 2001 in order to prepare rules and regulations on substitution-supported treatment of opiate addicts. The rules and regulations on the Performance of Substitution-Supported Treatment of Opiate Addicts was adopted by the German Medical Association on 22 March 2002 and published in the Deutsches Ärzteblatt on 24 May 2002. The current, revised version of the rules and regulations was issued by the Board of the German Medical Association on 19 February 2010 (BAEK 2010).

Legal foundations

In addition to the Amending Regulation on the Prescription of Narcotic Drugs, the Betaubungsmittelgesetz (Narcotics Act) and the Arzneimittelgesetz (Medical Products Act) set out the legal foundations for substitution treatment.

The physician providing treatment must meet the minimum requirements with respect to addiction-therapy qualifications and have a substitution license in order to be able to begin performing diagnostics and determining indications with the substitution. These minimum requirements are set by the medical associations. Patients may not undergo substitution treatment with another physician at the same time.

36 The exceptions (such as for example medical staff to fill in for the physicians providing substitution when they are on holiday) are set out in the Amending Regulation on the Prescription of Narcotic Drugs (BtMVV) and are contained in the regulation/rule.
Definition and objectives

As a scientifically evaluated form of therapy for manifest opiate dependency, substitution treatment requires a comprehensive overall strategy. It seeks to ensure survival, reduce the use of opiates and other narcotic substances and achieve abstinence from addictive substances, to stabilise the health situation and treat secondary illnesses, to reduce risks during pregnancy and after birth and to help the patients participate in society and working life once again.

Manifest opiate dependency (in accordance with ICD-10 F11.2) justifies the indication of a substitution-supported treatment. It should be used after weighing out whether it would be preferable to an abstinence-orientated treatment. If the substitution treatment offers a greater chance for success, then this is indicated. In the case of younger patients who have only recently become addicts, a substitution treatment should only be considered as a transitional solution. Substitution helps reduce risks particularly in the case of pregnant women.

Therapy

The overall strategy in substitution therapy also includes identifying additional somatic and psychological illnesses and if need be the initiation of co-treatment of these. The therapy strategy also covers assistance in arranging psychosocial measures. The involvement of the professional system of aid for substance abuse disorders and psychosocial assistance help achieve the identified therapy objectives. The scope and type of measures are based on the respective individual situations. The physician providing treatment should motivate the patient to initiate contact with the respective institutions and facilities. The physician providing treatment and the facility should act in consultation to determine the individual treatment needs. The progress of both treatment elements should be coordinated and reviewed on an ongoing basis.

Before the substitution is initiated it is up to the physician to perform a host of precautionary measures. A detailed examination of the patient should be performed and communication take place with actors who have provided treatment in the past. It must be ensured that there is no multiple substitution. The physician is obligated to submit a notice to the Substitution Register in codified form.37

The physician is required to obtain the permission of the patient for the therapy measures, and a written agreement should be concluded over the most important arrangements. This relates, for example, to the selection of the substitution substance and informing the patient about the effect, side effects and interactions. This also goes for modalities of ingestion under supervision, the daily administration, weekend arrangements and possible take-home arrangements. Abstaining from the consumption of other substances and checks and controls on adherence should be agreed upon as should the objectives of the therapy, criteria for breaking off the therapy and the required psychosocial assistance. The patient must release the physician providing treatment from the non-disclosure obligation (e.g. vis-à-vis the psychosocial counselling office, the Medical Association or chemists) and allow the notification of the treatment to the Substitution Register in coded form.

The regulation/rule refers to applicable provisions of the Amending Regulation on the Prescription of Narcotic Drugs with regard to the selection of the substitution substance; the physician is required to take into account the effect and side-effect profile in the planning of the therapy strategy. The initial dose shall be selected so as to ensure that an overdose can be ruled out including in the case of low opiate tolerance. The oral administration of the substitution substance should be personally supervised by the physician providing treatment. The regulation/rule contains specific arrangements for exceptions (such as, for example, filling in for a physician on holiday). The patient receives the substitution substance from the physician (or whoever is filling in for the physician) or (if allowed by

37 The notes contained in the rules and regulations e.g. on examinations and drug screening correspond to a great extent to the recommendations set out in the guideline “Opioid-Related Disorders: post-acute treatment” of the Association of the Scientific Medical Societies in Germany (AWMF), see pursuant hereto chapter 0, Therapies: substitution treatment.
law) by the chemist or medical personnel commissioned by the chemist. Agreements should be made by the physician and the chemist to ensure a smooth supply of substances.

Under some conditions in the take-home arrangements, patients can be subscribed the substitution substance to take under their own responsibility. The preconditions for this are that the phase of determining the right dosage of the substitution substance has been completed. The treatment must lead to a clinical stabilisation of the patient and the patient must not be consuming any additional substances. Moreover, it must be possible to rule out any hazards for the patient or other persons as a result, the patient must have maintained the contact to the physician and PSB and psychosocial reintegration must have reached an advanced stage. Under the Amending Regulation on the Prescription of Narcotic Drugs, the period of time is limited to seven days. The patient receives the substance from the chemists, no substances available at the practice may be provided.

The physician is in charge of checking and controlling the treatment. This includes checking whether the substitution substance has been taken properly and controls on abstinence from other addictive substances. The ongoing monitoring also primarily serves the purpose of deciding on “take-home prescriptions” and the initiation of measures in the case of dangerous consumption of additional substances (e.g. reducing the does or initiating inpatient withdrawal). In looking for the cause with respect to consumption of other substances, it should be checked whether the patient is experiencing a destabilisation in living conditions, the wrong dosage has been selected or there is a comorbid disorder or somatic illness.

Termination and discontinuation
A substitution can be regularly terminated in consultation between the physician and patient if it is no longer necessary or the patient no longer desires such. It is to be terminated by the physician if it no longer appears to be suitable, or if it is determined that there is an ongoing problematic consumption of other substances. The termination of substitution is to be avoided, as one must assume it to be associated with a high potential risk. All intervention possibilities (e.g. optimisation of therapy, adjustment of the dosage, a change in the facility) should be reviewed before treatment is discontinued. Only if the patient repeatedly violates agreements (e.g. does not come to appointments, refuses to undergo checks and controls) or other misconduct (e.g. use of violence against staff of the facility or endangering other persons by passing substances on to them) and a consideration of possible damage and benefits should treatment be discontinued. If it is discontinued, the patient should be provided the possibility of a regimented withdrawal, if need be in an inpatient setting.

Quality assurance
It is recommended that a manual be issued for internal quality assurance. Arrangements laid down by the regional medical associations and associations of national health care physicians apply to external quality assurance.

Diamorphine
The regulation was expanded in the version from 19 February 2010. In its new form it also covers the substitution of diamorphine, for which special arrangements exist. In order to perform treatment with diamorphine the patient has to have turned 23 and have been dependent on opiates for at least five years and currently consume opiates primarily intravenously. Serious somatic and psychological disorders must be present and the patient must have unsuccessfully undergone two prior treatments for dependency, of which in at least one oral substitution substance was provided for at least six months.

Accompanying psychosocial treatment is mandatory during the first six months. With substitution treatment, special requirements apply to informing the patient about the effect and dangers as well as the type of intravenous application. The administration of the substitution substance and the injection as well as return of the injection instruments must be provided under the supervision of a physician; a take-home prescription is not possible and is punishable as a criminal offence. The
special aspects of the substance (rapid flow and a shorter half-life) are to be taken into account in setting the dosage. Diamorphine can only be administered at facilities licensed for such by the respective regional authorities. Special requirements apply to the qualification requirements for the physician.

**Cannabis-related disorders**

The current Association of the Scientific Medical Societies in Germany guidelines on cannabis-related disorders were published in 2006 (Bonnet et al. 2006). These guidelines were first published in 2004 (Bonnet et al. 2004).

**Diagnostics**

Looking at the medical history of cannabis consumers, no somatic symptoms are generally evident aside from respiratory problems. Indications of increased consumption of other substances can be determined in the special addiction anamnesis. A discriminating social anamnesis is important, as many cannabis consumers are very young patients.

Indications of consumption and regular consumption can be found through urine and blood tests. A hair analysis can provide additional information on consumption e.g. the exact point in time of consumption. It is recommended to search for other substances (alcohol and illegal drugs) in the urine and blood tests.

Diagnoses are performed in accordance with the current international classification of illnesses (ICD-10) or DSM IV.

**Treatment**

For young patients, who have often begun consuming cannabis at a young age and also exhibit greater psychiatric comorbidity, individual treatment plans are necessary. Brief interventions with motivation-boosting goals are effective. Environment and family therapy interventions also have a major effect on adolescents.

The guidelines contain brief interventions combining motivation-strengthening and cognitive-behavioural elements of therapy along with individual counselling work along the lines of case management in accordance with current research findings\(^{38}\). Programmes for self-help groups which are based on the 12-step programme of Alcoholics Anonymous are also an effective approach, as is cognitive behavioural therapy.

Thus far there have not been any pharmaco-therapeutic strategies for preventing relapse and reducing consumption. The authors mention, however, that a recently developed antagonist (CB1 Cannabinoid Receptor Antagonist [SR141716]) could open up the possibility of treatment, similar to relapse prevention for opium addicts.

Generally the treatment of a single cannabis dependency is performed in an outpatient setting. Depending upon the severity of the withdrawal syndrome, the danger of relapse or outpatient therapy resistance and the severity of comorbid disorders, inpatient treatment may be indicated. In particular it is recommended that children and adolescents be treated as inpatients in order to be able to take into account the frequently serious psychological and social dimension of the addiction.

The treatment should comprise acute treatment (withdrawal treatment) and medical rehabilitation (rehabilitation). Treatment of an uncomplicated intoxication generally does not require any interventional measures going beyond supportive assistance. Patients with complicated intoxications associated with panic attacks (F12.02) react to “down-talking” or, if the patient does not respond, to the administration of benzodiazepines. Benzodiazepine can also be used for transient psychotic episodes (F12.04). The use of benzodiazepines and anti-psychotics is also an option in the treatment of longer-lasting psychotic episodes (F12.50) and possible delirious syndromes.

\(^{38}\) The guidelines provide a summary of reviewed strategies for the psychotherapeutic treatment of cannabis addicts from the U.S. and Australia. See Bonnet et al. 2006 p.156.
The treatment of symptoms accompanying the withdrawal syndrome usually do not require any pharmacological treatment. Patients profit from general physical and nursing measures in a qualified withdrawal syndrome treatment.

In serious cases, sleep disturbances can be treated with hypnotics and inner agitation and irritability with low-potency neuroleptics or sedative anticonvulsants. In the case of prominent vegetative withdrawal symptoms, clonidine can be used. Benzodiazepine should be avoided as a result of its high potential for causing dependency, but may be administered for up to 3 weeks if other substances are not sufficient. Secondary psychological and somatic illnesses should be treated individually depending upon the specific disorder.

With regard to the therapeutic relevance of cannabinoids, the guidelines address the fact that in Germany synthetic cannabinoids are licensed as category III sedatives (eligible for commercial trade and sedatives subject to prescription requirements). The psychoactive cannabinoids dronabinol and nabilone, for example, are used during chemotherapy to treat nausea and vomiting. Dronabinol is moreover used to treat the “AIDS-wasting” syndrome.

**Psychological and behavioural disorders resulting from cocaine, amphetamines, ecstasy and hallucinogens**

The latest guidelines of the Association of the Scientific Medical Societies in Germany on “psychological and behavioural disorders resulting from cocaine, amphetamines, ecstasy and hallucinogens” were published in 2006 (Thomasius & Gouzoulis-Mayfrank 2006). These guidelines were first published in 2004 (Thomasius & Gouzoulis-Mayfrank 2004).

As a result of the unsatisfactory data situation, these guidelines are more based on a consensus of experts. The authors emphasise that one special feature of the guidelines is that they are characterised by a lower level of substance specificity.

**Diagnostics**

Comprehensive diagnostic measures to achieve as precise a picture of the patient as possible forms the basis for a treatment. These include psychodiagnosics (identification of substance-related disorders in accordance with ICD-10), addiction anamnesis, psychopathological findings and assessment of treatment motivation and establishment of comorbid psychiatric disorders (also in accordance with ICD-10) and somatic and socio-diagnosics. At the same time, special aspects of the substances and substance-related disorders need to be cleared up.

**Treatment**

The guidelines cover both acute treatment as well as post-acute treatment. Different recommendations are made regarding the withdrawal/detoxification treatment for the various substances in the case of acute intoxication. In addition to the treatment of withdrawal syndromes, the respective treatment of secondary illnesses and medical emergencies, psychological-psychiatric diagnostics and measures to promote the use of an abstinence therapy and supportive measures in the social area are the goals in acute treatment.
Table 0.1  Treatment of acute, substance-related disorders with medication

<table>
<thead>
<tr>
<th>Substance</th>
<th>Type of disorder</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cocaine</td>
<td>Psychotic intoxication, nervous agitation</td>
<td>Temporary benzodiazepine</td>
</tr>
<tr>
<td></td>
<td>Withdrawal symptoms</td>
<td>Motivation-boosting tricyclical anti-depressives, amantadine</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>Psychotic intoxication, induced psychological disorders</td>
<td>Temporary benzodiazepine and neuroleptics</td>
</tr>
<tr>
<td></td>
<td>Withdrawal with rebound phenomenon</td>
<td>Tricyclical anti-depressives</td>
</tr>
<tr>
<td>Ecstasy</td>
<td>Psychotic intoxication, strong post-effects</td>
<td>Temporary benzodiazepine; caveat: no neuroleptica or anti-depressives antidepressants</td>
</tr>
<tr>
<td>Hallucinogens</td>
<td>Psychotic intoxication</td>
<td>Temporary benzodiazepine; caveat: no neuroleptics</td>
</tr>
</tbody>
</table>

Thomasius & Gouzoulis-Mayfrank 2006.

The goal in post-acute treatment is the treatment of disorders in psychological functions, treatment of physical effects, secondary and follow-up illnesses and treatment of the interactional, psychosocial and development-related disorders. Abstinence and reduction of substance consumption are partial goals of the treatment, which should ultimately make it possible for patients to run their own lives autonomously.

Post-acute treatment is possible both in an outpatient setting (in 80 to 120 individual or group meetings – with the inclusion of important reference persons – within a period of 18 months) and as short-term or long-term inpatient therapies (3 to 6 or 7 to 10 months). Additional treatment possibilities exist in the area of inpatient psychiatrics and psychotherapy and in specialised addiction departments in child and adolescent psychiatry and psychotherapy.

In addition to basic medical care, support should also be provided in dealing with social affairs.

The selection of the treatment setting is based on the clinical features of the substance-related disorder, the motivation of the patient for a certain procedure and the regional availability of treatment possibilities. A stable social environment can be a reason to opt for an outpatient form of treatment, while inpatient treatment is recommended in the absence of stable social and/or everyday structures. Inpatient treatment lasting more than 90 days is recommended for patients with fluctuating motivation and who especially consume cocaine through inhalation or intravenously.

Psychotherapeutic treatment is assigned a key importance in the post-acute treatment of cocaine, stimulants and hallucinogenic disorders.

Behavioural therapy/cognitive therapy, supportive therapy, psychodynamic therapy and family therapy can be applied in individual and group meetings.

Patients addicted to cocaine with several psychosocial and psychiatric disorders profit from procedures aimed at avoiding relapse more than other approaches. Family therapy approaches are recommended for adolescents. Psychological education and motivational intervention should be used as additional support in the post-acute treatment.

The authors recommend a sociotherapy which enables patients to cope with everyday problems. Patients are supposed to receive support with regard to their occupational situation, financial issues...
(debts), legal and bureaucratic matters and the avoidance of destabilising factors in their social environment. Easy-access programmes are helpful especially to people consuming intravenously (cocaine) or who are threatened by impoverishment (cocaine consumers, crack consumers and polytoxicomaniacs). The authors recommend the continuation of socio-therapeutic assistance through outpatient or inpatient therapy.

No general recommendations can be derived for substances with respect to pharmacological treatment in post-acute treatment as a result of the state of the art in research. If a substance-induced psychosis has been ruled out in the post-acute treatment, schizophrenia in the form of psychiatric comorbidity should be treated with neuroleptics.

Mothers who are dependent on cocaine and pregnant women must receive special attention. In addition to paediatric care, new-born children should receive child-psychiatric and intensive psychosocial assistance. The mothers should be assisted by youth and family aid institutions. The care functions of mothers require professional support in order to ensure that their children are cared for.

**Medication dependency (sedatives, hypnotics, analgesics, psychostimulants)**

The latest guidelines on “medication dependency” from the Association of the Scientific Medical Societies in Germany were published in 2006 (Poser et al. 2006).

The guidelines are broken down into three chapters on hypnotics/sedatives, analgesics and psychostimulants.

**Hypnotics/sedatives**

The guidelines understand hypnotics/sedatives to mean the substance groups or substances of benzodiazepine, Zolpidem/Zopiclon/Zaleplon, Clomethiazol (substances similar to barbiturates), γ-Hydroxybutyrat (GHB) and γ-Butyrolacton.

Aside from the therapeutic administration of medication, consumption of these can according to ICD-10 also cause an acute intoxication (F13.0), constitute harmful use (F13.1) or a dependency syndrome (F13.2). Of all the hypnotics/sedatives, benzodiazepine is prescribed most often as a result of its therapeutic effect. While harmful use of these substances is rather rare, dependency requiring treatment occurs relatively frequently. Abuse in the meaning of DSM-IV occurs more frequently within the framework of polytoxicomania, especially in connection with illegal drugs.

There is a need for treatment when a diagnosis is made according to ICD-10 or DSM-IV. A diagnosis is a special challenge in the case of medication dependency or abuse. On the one hand, the medications are usually prescribed for therapeutic purposes, while on the other illegal acquisition and uncontrolled consumption (especially of benzodiazepines) occur as well, frequently as additional consumption of illegal drugs. If a dependency is salient in such a case e.g. of opioids, the respective guidelines should also be taken into account. A low-dosage dependency can occur with benzodiazepines prescribed by a physician if the prescribed dosage is taken over a lengthy period of time.

In the case of acute intoxications, it should be checked whether a harmful use of other substances or a dependency is present. Patients can be monitored on an outpatient basis; while in the case of severe intoxications the patient should be placed in a hospital for observation.

In the case of harmful use without dependency, the discontinuation of the medication by the therapist is possible as a form of early intervention. The physician providing treatment or the addiction therapist should win the patient over to a life without sedatives and the avoidance of long-term effects with the aid of therapeutical talks (“motivational discussions”). In the case of dependency, hypnotics/sedatives definitely must not be discontinued suddenly. They are to be phased down in a controlled, gradual manner by the physician treating the patient.

If there is a low-dosage dependency (e.g. in the case of long-term treatment with benzodiazepines), withdrawal is not generally recommended, and is, rather, dependent on a risk-benefit assessment.
The execution of so-called long-term outpatient withdrawal can take place in family physicians’ practices or with general practitioners. Specialised clinics are recommended in complicated cases. The gradual reduction of dosages may take between 4 and 10 weeks in the case of long-term outpatient withdrawal.

Patients with a high-dosage dependency should be treated within the framework of a “fast inpatient withdrawal” which is performed within a period of 3 to 6 weeks in psychiatric clinics. Withdrawal takes place through a controlled reduction in the dosage.

Benzodiazepine dependency is frequently accompanied by alcohol dependency and polytoximania. In the case of alcohol dependency, the dosage of benzodiazepine is reduced after the alcohol withdrawal has been completed. In withdrawal from benzodiazepine, very high dosages may initially be necessary in the case of multiple dependencies. If there are multiple dependencies it is recommended that the respective guidelines on the consumed substances be taken into account.

Withdrawal treatment is urgently recommended in the case of pregnant women, as withdrawal treatment of new-born children is extremely complicated.

Treating withdrawal from benzodiazepine with medication (which can involve, for example, the administration of sedating tricyclical antidepressives against agitation and sleep disorders or anticonvulsives for seizure prophylaxis) should begin before the withdrawal so as to prevent withdrawal symptoms.

Psychological support should vary according to individual needs and can range from brief supportive interventions all the way to more cognitive or behavioural therapeutic techniques to manage anxiety and stress. Psychological education for specific additions is particularly important with regard to dependency syndrome, risks of relapse and harmful effects. Individual meetings are recommended, as these are more effective than group meetings in these cases.

In treating comorbid illnesses, it must be taken into account whether the psychological illness (frequently anxiety and depression-related disorders, borderline personality disorders, post-traumatic stress disorders and ADHS) existed prior to the dependence on hypnotics/sedatives. Such pre-existing illnesses often continue to exist during and after the dependency and require separate treatment. On the one hand, a dependency on medication can for its part set additional processes in motion which persist as follow-up illnesses following withdrawal and also justify a need for treatment.

**Analgetics**

Opioids and non-opioid analgetics are used as pain-killers. The authors of the guidelines state that, in spite of the inadequate data available in Germany, it can be assumed that harmful or non-intended use takes place on a relevant clinical scale. Persons who have had a previous addictive illness, particularly relating to opiates, are particularly at risk of developing a dependency on medication.

The guidelines describe signs of harmful or non-intended use (e.g. forged prescriptions, refusal to disclose sources from which such are obtained, opposition to changes in opioid therapy) and describe the special role which physicians are assigned in prevention (risks to be avoided; e.g. patients not being provided sufficient information, monodisciplinary indication, unclear therapy objectives or therapy objectives which have not been mutually agreed upon, continued prescription of opioids in spite of insufficient prospects of success for the therapy).

**Psychostimulants**

The guidelines describe the harmful use and dependency on psychostimulants (such as, for example methylphenidate [e.g. Ritalin®]). Because abusive consumption prevents use of psychostimulants, but these are not supposed to be withheld in the case of indicated treatment of patients (e.g. children with ADHS), the authors draw attention to the respective guidelines of the Society for Children and Psychiatric Treatment and Psychotherapy for Adolescents.
German Statutory Pension Insurance (DRV): guidelines on rehabilitation needs in the case of dependency-related illnesses

The 2nd version of the “Guidelines on Rehabilitation Needs in the Case of Dependency-Related Illnesses” from German Statutory Pension Insurance comes from 2005. It replaces the 1st version from 2003 (DRV 2005).

The guidelines refer to dependency-related illnesses in general terms. Statements and recommendations are made for special substance-related aspects in sub-chapters of the guidelines. Pathological gambling and behavioural disorders resulting from intensive use of computers and the Internet are taken into account as non-substance-related disorders.

Need for rehabilitation

In general there is a need for rehabilitation if a substance abuse disorder is present and the following preconditions have been met: a withdrawal treatment must have been completed, the person must be capable of undergoing rehabilitation and it must be possible for the rehabilitation to return the patient to gainful employment.

A dependency illness is considered to be present if the person is incapable of abstinence or has lost self-control or if these two systems occur periodically. ICD-10 and DSM-IV are used as the diagnosis criteria for diagnosing a dependency syndrome.

Rehabilitation programmes and benefits

Rehabilitation can be carried out on an outpatient or inpatient basis. The guidelines refer to an agreement between the health insurance schemes and Statutory Pension Insurance which sets out the criteria which apply to the facilities (e.g. with respect to personnel, funding agency, space, therapy offers and places) (DRV 2005, "Substance Abuse Disorder Agreement" in the annex to the guidelines). What measures are suitable for the patients must be decided on an individual basis. The most important criteria are, for example, the social and occupational integration of the patient, the living situation, capability of abstinence and active cooperation in the therapy or the degree of possible psychosocial disorders.

In the case of inpatient treatment, the therapy may last up to 26 weeks, with shorter therapies lasting between 12 and 16 weeks. Outpatient rehabilitation for addictions may last up to 18 months, in which a maximum of 120 individual or group therapy meetings can take place as well as up to twelve therapeutic discussions with important reference persons.

In the after-care, services can be provided by outpatient after-care if joining a self-help group is not enough. 20 individual or group therapy meetings are held within a period of half a year. The system of benefits also covers an adaptation phase which can follow rehabilitation. In the phase lasting up to 16 weeks patients are stabilised in their everyday lives, while the performance capability and capacities of the insured party to deal with stress are to be improved.

Aid in reintegration in working life is of central importance to rehabilitation, which is aimed at restoring the capability to work as a more general objective from the perspective of the Statutory Pension Insurance. Aid and benefits to help reintegrate insured persons help promote motivation for addiction rehabilitation and should be provided as early on as possible. A successful reintegration has a positive impact on abstinence and psychological stability.

Further development of guidelines

At present the guidelines of the Association of Scientific Medical Societies in Germany at development level S2 are being further developed under the auspices of the German Society for Research on Addictions (DG-Sucht) and the German Association for Psychiatry and Psychotherapy (DGPPN). The consensus process has not yet been completed, nor can it be predicted when the guidelines will be published (Fleischmann, personal communication). Work is taking place at present on a non-substance-related development of guidelines on the topic “psychosocial therapy”.
Even though experts emphasise that “addiction” should be a topic in this development process, it has thus far been ignored in the drafting of this report (Fleischmann, personal communication).

The rehabilitation guidelines of German Statutory Pension Insurance are currently being revised and the publication of the new version in 2010 is considered to be probable. The Statutory Pension Insurance is endeavouring to also involve the relevant specialised societies (e.g. German Association for Psychiatry and Psychotherapy and the German Society for Research on Addictions (DG-Sucht)) in the process of developing the guidelines. The guidelines are to be brought in line with the procedures developed in the guidelines of the Association of the Scientific Medical Societies in Germany, as this procedure enjoys broad general acceptance in the science community.

**Implementation process**

Gastpar and Schmidt (2006) point out that studies have yet to be conducted on the applicability and use of the guidelines in practice. A review of the relevance of guidelines in everyday practice should also provide a basis to assess the needs for improvement of guidelines with regard to their viability in practice.

The guidelines of the Association of the Scientific Medical Societies in Germany drafted in Germany are supposed to contribute to an improvement in quality in addiction aid through their application. The most important preconditions for the application of guidelines are the dissemination, availability and acceptance of them by professions providing treatment. With the publication of the guidelines of the Association of the Scientific Medical Societies in Germany and their free availability in the Internet it can be assumed that the degree of awareness of the guidelines is high among the relevant groups of professions. To date no data which can be validated is available; just as little is known about the use and application of the guidelines in actual practice.

Because the development of the guidelines has to be supported by a broad consensus among experts, it must be assumed that they meet with a high level of acceptance among the relevant professional groups in spite of the discussion over applicability and viability in the state of practice (see Koch 2006; Schmidt 2006 and chapter 11.1.4).

Because the guidelines of the Association of the Scientific Medical Societies in Germany are not regulations, it is left up to clinics and treatment facilities what internal standards they want to base their treatments on. Clinics must set out in their quality management systems, however, which guidelines their treatments are based on in order to achieve certification through an external auditor. It can thus be assumed that the guidelines of the Association of the Scientific Medical Societies in Germany are applied on a broad scale at the level of the clinics. (Fleischmann, personal communication).

The guidelines of German Statutory Pension Service are implemented at the level of rehabilitation facilities by the agreement on “Dependency-Related Illnesses” between the Statutory Pension Insurance and health insurance schemes contained in the annex defining the requirements applying to facilities with regard to the performance of outpatient and inpatient treatment measures and laying down the criteria for decisions on outpatient and inpatient treatment (DRV 2005).

The guidelines of German Statutory Pension Insurance are of decisive importance in the performance of rehabilitation measures, the reason being that they stipulate what can be paid for by the Statutory Pension Insurance (or the health insurance schemes). The Evidence-based Therapy Model (ETM) which is formulated therein is made available to facilities. The Classification-of-Therapeutic-Benefits (KTL) analysis\(^{39}\) determines to what extent the Evidence-based Therapy

\(^{39}\) KTL analysis: The Classification of Therapeutic Benefits (KTL) is a directory of therapeutic benefits drafted by the BfA (now German Statutory Health Insurance) which can be carried out during a medical rehabilitation. The results of a research of the literature, formulated as an evidence-based therapy module (ETM) are compared as treatment targets with the actual situation (as reflected in the release reports of the BfA (now the German Statutory Health Insurance) (see 0).
Model can be applied. An improvement in the supply of rehabilitation in actual practice is supposed to be achieved through feedback to the facilities and institutions (Brueggermann et al. 2004).
Chapter 11. History, methods and implementation of national treatment guidelines

11.1 History and overall framework

The public became aware of the drug addiction problem just after Estonia regained independence in the middle of the 90s. The first strategic document of combating drug addiction in Estonia was adopted by the Government of the Republic in 1997, when "Alcoholism and drug addiction prevention programme for 1997–2007" was approved. The Ministry of Social Affairs of Estonia was responsible for the implementation of the Programme. In 1998, an advisory committee was formed for the Programme, with the official name the Council of National Programme for Prevention of Alcoholism and Drug Addiction, the objective of which was to supervise and coordinate the Programme for Prevention of Alcoholism and Drug Addiction. Each year the Council defined the priority areas for the following year. In 1999–2000 one of the priority areas was treatment of drug addiction and creation of new treatment/rehabilitation facilities. The Ministry of Social Affairs did not implement the Programme for Prevention of Alcoholism and Drug Addiction itself, but it was the Estonian Foundation for Drug Prevention that was engaged in the process (National Report 2001).

The first drug addiction treatment guidelines were prepared in 2001 under the leadership of the Estonian Foundation for Drug Prevention in cooperation with the Pompidou Group of the European Council. Leading psychiatrists and psychologists of Estonia were involved in the development of the guidelines for drug addiction treatment. Altogether, eight psychiatrists and three renowned psychologists were engaged in the preparation of the guidelines for drug addiction treatment. Besides, Martien Kooyman M.D., Ph.D., expert of the Pompidou Group, was involved in the development of the guidelines. The primary source materials for the guidelines for drug addiction treatment were the guidelines of Great Britain "Drug misuse and dependence – guidelines on clinical management". At that time, the preparation of the guidelines for drug addiction treatment was conditioned by a continuously growing need to treat drug addiction in the country and by the wish to harmonise the principles of drug addiction treatment provided. The first drug addiction treatment guidelines primarily focused on the general topics of addiction, and the issue of treatment of opiate addiction in particular formed an insignificant part of the guidelines. The treatment guidelines developed in 2001 were approved by the Estonian Psychiatric Association only in 2005. Since the approved guidelines failed to pay adequate attention to the treatment of opiate addiction that was particularly a problem in Estonia, the existing treatment guidelines were started to be modified in 2006. In 2006–2007, the NIHD in cooperation with the Estonian Psychiatric Association was primarily engaged in the development of the new guidelines for opiate addiction treatment supplementing the old treatment guidelines. The initial guidelines completed in 2001 mainly focused on stopping using drugs particularly by way of detoxification. The aim of detoxification was set at immediate or step-by-step termination of taking drugs and alleviating or avoiding acute detoxification symptoms within a maximum of six months. An annex to the guidelines of drug addiction treatment, supplementing and specifying the existing guidelines approved by the Estonian Psychiatric Association Society in 2007, in addition to detoxification also provides for the so-called maintenance treatment with substitution medicinal products. The new treatment guidelines developed were also updated in the part of more exact dosing of medicinal products.

Since 2008, the NIHD, in cooperation with the Estonian Psychiatric Association, has been engaged in the development of new guidelines for drug addiction treatment, which should be completed by the end of 2010.

---

40 Since 2003, the NIHD has been implementing the national strategy for prevention of drug addiction in the area of administration of the Ministry of Social Affairs.
11.2 Existing guidelines: narrative description of existing guidelines

As mentioned above, specialists engaged in the treatment of drug addiction in Estonia have been using two consensus documents over the years: guidelines for drug addiction treatment (2001) and (guidelines of opiate addiction treatment 2007). The given documents are intended for use by all specialists who are concerned with drug addiction treatment. The first treatment guidelines developed in 2001 cover drug addiction treatment in a wider sense and focus just on detoxification, while the 2007 version is solely centred on opiate addicts, offering the following treatment types:

- **detoxification with substitution medicinal products** is a treatment of opiate addiction lasting a maximum of one month, during which substitution medicinal products are used;
- **substitution treatment** is a treatment of opiate addicts involving psychosocial rehabilitation, where substitution medicinal products are used and which lasts over one month;
- **supporting maintenance treatment** is a treatment of opiate addicts, where substitution medicinal products are used and which lasts over one month; the main objective of this treatment is harm reduction and improvement of the patient’s life quality. Supporting maintenance treatment does not set the objective of getting rid of addiction or recovery of the patient’s ability to work. Supporting maintenance treatment should be started only in the case of patients who could not be made to stop using drugs and whose treatment motivation could not be increased either during repeated detoxification episodes or during substitution treatment that had lasted for at least 6 months; who are HIV positive and in whose case due to maintenance treatment it will be obviously possible to avoid the spreading of infectious diseases and other health problems and whose life quality can be improved this way.
- **rehabilitation of opiate-addicted patient** is rehabilitation of drug addicts carried out either in day care centres or rehabilitation communes (Guidelines for opiate addiction treatment 2007). As an explanation, such rehabilitation treatment aimed at drug addicts in Estonia is defined as rehabilitation. Elsewhere in the world, such service is frequently called follow-up treatment or such services are just considered as drug addiction treatment without medicines. The guidelines set out that rehabilitation in the narrow sense of this word starts only after the addict has stopped using drugs and has undergone substitution treatment. Rehabilitation does not provide for connection with the provider of treatment service.

New guidelines for opiate addiction treatment that will be completed by the end of 2010 are more clinical and detailed than the previous ones and also include the description of the combined effect of different medicinal products. The development of the new guidelines for opiate addiction treatment was mainly based on the WHO’s treatment guidelines "Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence" and in Lithuania on the treatment guidelines “Addictive disorders treatment for opioid users with Methadone (2009)’’.

11.3 Implementation process

Two guidelines for drug addiction treatment that have been in use in Estonia to date are advisory consensus documents, which have been approved by the specialists association, namely the Estonian Psychiatric Association. Similarly to the guidelines of drug addiction treatment, all treatment guidelines in Estonia are approved by specialists associations. It is unknown how many specialists engaged in drug addiction treatment proceed from these guidelines. The topic related to the guidelines for drug addiction treatment were in some respects discussed in "Research of evaluation of methadone substitution treatment quality and need for services in Estonia" financed by UNODC in 2008 and in the research of mapping publicly financed rehabilitation centres aimed at drug addicts and client satisfaction with the service. In the research report treating methadone substitution treatment, a conclusion was made that providers of substitution treatment lack unambiguous guidelines that can be used in practice. To be more precise, the research found that there is no uniform understanding of the nature of substitution treatment and its objectives (Abel-Ollo et al., 2008). Also, there are references in the rehabilitation services research report that not all service providers currently proceed from the advisory guidelines for opiate addiction treatment or these guidelines are considered insufficient (NIHD, 2009). Such findings indicate that treatment
guidelines are not uniformly used and unambiguously understood by specialists, and the improvement of treatment quality and wider use of the guidelines should be emphasised in the treatment guidelines. As a particular solution, the specialists participating in the UNODC research proposed the development of national drug addiction treatment standards and determination of the uniform treatment structure and development trends. Also, the rehabilitation centre evaluation report provides, as a future perspective, for the development of service descriptions that would be uniform and specific as to their structure. As one of the solutions, the UNODC evaluation research also recommends approving the guidelines for opiate addiction treatment, which will be completed in 2010, at a high level in order to avoid their becoming of advisory nature, which are not followed by all the specialists of the area.

11.4 Comparision with the WHO guidelines

Table 28. Comparison of Estonian treatment guidelines with the WHO standards

<table>
<thead>
<tr>
<th>Name of Assessors: KATRI ABEL-OLLO</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Choice of treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 For the pharmacological</td>
<td>X</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>treatment of opioid dependence,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>clinicians should offer opioid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>withdrawal, opioid agonist</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>maintenance and opioid antagonist</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(naltrexone) treatment, but most</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>patients should be advised to use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>opioid agonist maintenance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>treatment. Do the present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>guidelines include this</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3. For opioid-dependent</td>
<td></td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>patients not commencing opioid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>agonist maintenance treatment,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>consider antagonist pharmaco</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>therapy using naltrexone</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>following the completion of opioid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>withdrawal. Do the present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>guidelines include this</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Opioid agonist maintenance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1 For opioid agonist</td>
<td>X</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>maintenance treatment, most</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>patients should be advised to use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>methadone in adequate doses in</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>preference to buprenorphine. Do</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>the present guidelines include</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>this recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2 During methadone induction,</td>
<td>X</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>the initial daily dose should</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>depend on the level of neuroadaptation;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>it should generally not be more</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>than 20 mg, and certainly not more</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>than 30mg. Do the present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>guidelines include this</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3. On average, methadone</td>
<td>X</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>maintenance doses should be in the</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>range of 60–120 mg per day. Do</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>the present guidelines include</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>this recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4 Average buprenorphine</td>
<td>X</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>maintenance doses should be at</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>least 8 mg per day. Do the present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>guidelines include this</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 Methadone and buprenorphine</td>
<td>X</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>doses should be directly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>supervised in the early phase of</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>treatment. Do the present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>guidelines include this</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.6 Take-away doses may be</td>
<td>X</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>provided for patients when the</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>benefits of reduced frequency of</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>attendance are considered to</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>outweigh the risk of diversion,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>subject to regular review. Do the</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>present guidelines include this</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.7. Psychosocial support should</td>
<td>X</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>be offered routinely in</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
association with pharmacological treatment for opioid dependence.
Do the present guidelines include this recommendation?

3 Management of opioid withdrawal

<table>
<thead>
<tr>
<th>3.1. For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used. Do the present guidelines include this recommendation?</th>
<th>X</th>
</tr>
</thead>
</table>

3.2. Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?

| □ | X | □ | □ |

3.3 Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?

| □ | X | □ | □ |

3.4 Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence. Do the present guidelines include this recommendation?

| X |

4 Pregnancy

4.1 Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy. Do the present guidelines include this recommendation?

| □ | X | □ | □ |

4.2 Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered. Do the present guidelines include this recommendation?

| □ | X | □ | □ |

WHO guidelines coherence: only to be applied to guidelines applied for guidelines on closed settings
Drug treatment guidelines for the so-called closed settings are missing in Estonia

| 1. Do the present guidelines agree with the “Clinical guidelines for withdrawal management and treatment of drug dependence in closed settings”? | □ | □ | □ | X |

BACK TO TOP
11. History, methods and implementation of national guidelines

11.1 Introduction

The first move to standardise treatment for drug dependence in Ireland coincided with the public health scare in the mid-1980s regarding the spread of HIV/AIDS, and the recognition that risky practices associated with injecting drug use were contributing to the spread of HIV infections. This recognition saw a shift towards a decentralised network of drug treatment centres and satellite clinics, accessible and acceptable to potential service users, which provided a range of both harm reduction options, including substitution treatment, needle exchange and outreach services, and treatment options (Butler 2002a) (Butler 2002b). This shift to a dispersed and more complex system of responses to problem drug use meant that the maintenance of a consistent standard of service was more challenging than before.

In 1987 the Medical Council, a statutory body tasked with promoting and better ensuring high standards of professional conduct and professional education, training and competence among registered medical practitioners, issued guidelines for the prescription of controlled drugs under the Misuse of Drugs Act 1977 (Expert Group on the establishment of a protocol for the prescribing of methadone 1993) (Appendix B).

In 1993, following a recommendation by the National AIDS Strategy Committee, the Minister for Health convened an Expert Group on the Establishment of a Protocol for the Prescribing of Methadone. This ‘expert group’ comprised personnel from the Drug Treatment Centre, the Eastern Health Board, the Irish College of General Practitioners, Merchants Quay (a voluntary drug treatment service provider) and the Department of Health. It was assisted by the Pharmaceutical Society of Ireland (PSI) and the Irish Pharmacy Union (IPU). The Expert Group published a report setting out a protocol for the management of drug users in primary care (Expert Group on the establishment of a protocol for the prescribing of methadone 1993). Endorsing the Medical Council’s guidelines, published 6 years earlier, the protocol covered the prescribing of methadone, the registration of drug users and the licensing of general practitioners to treat drug users.

Between 1996 and 1998 a series of reports endorsed the 1993 methadone prescribing protocol and called for the formal adoption of national guidelines. The Ministerial Task Force on Measures to Reduce the Demand for Drugs (Ministerial Task Force on Measures to Reduce the Demand for Drugs 1996), whose reports formed the basis for Ireland’s first national drugs strategy in 2001, recommended that the GP/Pharmacist methadone prescription/dispensing scheme should continue to be expanded, evaluated and strictly regulated. In its policy document on drug misuse published in 1996, the PSI acknowledged the valuable role played by methadone treatment in the management of opiate addiction. It encouraged pharmacists to participate in methadone dispensing in accordance with specific guidelines, which were in agreement with the recommendations in the Protocol and with Department of Health policy. In 1997 the Irish College of General Practitioners (ICGP) published a report by a task group on drug misuse, which recommended that general practitioners become involved in the treatment of opiate misusers in their own local communities. It also recommended that methadone treatment as described in the 1993 Protocol should continue as a valid form of treatment for opiate dependence.42

41 The Pharmaceutical Society of Ireland is the regulator of pharmacy in Ireland. The Pharmacy Act 2007 dissolved the old Pharmaceutical Society of Ireland (established in 1875) and re-established it as a statutory body. The Irish Pharmacy Union is the professional, representative body for community pharmacists.

42 The executive summaries of the PSI’s 1997 policy document on drug use and the ICGP’s 1998 task group report on drug misuse are both included in the appendices to the report of the Methadone Treatment Services Review Group (1998).
In 1997 a Methadone Treatment Services Review Group was set up to consider the arrangements in place for the management and care of heroin dependent drug misusers by general practitioners and pharmacists in Ireland and to advise the Minister on the approach to be taken in the future. The Review Group concluded that methadone, as part of a comprehensive programme of care, was still a valid treatment for opiate-dependent persons. It recommended that services should be developed using the 1993 Protocol for the Prescribing of Methadone; that methadone should be available free of charge to all persons undergoing methadone treatment for opiate dependence; and that the methadone treatment protocol scheme should be available nationally. Recommendations were also made on the type and concentration of methadone to be used, on the roles of general practitioners and pharmacists, and on the relationships between treatment centres, general practitioners and pharmacists. The Review Group also recommended that the methadone monitoring scheme should be placed on a statutory basis by the making of regulations under Section 5 of the Misuse of Drugs Act 1977 (Methadone Treatment Services Review Group 1998).

On foot of the Methadone Treatment Services Review Group’s report, the Methadone Treatment Protocol (MTP) was drafted and activated when the Misuse of Drugs (Supervision of Prescriptions and Supply of Methadone) Regulations, 1998 (S.I. No. 225/1998) were published.

To ensure compliance with the MTP, the ICGP and PSI have both published treatment guidelines, which are described in Sections 11.2.1 and 11.2.2. The review process for the MTP is described in Section 11.3.1.

11.2 Existing national guidelines: narrative description of existing guidelines

The current methadone treatment protocol covers the statutory and regulatory issues around methadone prescription and dispensing and does not deal with any clinical or treatment guidelines per se (Methadone Prescribing Implementation Committee 2005).

Appendix A (dated 1993) provides a brief summary of good practice in relation to methadone prescribing. It suggests that methadone should be started at a low dose (dose not specified) and supervised daily. For withdrawal, it recommends starting on 30 to 40 mg and reducing by 5 mg increments. It recommends methadone for pregnant women. There are also recommendations around providing comprehensive medical, social and psychological care for the client on methadone. In relation to benzodiazepines, the protocol states that they can be useful in the short term but GPs participating in the methadone programme need to be aware of the potential for abuse of these drugs.

Guidelines have been developed for managing opiate users in the primary-care setting – specifically for general practitioners (GPs) and for pharmacists. Guidelines have also been developed for drug treatment in prison settings, and for clinicians prescribing benzodiazepines. These are all described in the following sections.

11.2.1 Management of opiate users in the primary care setting

In January 2008, the ICGP published revised guidelines for working with opiate users in primary care (Irish College of General Practitioners 2008). The guidelines were revised by a representative group of GPs who had experience in managing the care of individuals with an opiate misuse problem. Service users were not involved in developing these guidelines. The document deals only with methadone as a substitution treatment; buprenorphine is not currently available in Ireland (a small pilot project with regard to the use of buprenorphine in substitution treatment is ongoing (Alcohol and Drug Research Unit 2009)).

The review of the guidelines drew on available international evidence and guidelines, including the NICE guidelines, ‘Methadone and Buprenorphine for Managing Opioid Dependence’, which contain
recommendations based on ‘current practice that has evolved over the years’ (National Institute for Health and Clinical Excellence 2007).

The document has 11 sections:
1. Methadone Treatment Protocol
2. Aims and objectives of treatment
3. Assessment and management options
4. Detoxification
5. Methadone treatment
6. Special groups and substitute prescribing
7. Drug-related deaths and overdose
8. Other problems
9. Management of other drugs of misuse
10. Blood-borne viruses in opiate users
11. Non-methadone alternative therapies

Notable features of these treatment guidelines are the following:

After initiation assessment
The document states that not every client will be suitable for treatment in primary care, for example those with a history of violent behaviour, polysubstance addiction or a psychiatric problem.

Commencing methadone
The starting dose should be no more than 30 mg daily, with consumption supervised daily at this stage.

Stabilisation/destabilisation
It is recommended that the dose be increased by no more than 10 mg at a time until the client is stable. Usually clients stabilise on doses between 60 and 80 mg. On the clinical judgement of the doctor, supervision of consumption may be gradually reduced from daily, to thrice weekly, then twice weekly etc. However, for amounts larger than 80 mg, the guidelines state that it may be ‘prudent’ to continue with twice-weekly supervision because of the risk of overdose.

With regard to destabilisation, advice is provided on how to respond to the early signs of destabilisation. The guidelines recommend that management of the client should be supportive rather than punitive.

Pregnancy
A short section on pregnancy emphasises the need to stabilise the woman’s drug use during pregnancy. If necessary, the woman should be offered admission to an in-patient unit for stabilisation on methadone (pregnant women receive priority for inpatient admission).

Use of sedation
The guidelines recommend that the current good-practice guidelines for the prescription and use of benzodiazepines (The Benzodiazepine Committee 2002) (Department of Health and Children 2002) be followed when prescribing benzodiazepines (see section 11.2.4 below). They specify that benzodiazepine prescriptions should be reviewed monthly (to avoid dependence) and that there should be regular communication between the client’s different treatment providers to ensure benzodiazepine prescriptions are not duplicated.

Detoxification/withdrawal
The guidelines state that detoxification/withdrawal from methadone is more likely to be successful if psycho-social support is available. However, the type and location of the support, and the role of the GP in this process, are not outlined. They recommend that, in negotiation with the client, small
reductions (amount not specified) are more likely to be successful when aiming to reduce or come off prescribed methadone.

Use of sedation in withdrawal
The guidelines recommend that benzodiazepines should not be prescribed for opiate users to help reduce withdrawal symptoms. They state that there is no evidence of benefit to the client and there is a risk that the tablets may be abused or diverted. If a client is on benzodiazepines, it is recommended that a detoxification from benzodiazepines be conducted before commencing the methadone detoxification.

11.2.2 Management of service provision to opioid misusers by pharmacists
As part of their overall guidance manual, the PSI has included a short section on the management of service provision to opioid users (The Pharmaceutical Society of Ireland (Standards and Practice Unit) 2008). The section lists the criteria under which the pharmacist should operate. Any pharmacist providing methadone should:

• be aware of, and comply with relevant legislation,
• ensure that persons are not stigmatised and confidentiality is maintained when they use the service,
• ensure the appropriate protocols, facilities and resources are available to safely deliver the service, and
• ensure all staff are properly trained to manage the programme.

In particular, the document states that the pharmacist should draw up a written protocol with the person receiving methadone maintenance. This protocol should set out what is expected from both parties, standards of behaviour, confidentiality and how the treatment is to be provided. Specific procedures such as the storage of the drugs or maintaining records are also outlined, and the importance of good communication between the pharmacist and client is emphasised.

11.2.3 Drug treatment clinical policy in the Irish Prison Service
In January 2008 the Irish Prison Service (IPS) published a comprehensive drug treatment clinical policy (Irish Prison Service 2008). The document was created by the IPS, based on European methadone guidelines, but it does not give the names or designations of those who contributed. There is no time line or date given for evaluation or review of the document.

The policy contains a detailed section on methadone treatment, outlining the background and rationale for methadone treatment, as well as the clinical management of a prisoner on methadone and the logistics of dispensing. Specifically, it includes:

• clinical interdisciplinary care planning,
• methadone treatment guidelines,
• assessment – treatment plans and treatment goals (induction, maintenance and detoxification),
• criteria for treatment priority,
• use of methadone – ordering and dispensing, and
• administration and recording of methadone.

Methadone treatment
The policy outlines the processes necessary for methadone treatment under different circumstances, including when a prisoner is already on methadone, when treatment is to be initiated in prison, and when a prisoner on methadone is due to be released.
The document states that in general the initial starting dose should be between 10 and 20 mg. The document also states that if there is considerable tolerance to opioids, the starting dose could be between 25 and 40 mg but cautions that, if there is any doubt, it is better to start on a lower dose. Normally, an individual will stabilise on 60–120 mg per day.

Withdrawal and detoxification
As set out in these guidelines, the policy of the IPS is to offer detoxification to clients who have a history of drug use unless they are (1) already on methadone maintenance treatment, (2) HIV positive, or (3) pregnant.

The document states that evidence shows that the slower the reduction of the methadone dosage the greater the likelihood of successfully coming off methadone treatment (dosages not specified). It recognises psychological support along with aftercare as critical in this process.

The lofexidine detoxification and alcohol withdrawal guidelines have been adapted from The Maudsley Protocols. Guidelines for the use of naltrexone, as part of an overall programme of addiction treatment, along with psycho-social support, are outlined in the document. The guidelines state that naltrexone should only be prescribed by a medical person experienced in its use. The use of injectable naloxone for reversing accidental opiate overdose is not covered.

Pregnancy
Pregnant women are specifically mentioned in the document. Objectives in the care of pregnant women are:

- stabilisation of mother’s drug use,
- retention of mother in obstetric and drug treatment service and ensuring adequate support and through care in the community,
- delivery of a full-term baby with healthy birth weight,
- avoidance of *in utero* exposure to HIV/hepatitis,
- minimisation of the occurrence of neonatal abstinence syndrome, and
- promotion and support for positive physical health, mental health and social wellbeing throughout and after pregnancy.

The document states that during pregnancy it is advisable to stabilise the woman on methadone, rather than attempt to detoxify. However, if a woman wishes to detoxify during her pregnancy, it is recommended that it should be done after the 12th week of pregnancy but before the 32nd week, to reduce the risk of premature labour.

Psychological care
The policy devotes a chapter to the importance of the psychological and social aspects of drug treatment. The guiding principles are case management and care plans and a therapeutic and supportive environment within the prison.

Other issues
Issues around blood-borne viruses, including testing, clinical management and immunisation, are also addressed in the policy. The document states that the misuse of benzodiazepines is an endemic problem in the Irish prison population and provides policies and guidelines around assessment of dependence, prescribing and detoxification.

The document states that an interdisciplinary team will provide treatment for problem cocaine use on an individual basis. There is a range of treatments available including counselling and cognitive behavioural therapy, along with appropriate referrals to medical or psychiatric services as necessary.
The document also states that it is the policy of the IPS, in accordance with the standard prevailing in the community, to develop a dual diagnosis service for those patients with addiction problems and mental health problems.

11.2.4 Good practice guidelines for the prescription and use of benzodiazepines

In December 2002, the Minister for Health and Children, Micheál Martin TD, launched the Report of the Benzodiazepine Committee (The Benzodiazepine Committee 2002) and its Good Practice Guidelines for Clinicians (Department of Health and Children 2002).

The Benzodiazepine Committee was set up by the Minister in June 2000 to ‘examine the current prescribing and use of benzodiazepines; to consider recommendations on good prescribing and dispensing practice, paying particular attention to the management of drug misusers’. The Committee comprised doctors working in addiction, with input from psychiatrists and others working in the area of addiction around the country. The Committee made no recommendations for evaluation of the report or review of the success of the guidelines.

The report envisaged the continued use of benzodiazepines as versatile and valuable drugs in clinical medicine, for example in treating insomnia, epilepsy, muscle spasms, some forms of anxiety, panic and pre-surgical stress. They anticipated that fostering rational prescribing practices for these drugs would reduce the prevalence of inappropriate use, the number of patients who become dependent on them, and consumption by known opiate users.

The report made 24 recommendations including the introduction of a monitoring system to inform GPs of their prescribing patterns and to allow appropriate action where there is a suspicion of irresponsible prescribing. The report signalled the need for greater awareness among professionals (including all hospital and institutional healthcare providers and pharmacists) and the general public about the use of benzodiazepines and made a number of recommendations in this area.

The report also recommended ongoing evaluation and monitoring of the use and misuse of benzodiazepines in Ireland, particularly in the private sector, among older people and drug users attending drug treatment clinics.

The good practice guidelines recommend GPs to critically and urgently review their current level of benzodiazepine prescribing, regard the prescription of benzodiazepines to opioid users (and other drug users) as an exceptional rather than a routine clinical decision, and routinely advise patients dependent on opioids that the concurrent use of benzodiazepines greatly increases the risk of overdose. The guidelines outline four methods for benzodiazepine withdrawal/ detoxification.

11.3 Implementation process

11.3.1 Methadone Treatment Protocol and associated guidelines

In 1997 the Department of Health and Children set up the Methadone Treatment Services Review Group to assess the use of methadone in the treatment of heroin dependence. Membership of this Review Group was similar to that of the 1993 Expert Group, and reflected the various agencies with a role in the provision of services for drug misusers, including the Department of Health, the then Eastern Health Board, the ICGP and the PSI. Representatives from the Merchants Quay Project, Department of General Practice in University College Dublin, and the IPU also participated in the meetings of the Review Group.
The Review Group examined the existing protocols for good practice in the prescribing and dispensing of methadone and pointed to appropriate controls that could be put in place. It also set out the basis on which methadone treatment should continue to be developed and recommended a concise framework for the future operation of the Scheme. The framework was enshrined in statutory regulations introduced in 1998 (see Section 11.1).

11.3.2 Methadone Prescribing Implementation Committee, 2002

A Methadone Prescribing Implementation Committee, comprising representatives from the then Eastern Regional Health Authority, the seven health boards outside the eastern region, General Medical Services (Payments) Board, the ICGP, the PSI and the Department of Health and Children was subsequently established to oversee the implementation of the 1998 MTP. In 2002 this committee commenced a review of the implementation of the MTP (Methadone Prescribing Implementation Committee 2005).

Submissions were received from 46 interested parties and were analysed to identify themes and recommendations were made to address the themes identified, which included the following:

Representation on the Methadone Prescribing Implementation Committee
A number of submissions identified the need to invite representatives from the community, service users, the voluntary sector, the Drug Treatment Centre Board, the former Area Health Boards and the Irish Psychiatric Association onto the committee. The committee agreed to invite representatives of the Drug Treatment Centre Board, the former Area Health Boards and the Irish Psychiatric Association to be represented on the committee.

The regulations
Several submissions requested revisions to the prescribing of methadone. None of these suggestions were taken on board as it would have meant re-writing the regulations.

Clients’ experiences of methadone treatment services
Clients attending methadone treatment programmes requested that all clients should participate in their treatment plan, stable clients should not need to attend weekly, individual appointment times should be given to clients, clients continuing to use drugs chaotically should be treated separately from more stable clients, and the issue of privacy with respect to urinalysis should be addressed. The committee recommended that it would be more appropriate to address these issues through the service users’ charter in each HSE area.

General practitioners
A number of submissions stated that there was a need to take a co-ordinated approach to methadone treatment outside the HSE Eastern Region and to increase the recruitment of level 1 and level 2 general practitioners throughout the country. The committee stated that it would review the role of the National General Practitioner Co-ordinator to ensure greater support to the areas outside the Eastern Region. A small number of general practitioners requested an increase in the number of clients that a practitioner was permitted to treat. The committee stated that it would deal with such requests on an individual basis. It was suggested that training on treating opiate misuse be included in undergraduate and postgraduate medical training. In addition, it was suggested that specialist methadone training should continue and that completion of such training should be one of the criteria for GMS posts in deprived areas. These ideas were welcomed by the committee and were to be recommended to the relevant authorities. It was also suggested that general practitioners be given the resources to comply with the requirements of the National Drug Treatment Reporting System. Such compliance is a condition of the general practitioners contract negotiated in 2003.

Pharmacists
Pharmacists requested joint training with other health professionals, which the committee considered a useful suggestion. The need to increase the recruitment of pharmacists was raised. The committee recommended the employment of a liaison pharmacist for the HSE areas outside the Eastern Region. Some pharmacists requested routine hepatitis B vaccination; this is available free from the HSE to all participating pharmacists and their staff. Pharmacists and clients raised the issue of security and privacy in pharmacies. The committee reported that these issues were outside their remit as they had resource implications, and noted that grants were available through the HSE for upgrading premises. Some pharmacists reported that a regular client might present to a pharmacy without a prescription and the pharmacists experienced a dilemma: to follow the regulations, or to fulfil their duty of care to the client. The committee took a pragmatic view, stating that the pharmacist should provide the previously prescribed treatment, document the experience and ensure the client seek an up-dated prescription as soon as possible. Actions should be taken to prevent this practice being repeated on a regular basis.

Co-ordination between services and continuity of care for clients

According to the text of the submissions, the lack both of co-ordination between psychiatric services and drug treatment services and of continuity of care between prison services and drug treatment services needed to be addressed. The committee agreed with these statements and welcomed the establishment of a national committee to develop protocols for transfer of clients between the prison services and the HSE. The committee stated that structures should be developed to ensure that clients on methadone treatment who require psychiatric treatment are not at a disadvantage.

11.3.3 External review of MTP, 2010

In June 2010 an external review of the MTP was initiated to maximise the provision of treatment, to facilitate appropriate progression pathways (including exit from methadone treatment where appropriate) and to encourage engagement with services. The HSE has commissioned Professor Michael Farrell, Professor of Addiction Psychiatry and Director of Postgraduate Medical Education in the Institute of Psychiatry London, to carry out the review, in conjunction with Professor Joe Barry, Professor of Population Health Medicine, Trinity College Dublin. Submissions have been invited from interested parties, including the community and voluntary sectors.

The terms of reference for the review are to:

- review the MTP with regard to maximising provision of treatment including detoxification, stabilisation, and rehabilitation,
- review the MTP with regard to clinical governance and audit,
- review the MTP with regard to effectiveness of referral pathways,
- review the MTP with regard to the enrolment of GPs, the training of GPs, the criteria for Level 1 and Level 2 GPs, and the GP co-ordinator role,
- review the MTP with regard to urinalysis testing – its appropriateness and efficacy;
- engage with the Department of Justice with regard to the prescribing of methadone in Garda stations, and
- review the MTP with regard to data collection, collation and analysis.

11.3.4 Drug treatment policy in Irish prisons

To date there has been no evaluation of the new policy in prisons.

11.3.5 Benzodiazepines

Action 41 the National Drugs Strategy 2001–2008 (Department of Tourism Sport and Recreation 2001), tasked the Department of Health and Children with overseeing implementation of the recommendations in the report on benzodiazepines (Section 11.2.4). Speaking at the launch of the report on 10 December 2002, the Minister for Health and Children said, ‘The co-operation of key
players from a wide spectrum of sectors will of course be pivotal in helping to realise this objective. I am confident that this co-operation together with a heightened public awareness of the risks inherent in inappropriate use will result in a reduction in misuse and dependency in this country.’

No formal evaluation of the success of the guidelines has been conducted. In 2009 the Steering Group that drafted the National Drugs Strategy (interim) 2009–2016 (Department of Community Rural and Gaeltacht Affairs 2009) stated that the implementation of the recommendations had been slow and that several important issues still needed to be addressed. These included a review of the benzodiazepine regulatory framework which deals with monitoring and application of sanctions. The Steering Group noted that while there had been improvements in the system to monitor prescribing within the public health system, prescribing in the private sector still needed to be tackled. It called for the Irish Medicines Board to review both the regulatory system and the implementation of the guidelines.

Although no formal evaluation has been conducted, several studies have examined benzodiazepine use in Ireland. A study published in 2009 (Flynn 2009) noted that, in spite of the introduction of the guidelines seven years previously, the Irish health service had doubled the amount spent on tranquillisers and sedatives. The author stated that there was significant incorrect prescribing and distributing of these drugs. Long and colleagues (Long, J and Lyons 2009) reported that the misuse of tranquillisers and sedative drugs (mainly benzodiazepines) was common among the Irish population, while benzodiazepines were implicated in 30% of drug-related deaths in Ireland between 1998 and 2005 (Lyons, Suzi, et al. 2008).

11.3.6 Drug users’ views on the health services

A collaborative piece of action research was published in 2005 which sought to identify the issues encountered by drug users in their dealings with the Irish health services (O'Reilly, et al. 2005). Focus groups were held with 25 drug users from Dublin city. The study revealed many problems, including negative or discriminatory attitudes and treatment by health care staff.

The study dealt with issues to do with drug treatment, particularly methadone maintenance treatment. Some participants felt that GPs were reluctant to take on drug users and, since GPs are gate keepers for medical cards, this created obstacles to health care. Concerns in relation to treatment services included privacy and confidentiality, and a consequent reluctance to enter counselling. Another theme to emerge was the perceived need to develop a more holistic, individual-centred approach to the multi-faceted problems being encountered by users. A broad consensus came out of the focus groups that methadone was not the whole answer to these complex issues.

One of the expected outcomes of the study was that the opinions of drug users would be considered by the health service in future. Since then, the Union for Improved Services Communication and Education (UISCE) has joined the Methadone Prescribing Implementation Committee.

11.3.7 GPs’ perceptions of implementing the Methadone Treatment Protocol (MTP)

Almost one-third (32%) of opiate users prescribed methadone substitution are cared for in private general practice in Ireland. In light of this information, the ICGP conducted a postal survey in 2006 to determine the attitudes of Irish GPs to the MTP (Delargy 2008).

A questionnaire was sent to 600 GPs who were recorded on the ICGP’s drug misuse database as having received training in the management of methadone clients. Just under 35% (207) responded. It is notable that 247 GPs had patients on the Central Treatment List at the time of the study.
Almost half of the GPs who responded were aged between 46 and 60 years and 29% were female. Two out of every three practices were situated in an urban area. Just over two-fifths of the GPs said that illicit drugs were a major problem in their practice area; the majority of these GPs practised in an urban location. Ninety-two per cent confirmed that they had attended special training in methadone treatment.

Of the 207 GPs who completed the questionnaire, 72% were providing patients with methadone treatment at the time of the survey. Over half had 10 or fewer patients. Only 35 prescribing doctors or their staff did not want any more patients. Forty-six GPs were willing to take more patients, which suggested that there was capacity to transfer suitable clients to a normal health care environment.

The vast majority of GPs thought that the MTP was beneficial to patients, though some said that methadone was addictive and difficult to get off.

The types of training that GPs considered most useful were small locally-based continuing education networks, individual mentoring, and distance learning.

The additional services most desired by GPs were addiction counselling, in-patient detoxification and rehabilitation beds, and employment schemes.

11.4 **Comparison of treatment guidelines with WHO guidelines**

Within each section above, where relevant, each item of the WHO questionnaire is alluded to. In general, comparison of the three Irish treatment guidelines dealing with methadone (Irish College of General Practitioners 2008) (Irish Prison Service 2008, Methadone Prescribing Implementation Committee 2005) with the WHO questionnaire revealed only limited congruences as the approach adopted in the Irish guidelines differs from that adopted by the WHO. However, since the start of methadone treatment in Ireland, there have been positive changes in response to previous studies and reviews, such as including services users in the MPIC committee, and the current review of Ireland’s methadone treatment protocol is regarded as timely.
GREECE

CHAPTER 11: HISTORY, METHODS AND IMPLEMENTATION OF NATIONAL TREATMENT GUIDELINES

11.1. History and overall framework

In Greece, national treatment guidelines are available for the substitution treatment only. There is 15 years history of laws and decrees specifying the philosophy, the objectives and the admissions criteria of the substitution programme. There are also guidelines for the implementation of the programme issued by the coordinating agency for drugs demand reduction in Greece, OKANA (Organisation Against Drugs). Since OKANA is by law the only responsible agency for the implementation of the programme, its guidelines should be considered national.

The founding law of OKANA (L. 2161/93) already provided for the implementation of the substitution units, but the programme started at a pilot phase in 1995, with the Ministerial Decree 25/22-3-95 which specified the philosophy, objectives and admissions criteria of the programme. These were amended in 2002 (M.D. 100847/9-10-2002).
In 2002, OKANA issued the operational framework of the substitution units, acting as official guidelines for the implementation of substitution programme. Initially they refer to methadone only, since buprenorphine was still in the pilot phase since 2001.

The programme started as detoxification and treatment aiming at total abstinence from all drugs, including methadone. At the time there was a considerable opposition to the use of substitutes for drug treatment, originating mainly from the drug free programmes, either because they felt “threatened”, or because they were in principle against it; “threatened” because in Greece the vast majority of treatment programmes (public, NGO) are financed by the state, and, the vast majority of clients in treatment are heroin users, and the main argument against substitution was that substituting one drug with another cannot be considered treatment. The investment of the state in methadone programmes combined with the existing predominance of substitution programmes in Europe, could have contributed to the “insecurity” of the drug free agencies, expressed by negative attitudes towards it at the time. The fact that the supporters of the substitution presented methadone as a “panacea” to dependence did not help to it being accepted.

It might be due to these reactions that the first law, in 1995, defined the programme as “detoxification” (stressing though the need to retain users in the programme by enhancing incentives), specified the age of admission to over 22 and foresaw at least one previous attempt in a drug free programme.

In the following years, the reactions subsided for various reasons: a) the proportion of abstinent users after the two years duration of the programme was around 10%, quite below the drug free rate, and this was considered a “failure” of the programme, which rather “strengthened” than “threatened” the role of drug free treatment, b) the waiting list and the waiting period of the substitution programme was increasing rapidly, and it was thought that motivated users would be inclined to join drug free programmes (this was a myth, as data collected by the Focal Point suggested that only a 2% of the individuals in the waiting list had actually participated in drug free programmes while waiting), c) users of drugs other than heroin (cannabis, cocaine) were motivated to seek treatment, and they would inevitable address the drug free agencies, d) the concept of early intervention gained ground and interventions for adolescents and young adults were implemented by the drug free agencies, e) the budget of the drug free agencies increased, disproving their fears for the opposite, and f) ideas and concepts prevalent in Europe, such as harm reduction, increasing the user’s well-being, reducing drug related deaths, became widely spread in Greece, changing the overall attitude towards dealing with the drug problem.

The change of attitudes and the evaluations of the substitution programmes in Europe led the policy makers to introduce modifications to the objectives of the substitution programme and in 2002 the Ministerial Decree
established harm reduction as the main objective of the programme (not abandoning the abstinence goal). It also decreased the lower age limit to 20 from 22.

Nowadays, all treatment modalities co-exist harmoniously under the concept of treatment pluralism, the belief that not all treatments are suitable for all users, and the right of users to choose the modality they consider most appropriate for them.

In 2009, there were 22 substitution units nationwide (7 methadone units and 15 buprenorphine) and 44 drug free agencies. There were 5,360 clients in substitution and 2,378 in drug free treatment.

11.2. Existing guidelines: narrative description of existing guidelines
There are no national guidelines for drug free programmes in Greece. The two major agencies, KETHEA and 18 ANO have each issued their own guidelines, which will not be presented as they are not national.

11.2.1. Objectives of the Substitution and Maintenance Programme established by law

These objectives, established by the Ministerial Decree in 2002 are presented in Table 11.1.

<table>
<thead>
<tr>
<th>General aims</th>
<th>Specific objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimizing drug related risks</td>
<td>To retain drug users in the programme by enhancing incentives</td>
</tr>
<tr>
<td></td>
<td>To decrease parallel drug use</td>
</tr>
<tr>
<td></td>
<td>To decrease antisocial and criminal behaviour</td>
</tr>
<tr>
<td></td>
<td>To decrease the probability of being infected by infectious diseases and transmitting them to others</td>
</tr>
<tr>
<td>Detoxification from drugs</td>
<td>To consolidate a normal way of living, to improve family and social relations and to increase the interest in education/training in order to achieve occupational rehabilitation</td>
</tr>
<tr>
<td></td>
<td>To abstain from opiate drug use</td>
</tr>
<tr>
<td></td>
<td>To abstain from other drug use</td>
</tr>
<tr>
<td></td>
<td>To abstain from alcohol abuse</td>
</tr>
<tr>
<td></td>
<td>To decrease antisocial and criminal behaviour and promote health</td>
</tr>
<tr>
<td></td>
<td>To increase employment perspectives or productive occupation through training and social rehabilitation</td>
</tr>
</tbody>
</table>
11.2.2. Admissions criteria

The same Ministerial Decree specified the following admissions criteria:
- The user must be a chronic IV heroin or other opiates user
- Physical and psychological dependence must have been established
- The user must be over 20 years old
- If the user is under 35 years old must have at least one certified unsuccessful treatment attempt in one of the accredited by the MoH drug free programmes
- The user must not have psychiatric comorbidity
- The users must sign a written consent to the conditions of the therapeutic contract, violation of which can result in sanctions decided and imposed by the therapeutic team of the unit.

Changes in relation to the previous criteria set in 1995 refer to criterion 3 (the Lower age was 22), and criterion 4 (the condition for a previous drug free attempt was requested by all users, not only those under 35).

The Ministerial Decree foresaw that OKANA should a) decide on the cases where exceptional admissions are needed (priority admissions), b) draft an operational framework of the units. Both should be decisions of the Management Board of OKANA and ratified by the MoH.

11.2.3. Guidelines of the substitution and maintenance programme issued by OKANA

The book by Annette Verster and Ernst Buning “Methadone Guidelines”, published by EuroMethwork in 2000, was translated in Greek, published and handed out to the methadone units as general guidelines for the substitution programme (methadone administration) in 2002. The book is quite known and its contents will not be presented.

In parallel, OKANA issued the operational framework of the programme, which serves as specific guidelines.

Operational framework of the substitution programme
The operational framework includes the main aims and specific objectives and the admissions criteria established by the Ministerial Decree presented above. It also specifies the criteria for exceptional admissions (priority admissions).

I. Admissions

A user who wishes to join the substitution programme must complete and sign an application form to the Centre for Reception, Information and Orientation of OKANA. There he/she is assessed through structured interview and they join the waiting list.

A client who does not fulfill the admissions criteria can be exceptionally accepted to the programme, provided he/she is already in the waiting list and following approval of the OKANA administration, in the cases below:

- age over 55 years old
- parent of an under aged child
- first degree relative or spouse to a user who is already participating in the programme
- diagnosis of cancer, bacterial endocarditis, kidney deficiency, diabetes, liver cirrhosis, HIV/AIDS, active tuberculosis, or combination HCV/HBV, HBV/HDV
- transplant of cardiac valve or other vital organ
- pregnancy
- disability degree >67% (according to the Regulation for Degree of Disability Assessment)
- relapse following prior completion of the substitution programme.

II. Centre for Reception, Information and Orientation of OKANA

The Centre accepts application and starts assessment of the user’s condition. During the first session, the clients’ record is opened, their medical and drug history is discussed and TDI is administered. In the second session the clients are informed on the phases and the units of the programme and they are oriented to the suitable units for their situation (e.g. younger clients are oriented to short-term units). The third session is the placement of the clients to a unit. The whole procedure should last one week.

In each unit the group of therapists (Therapeutic team) is responsible for several decisions, depending on the treatment phase, the specific aim of the unit and the degree of tolerance to relapses.
III. Sort - term Unit (STU)

**Phase 1: Motivation.** This phase should last 3 months. The aim is the provision of information about the programme, the preparation for the initiation of the substitute administration, the stabilisation of the dosage, and the preparation for Phase 2, psychosocial improvement and maintenance or detoxification. The ratio of therapists to clients is 1/20.

*Therapeutic approach.* Detailed medical and psychosocial assessment, creation of an individualised treatment plan, signing of the therapeutic contract, participation of the client in groups for stabilisation, information, motivation relapse prevention. Stabilisation and gradual increase of substitute dosage. Re-assessment by the end of the 3 months period.

*Assessment tools.* Medical assessment, psychosocial assessment (EuropASI), assessment of the therapeutic procedure.

*Therapeutic tools.* Safe substitute administration, individualised dosage, gradual increase and stabilisation, in response to client’s needs. The client participates in the stabilisation group.

*Stabilisation group.* The participation in this group is mandatory for 1 week, 30 minutes a day. The purpose is to get the client well informed on the nature of the substitute, the stabilisation procedure, dealing with withdrawal symptoms, and relapse prevention and management.

*Information group.* Clients who showed high compliance and consistency in the stabilisation group can participate in the information group, once a week for one month. The aim of this group is provision of information on the operation of the programme and its various phases.

*Motivation and relapse prevention group.* Participation on a weekly basis for 6 weeks. The aim of this group is to strengthen the social skills, self confidence and the motivation for abstinence.

*Individual sessions.* Every client should have individual sessions with their therapist, twice a week, aiming at psychosocial counseling and support. In the last session the client is reassessed for the next phase. The final decision for the client’s moving to the next phase belongs to the therapeutic team.

**Phase 2: Psychosocial improvement, stabilisation or detoxification.** This phase lasts 3-12 months and aims at assisting the client to achieve detoxification or improving their psychosocial state, depending on the client’s wish.

*Therapeutic approach.* Detailed reassessment of the client’s situation and creation of a treatment plan (detoxification or improvement). In collaboration with the patient, the dosage of the substitute decreases gradually. Incentives are given to the clients, such as “take home” doses.
Assessment tools. Medical assessment, psychosocial assessment (EuropASI follow-up form), assessment of therapeutic process (client’s progress assessed through the Offered Services Monitoring Record).

Therapeutic tools. Treatment plan, therapeutic contract signed. Client’s legal, medical and welfare problems are cared for. The family or important others are made use to facilitate the client’s effort. A nine months’ detoxification programme is foreseen for the clients who have made a plan aiming at abstinence, while individual and group counseling sessions are being held, twice and once a week respectively, for the clients who aim at detoxification and maintenance, separately.

Lack of compliance to the groups. Every effort should be made to assist the clients to comply with the therapeutic procedure and the regulations of the programme. Clients who are systematically absent, late or violate the rules of non-parallel use, are referred to the low-threshold unit. These clients can return to the Short-Term Unit under certain conditions (evidence of compliance, responsible behaviour, strong motive).

IV. Long-Term Unit (LTU)

The aims of this unit are administration of substitution treatment for relapse prevention and for strengthening and maintaining the social and professional integration of the clients.

Conditions for admission:
- clients who have successfully completed Phase 1 of the STU and their request have been approved by the therapeutic team,
- clients referred by Phase 2 of the STU for psychosocial improvement and stabilisation, and
- clients with chronic diseases, who have diagnosed psychiatric comorbidity (despite the Ministerial Decree stating the opposite, see 11.3: “implementation process”), who are over 50 years of age, or who during their admission to the programme were assessed by the therapeutic team that they would do better in the LTU. All clients are asked to sign a therapeutic contract.

Treatment approach and procedure:
- Administration of the substitution treatment in doses fully covering the client’s needs
- Care for psychiatric problems in case of comorbidity by the psychiatrist of the unit or in liaise with a psychiatric unit of a public hospital
- Care for medical problems by the general practitioner of the unit or the liaised hospital special unit
- Psychosocial support through group or individual counseling for relapse prevention and integration
- Harm reduction interventions
- Vocational training and counseling through specialised programmes

43 The Low-Threshold Unit functioned for one year only, 2003, and thereafter it was merged to the Long-term Unit
• Assistance to abstinence in cases where the client decides for it. This can start inside the LTU and can be continued in STU, depending on the decision of the therapeutic team.

V. Social Reintegration Unit (SRU)

The aim of this Unit is the achievement of the best possible adaptation of the clients at family, social and vocational level and the parallel abstinence or maintenance state reached when exiting the previous stages of the substitution programme.

The SRU consists of two phases, the pre-reintegration and the reintegration.

Pre – reintegration Phase. In the last weeks of the substitution administration programme (STU/LTU) the client has 2-4 individual sessions with his/her therapist and one of the therapist of the SRU. These sessions aim at facilitating a smooth transition to the SRU. At the end of this phase the therapeutic contract of social reintegration is signed.

Integration phase. The client stays in the SRU at least one year. The programme consists of individual and group sessions once a week each, weekly urine tests and promotion to the labour market. At this stage administration of naltrexone is possible. In cases that the therapeutic team consider that the conditions for a client’s participation in SRU are not met at a certain moment in time, the client is referred back to the STU/LTU, where he/she has to stay for at least one year before the return to the SRU can be considered.

Successful completion of the Programme. Clients are considered to have successfully completed the Substitution Programme when they have:
• completed all the phases of treatment
• completed at least one year in the SRU, in total abstinence from all illicit substances and alcohol
• not been arrested for drug related offenses while participating in the Programme.

Table 11.2: Phases of Social Reintegration

<table>
<thead>
<tr>
<th>Phase</th>
<th>Content</th>
<th>Aim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre –reintegration (strengthening and stabilisation) 1 month</td>
<td>Detachment and “farewell” to STU 4 common sessions with therapists of STU and SRU</td>
<td>Preparation for admission in the SRU</td>
</tr>
<tr>
<td>Integration phase 12-24 months</td>
<td>Individual support and counseling</td>
<td>Promotion to the labour market</td>
</tr>
<tr>
<td></td>
<td>Group counseling</td>
<td>Support in finding or sustaining a job</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Re orientation in the relationships with family and friends</td>
</tr>
</tbody>
</table>
VI. Policy for the retention of clients to the Programme

Premature discharges should have a therapeutic rather than a punitive nature, and they should include the perspective of readmission to the programme. The compulsory period out of the programme ranges between 6 to 12 months, depending on the severity of the reason for discharge. Each Unit should make every effort to limit the number of premature discharges.

Reasons for premature discharge are:
- the non-reduction of use of other psychotropic substances in spite of the repeated warnings to the client
- repeated acts of violence in the premises
- drug trafficking in the premises and the abuse of the privilege to personal use of the substitute.

Monitoring and dealing with relapse:
- Urine tests. As they may be considered demeaning for the client, efforts should be made to reduce them up to once a month for the clients with satisfactory process.
- Relapse. Increased individual sessions and increase of the dose of the substitute can be used to reduce risk of relapse. Discharge because of repeated relapses is only justified when all other efforts and measures have been strained and/or the risks involved are great (parallel use of other substances or opiates, driving). The number of relapses tolerated is decided by the therapeutic team, who also decides referral to the LTU when considered that the STU regulations are too demanding for the client at that particular moment in time.

Dealing with violence and breach of the regulation. In cases of violent behaviour inside the premises and/or systematic breaching the programme regulation, the therapeutic team may decide to refer the client form the STU to the LTU.

In cases of violence, weapon possession and use, the foreseen actions are:
- immediate initiation of detoxification or referral to LTU
- reconsidering admission to STU after one year provided the client has not exhibited the same behaviour in the meantime.

In cases of life threatening behaviour, use of weapons, deceit, drug trafficking inside the premises, giving the personal dose of substitute to others, the foreseen actions are:
- immediate initiation of detoxification or referral to LTU
- discharge for at least 6 months
- in case of readmission (after the period of discharge) the client is admitted to a different than the initial unit
- in case of repetition of the inappropriate behaviour the client is permanently discharged from the Programme.

System of incentives:
“Take home”. “Take home” doses are effective for the clients whose progress is satisfactory, after decision of the therapeutic team. Conditions for “take home”: no parallel use for at least 4 months and good conduct and compliance with the regulation. For clients who meet these conditions the take home system starts for the weekends for a 3-months period. If the conditions are still met after the 3-months period, he/she is given the right to take home doses for 5 consecutive days once every 6 months.

- **Social welfare assistance.** The client is assisted to claim social welfare benefits and to stay in the special hostels provided if he/she is homeless.

### VII. Special issues

**Illness.** When a client is ill (certified by doctor or hospital) relatives can take the daily dose, after signing a written commitment.

Clients form other countries. EU citizens, who participate in a substitution program in their country and visit Greece, can be temporarily accepted to the Greek SP, under the following conditions:

- presentation of document from the substitution programme in the country of origin about the foreign client’s personal details and dose
- personal submission of application of the foreign client in the Centre for Reception, Information and Orientation of OKANA
- acceptance of the regulation of the Greek substitution programme
- setting a predetermined period of substitute administration.

### VIII. Successful participation – successful completion of the programme

A client is considered to have a successful participation in the substitution program, irrespective of the duration, when he/she has reduced psychotropic substances use, has reduced criminal behaviour or any other involvement with the law, and presents overall improvement of his/her well-being.

Clients who aim at detoxication and leave the programme when reaching abstinence, can be reaccepted with a new 12 months contract, if they relapse within a period of 3 months after leaving.

### 11.2.4. Amendments

The operational framework described above was amended a few months after its endorsement. The amendments are:

- Buprenorphine is introduced to the STUs.
- **Reception of clients and referrals to Units.** Clients in the waiting list will be invited, in turn, to enter the programme by the Centre for Reception, Information and Orientation of OKANA. Those who meet the conditions for buprenorphine administration, will be
informed on the medicine’s advantages and that if after test period of 20 days treatment with buprenorphine it is confirmed that the medicine is not suitable for them, they can go back to methadone. The STU will receive clients who enter substitution treatment for the first time, while the LTU will receive clients who have participated in the substitution programme for at least 6 months in the past. If these clients ask themselves to enter the STU for detoxification, it has to be assessed that they can respond to the demands of the STU.

- **Long-Term Unit.** The Low-threshold and the LTU will gradually merge.

- **Dealing with relapses.** In the STU, Phase 1, the client is referred to the LTU in the 4th relapse to opiates, cocaine, benzodiazepines, and/or alcohol. In Phase 2 in the 8th relapse to all the aforementioned substances. Cannabis and amphetamines use is monitored at longer intervals than the other substances’ use. Only clients who are free from all substance use are referred to the social reintegration unit. Clients who are stabilised (no relapses) are referred to the LTU after 6 months’ participation in the STU. In the LTU, cannabis use does not constitute reason for discharge. In case of any substance use during the first 2 months of the programme, no “take home” is given. The client is referred to the low-threshold unit (and when it is abolished discharged for 6 months) in case that urine tests are positive for 3 consecutive times in a 30 days period, and/or after the 12th relapse in a year’s period. Positive urine test in alcohol and benzodiazepines are treated with counselling and possible reduction of the dose for preventive reasons.

### 11.3. Implementation process

The guidelines discussed above form the theoretical background for the operation of the substitution programme, implemented at national level exclusively by OKANA.

In practice, there are quite a few differences among the 22 nationwide units of OKANA. It should be stressed that the guidelines were formulated when substitution units existed only in Athens and Thessaloniki. Through the years, 22 new units were founded in different cities, 16 of them operate in the premises of public regional hospitals.

In almost all of these cities, the one and only existing unit operates as a long term unit – the level of tolerance to relapses is considerably affected, since the philosophy of the programme is mainly harm reduction.

The size of the waiting list also affects they way units function. In Athens, the waiting list has been quite high for the last 5-6 years (3,771 users in 2009), in Thessaloniki it has been significantly lower (1,117 users in 2009), while 670 users were in 2009 in the waiting lists of all other cities. OKANA being severely criticised by the Media for the waiting list in Athens, is in constant pressure to maximise the capacity of the Athens’ units, which operate beyond capacity.
As it is obvious from the description of the guidelines, the therapeutic team of each unit has a broad mandate and is responsible for many decisions that concern the client. As expected, therefore, the teams in different units make different decisions, so that eventually each unit operates under slightly different rules. Their main differences refer to level of tolerance of relapses.

The main issues of the guidelines which were considered by the therapeutic team(s) necessary to “disregard” are a) one of the admissions criteria of the Ministerial Decree which stated that the users should have psychiatric comorbidity (as the majority of heroin users have dual diagnosis), and, b) the times of relapses tolerated before discharge stated in the operational framework (in most cases this number is increased).
11.4. Comparison with the WHO guidelines

<table>
<thead>
<tr>
<th>Name of Assessors:</th>
<th>Yes</th>
<th>No</th>
<th>N.A.</th>
<th>No answer</th>
</tr>
</thead>
</table>

### 1. Choice of treatment

1.2 For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment.

Do the present guidelines include this recommendation?

### 2. Opioid agonist maintenance treatment

2.1 For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine.

Do the present guidelines include this recommendation?

2.2 During methadone induction, the initial daily dose should depend on the level of neuroadaptation; it should generally not be more than 20 mg, and certainly not more than 30 mg.

Do the present guidelines include this recommendation?

2.3 On average, methadone maintenance doses should be in the range of 60–120 mg per day.

Do the present guidelines include this recommendation?

2.4 Average buprenorphine maintenance doses should be at least 8 mg per day.

Do the present guidelines include this recommendation?

2.5 Methadone and buprenorphine doses should be directly supervised in the early phase of treatment.

Do the present guidelines include this recommendation?

2.6 Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review.

Do the present guidelines include this recommendation?

2.7 Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence.

Do the present guidelines include this recommendation?

### 3. Management of opioid withdrawal

3.1 For the management of opioid withdrawal, tapered doses of

---

44 Guidelines do not officially cover buprenorphine treatment
<table>
<thead>
<tr>
<th>Name of Assessors:</th>
<th>Yes</th>
<th>No</th>
<th>N.A.</th>
<th>Specify</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>opioid agonists</strong> should generally be used, although alpha-2 adrenergic agonists may also be used. Do the present guidelines include this recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.2</strong> Clinicians** should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal.** Do the present guidelines include this recommendation?</td>
<td>✗</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>3.3</strong> Clinicians** should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal.** Do the present guidelines include this recommendation?</td>
<td>☐</td>
<td>✗</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>3.4</strong> Psychosocial services** should be routinely offered in combination with pharmacological treatment of opioid withdrawal.** Do the present guidelines include this recommendation?</td>
<td>✗</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>4</strong> <strong>Pregnancy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4.1</strong> Opioid agonist maintenance treatment** should be used for the treatment of opioid dependence in pregnancy.** Do the present guidelines include this recommendation?</td>
<td>✗</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>4.2</strong> Methadone maintenance** should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered.** Do the present guidelines include this recommendation?</td>
<td>☐</td>
<td>✗</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- Do the present guidelines agree with the “Clinical guidelines for withdrawal management and treatment of drug dependence in closed settings”?</td>
<td>☐</td>
<td>✗</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
HISTORY, METHODS AND IMPLEMENTATION OF NATIONAL TREATMENT GUIDELINES

HISTORY AND OVERALL FRAMEWORK

Although well-defined drug dependence-related therapeutic intervention programs, including morphine maintenance, have existed since 1932, it was not until 1967 that drug addiction programs linked to the framework of the outpatient centres providing care for alcoholism began being carried out under the National Psychiatric Care Board, Mental Health Services.

Around 1979-1980, several different specific centres providing care were created (DROSS at the “Hospital del Mar” in the City of Barcelona; Red Cross within the Municipal Government of Madrid; Bétera Hospital in Valencia) driven by the unanticipated overwhelming increase in the problems resulting from heroin abuse leading to addiction and the total lack of any Government Agency to suitably intervene. Attempting to achieve a more broad-ranging response from the Central Government, Mental Health was left out of the initiatives undertaken by the Municipal Governments.

In November 1975, studies were begun for preparing a “White Paper” on the part of the Alcoholism and Drug Dependence Services, including a detailed list of social, medical and psychological aspects suitable for dealing with the conflict through the Central Government Administration. It was around this same time that Spain began its transition to democracy, which reached its climax in 1978 with the passage of a Constitution by means of which Spain became a social, democratic State governed by laws, being organized into a State by way of the existence of 17 Autonomous Communities and two Autonomous Cities.

In 1985, the National Plan on Drugs and the Government Delegation to the Plan were created, the objectives of which included coordinating and bolstering the drug-related policies carried out through the different Central, Autonomous Community and Municipal Governments and through the social organizations. In this regard, special mention must be made of the fact that a Plan of an Autonomous Community scope exists in each one of Spain’s Autonomous Communities and Autonomous Cities. One of the first and most important matters with which the National Plan on Drugs had to deal was the heroin epidemic, which was worsened considerably by its being associated with AIDS.

The professional and administrative structures of the Autonomous Community agencies providing care for drug dependencies have differed in the past and continue to do so today. Currently, most fall within the framework of reference of Public Health and Healthcare, although there are still some systems with intervention models closer to the Social Services. Treatment quality assurance and quality control are in place in all of the National Health System’s medical services.

EXISTING GUIDELINES: NARRATIVE DESCRIPTION OF EXISTING GUIDELINES

During the 1986-1992 period, the Government Delegation for the National Drug Plan published the “Community and Drugs” journal, which, in addition to its regular issues, also published a number of Monographic Issues. Original studies on the different areas of intervention in drug dependencies (epidemiology, prevention, treatment, social reinsertion,
etc.), recommendations and basic procedures, as well as critical reviews of literature published both in Spain and internationally were featured. It must nevertheless be said that the different Autonomous Community Plans on Drugs have the authority to prepare their own rules for taking action in regard to providing care and assistance for drug users, although the general guidelines are usually agreed upon within the different bodies coordinating the National Plan on Drugs, in which representatives from these Autonomous Community Plans take part.

The majority of the Good Practices Guides or Manuals have been produced by the Scientific and Professional Societies working in the fields of drugs and alcohol, particularly the Spanish Scientific Society of Studies on Alcohol, Alcoholism and Other Drug Dependencies (SOCIDROGALCOHOL), which, since 1972, has been bringing together physicians, nurses, psychologists, social workers, attorneys, sociologists and any other personnel working on these topics.

This Scientific Society has been publishing a widely-disseminated journal titled “Addictions” since 1989, most of its monographic issues and supplements since 2003 actually being, in practice, good practices or intervention guides which have been widely disseminated and followed. The first issue was devoted to tobacco in 2003.

Mention must be made of one existing precedent. Thus, as of the late 1880’s, the Central Government Delegation for the National Plan on Drugs published a total of ten publications in the form of handbooks as part of the “Taking Action is Possible” collection. The major groups of professionals for whom these handbooks were published included primary care professionals, pharmacists, coroners, social workers, etc.

Strictly speaking, the first clinical Guide for the treatment of opiate dependence was published in 2007, as a monographic issue published by the SOCIDROGALCOHOL Scientific Society, under the coordination of Dr. Juan José Fernández Miranda. The latest Guide, available since 2008, is the “Clinical Guide for Psychological Intervention in Addictions” coordinated by Elisardo Becoña and Maite Cortés. SOCIDROGALCOHOL promotes the publication of high-quality monographic studies, the methodological aspects of which are based on the principle of evidence.

Apart from the above, some Professional Associations have been publishing good practices manuals since 2005, such as is the case of the National Council of Professional Social Workers and Case Workers, focusing quite specifically on the social emergency centres.

Within the 1999-2004 period, two Consensus Conferences on Alcohol and Drugs organized by the Spanish Psychiatry Society have also been held, having been well-considered and having included “guideline” criteria for diagnosis, assessing the degree of severity and the treatment-care of alcoholism and other dependencies. Unfortunately, there is sometimes not enough coordination among the Psychiatry networks, the Mental Health Teams and the Drug User Care Teams for the conclusions of any consensus reached to make its way all of the professionals working in these fields.

Within the 1974-1978 period, a break was made with the former tradition of psychiatrists heading the care provided, the bio-psycho-social model then having become almost exclusively a psycho-social gesture, with rigid drug-free programs up until 1995 and the years in following.

The treatment itinerary included many care and treatment variables, having included, sooner or later, a stage involving being admitted to a Therapeutic Community, which was of extremely prime importance and high effectiveness. The therapeutic communities have been and currently continue to be an irreplaceable link in the chain and have progressively
adapted to the change in the population for which they provide care. Many of these Communities are currently admitting patients on methadone maintenance or who have a mental disorder, which were formerly factors determining ineligibility for admission.

Reducing the harm and risk entailed some extremely serious difficulties for carrying them out within the context of drug dependence care networks of a psycho-social rationale, which considered addiction to be a deviated yet voluntary behavior, with almost exclusively cognitive-behavioral programs focusing on the drug-free modality. Being expelled from the program for detected drug use was the general rule, entailing the impossibility of returning to the program until several months later, which gave rise to situations of social exclusion and disadvantage. Keeping the patients in treatment was not considered a priority.

The legal changes having made the methadone maintenance programs possible, with a strict good practices protocol, were first gotten under way in 1990 by way of a bold Decree by the Ministry of Health and Consumer Affairs. This process was undoubtedly facilitated by the major degree to which AIDS was spreading and the determined measures taken in reducing the risk of sero-conversion and infection in all scenarios, including the prison environment.

The implementation of the aforementioned Decree nevertheless met with a major degree of opposition and hindrance on the part of both certain sectors of the public opinion and groups of care associations and some Professional Association, which considered them as being “giving up” or “throwing in the towel”. The methadone maintenance programs were authorized solely in the Government Administration drug user care networks. As of 1997, the development and implementation of these programs was spectacular nationwide in Spain. The number of individuals for whom care was provided in methadone programs throughout Spain rose from 4,718 in 1991 to 84,731 in 2001. These programs were carried out in conjunction with many additional public health, health education and outreach actions plus measures facilitating accessibility to treatment and for keeping in touch with patients.

Around 1996, drug users began being considered as being excluded, delinquent or socially menacing individuals, but rather as recurrently chronically-ill individuals in need of specific treatment and monitoring their own individual health so as to also safeguard public health. Modern, complex Autonomous Community laws were also drafted viewing substance abuse as just one type of addictive behavior, governing the widely-varying modalities of care and treatment.

In Spain, all of the drug dependence treatments carried out by centres and services pertaining to the public sector under any regimen, whether on a hospitalized or outpatient basis, are free of charge and universally available to all, including those for reducing the harm and risk as a whole and admission to specific drug units, hospital detox units or psychiatric treatment on a general hospital or psychiatric ward.

Studies and trials were conducted with LAAM and buprenorphine in those cases in which methadone was not the suitable solution, mostly due to an interaction with anti-tuberculosis or anti-retroviral drugs. In many Autonomous Communities, it was even possible to conduct sequenced blood methadone bioavailability titrations in cases of a poor result from maintenance at extremely high daily doses, despite the appropriate direct supervision of the treatment as a whole. The cost/day of LAAM and buprenorphine, which is much higher than that of methadone, also led to their use being confined to a residual group of patients. The same criterion has been applied to the naltrexone-buprenorphine combination. LAMM ceased being prescribed when its potential dangerous side effects were published, although no intolerance or complication was recorded in Spain as a result of this combination having been administered.
The proposed scheme of comparison regarding the WHO model of treatment for opiate dependence and, in particular, the maintenance programs, would give rise to the ways in which Spain was intervening agreeing totally with those of the U.N. agency. The only discrepancy is related to the fact that, in Spain, both buprenorphine and its combination with naltrexone are currently second-line treatment options when methadone is not the appropriate solution.

Implementing the recommendations of the guides has posed no problem, no response worthy of special note having arisen. It must be said that the intervention models for treating individuals who abuse opiates are totally homogeneous throughout the entire county in Spain.

Exactly the same situation of full agreement applies if a comparison is drawn between the WHO recommendations and those of Spain with regard to prisons. As of the early 1990’s, all prisons offer the possibility of undergoing treatment for drug dependence with a wide range of options, from drug-free programs, including prior detoxification, to harm reduction programs, not to mention the needle exchange and health kit distribution programs. Similarly, it is also possible for qualifying eligible prison inmates to start a methadone program.
FRANCE

Introduction

Rationale and objectives

The present chapter provides an insight on the place and the role of guidelines regarding the harmonization and improvement of drug addiction treatment in France. Hereafter the term “guidelines” is used to qualify a compilation of recommendations. It might be used alone in a purpose of fluency, but being understood that it refers to guidelines on treatment related to illicit drug addiction.

Many studies demonstrate the positive influence of the application of evidence-based professional guidelines on the organisation and the quality of a care system (Grimshaw et al. 2004). This kind of document appears as a key tool to bridge the gap between evidence and practice (Cabana et al. 1999). As a matter of fact, during the last decades, many countries have shown an increasing interest in the implementation of good practice guidelines. In 2009, the World Health Organization (WHO) too published guidelines for psychosocially assisted pharmacological treatment of Opioid Dependence (WHO 2009). Vesting a mission of promotion of good practices, the European Monitoring Centre on Drug and Drug Addiction (EMCDDA) question themselves about the extent, scope and conditions of application of drug treatment guidelines in the Member States of the European Union (EU).

According to the definition from the U.S. Institute of Medicine used by the EMCDDA, guidelines are “systematically developed statements to assist practitioners and patients’ decisions about appropriate interventions for specific circumstances” (Field et al. 1992). But guidelines are neither a collection of ready-made solutions, nor a so-called "cookbook medicine". They are not more likely to reflect individual opinions. In contrast it must be a decision-making tool for healthcare professionals that are not based on intuition or ideology but rather on scientific findings supporting their application in practical work (Helou et al. 2000).

In France, the High Authority for Health (HAS), former ANAES, defines clinical practice guidelines as “proposals developed according an explicit method in order to help healthcare professionals and patients to seek for the most suitable care related to specific clinical situations”. Guidelines are based on systematic literature reviews and expert opinion. They can be requested by diverse public or private bodies (Health ministry, scientific societies, associations, etc.). In the field of drug addiction, demands are generally referred to the HAS which can also launch a reflection at its own initiative.

Referring to evidence is essential to ensure the quality of guidelines (Brownson et al. 2003). But stating scientific evidences does not induce best practices in itself. The implementation of guidelines depends on many factors, affecting in particular the reliability of the recommendations and their acceptance by the target-public (Grol, R. 1997) (Grol, R. et al. 1998). These factors partly intervene when guidelines must be diffused towards professionals. Therefore, contribution from all the stakeholders is essential not only to gather reliable and up-dated data, but also to define a relevant and realistic implementation strategy (Hartnoll 2004).

In the light of these elements, both the definition and implementation processes of the targeted guidelines are considered in this study of the French situation. According to the EMCDDA’s query, an historical narration of the emergence of the guidelines developed in France precedes the description of these two phases. From then on, the evocation of the implementation of guidelines designates not only their application by the targeted professionals but also the whole accompanying measures deployed in this aim (since the final utilisation of guidelines has not been evaluated in general). The focus is on the

45 Agency for Accreditation and Evaluation of Scientific Evidence.
treatment of illicit drug uses, excluding the issue of the addiction to licit drugs (alcohol, tobacco, etc.). The main objective is to figure out possible ways, in the national context, to enhance a better integration of knowledge of evidence-based good practices in respect to drug addiction treatment. A comparison with the guidelines edited by the WHO is to be found in Annex IV.

Method
The study covers five out of the six identified treatment guidelines related to illicit drug use. The inclusion of the guidelines dealing with detoxification (1998) has not appeared relevant given the French context characterised by the predominance of opioid maintenance treatment and the regular decrease of both demand and supply of opioid detoxification programmes. The final list of the studied guidelines is:
- Access to methadone in France (Auge-Caumon et al. 2002)
- Therapeutic strategies for opiates addicts: place of substitution treatments (ANAES 2004)
- Abuse, addiction and polyuse: strategies of care (HAS 2007)
- Strategies of care for cocaine users (HAS 2010)

A review of key documents – official political or legislative texts and the treatment guidelines themselves – was carried out as a first step.

The development and the implementation of addiction treatment guidelines being poorly documented, an original data collection was required. Therefore, 15 field experts, field actors and stakeholders (i.e. 80% of the interviewees originally selected for their deep knowledge of the question) expressed their perception of the events and the existing logics and stakes, through semi-structured face-to-face interviews. The aim was to gather the institutional, professional, researchers and users’ standpoints all together. Finally a benchmarking model has enabled to highlight the strengths and gaps of the successive guidelines and to some extent to visualize the technical evolutions of their development.

History and overall framework of the substitution
The law of 31 December 1970 sets the legal framework of the drug policy in France. It stipulates that drug use is an offence but drug users can avoid prosecution by complying with a drug treatment, ever since anonymous and free of charge. The objectives of this law are also to repress trafficking and to control the use of drugs (Derks et al. 1999) (Angel et al. 2005). From then on drug addiction has become a matter of national solidarity directly within the competence of the State. In 1982 a cross-departmental body was established to coordinate the public action in the fields of prevention, health and social care, law enforcement and international cooperation. This body became the interministerial Mission for the fight against drug and drug addiction (MILDT). It operated under Ministry of Health before coming under Prime Minister in 2009. This so-called law of 1970 has not been fundamentally modified since then but many ministerial directives (decrees and circulars) were issued to supplement the patterns of health and social care towards drugs addicts.

Historically, drug treatment responses developed in France have largely been influenced by a psychoanalytical approach. In the 60s, drug addicts were addressed to psychiatric hospitals for detoxification, like alcoholic people. At that time, treatment basically focused on abstinence. In a way, from the adoption of the anti-drug law, the State entrusted the specialists, mainly psychiatrists and psychologists, with the care to drug addicts: the psychological and behavioral disorders implicated in addiction appealed to individual clinical

---

46 Loi n°70-1320 du 31 décembre 1970 relatif aux mesures sanitaires de lutte contre la toxicomanie et de l’usage illicite des substances vénéneuses
responses. These professionals developed a psychoanalytical approach, based on a relation of trust between the drug-addicted patient and the practitioner and still aimed at abstinence. This practice became more and more professionalized over the 70s. The overrepresentation of psychiatrists in the edification of drug treatment knowledge must also be related to the relative reluctance from the traditional health system to undertake drug users, seen as a problematic population. Furthermore, the predominance of specialists in the field might have contributed to arise the feeling among general practitioners (GP) that this issue was not their affair especially since they were poorly trained on the subject. Until the early 1990s, the more curative vision of drug addiction related care tended to delay a more global apprehension of the problem and finally the acceptance of the pragmatic approach of risk reduction (Boekhout van Solinge 1996). The main professional actors thought that prescribing opiates to a drug addict could not but comfort the ascendency of the product over the patient. For the political authorities, the extension of substitution would have left the door opened for the liberalization of drug use.

The beginning of the 1990s has seen a volte-face, particularly because of the HIV epidemic. A social movement emerged uniting sociologists, activists from the AIDS support groups, humanitarian associations, public health specialists, GPs and also drug users themselves. It pledged in favor of risk reduction policy and methadone programmes denouncing the dramatic health repercussions of the drug policies in force. These actors were inspired by several European examples (in particular Belgian, Dutch and Swiss experiences) but also by changes observed in their everyday practice. Actually, the humanitarian sector coped with a crisis situation due to the increasing demand of care from HIV infected drug injectors. In parallel, in face of the important and increasing wave of drug users needing care related to HIV infection, more and more GPs and hospital professionals were confronted with specific addiction health probems among these patients. Drug addiction has become a matter of intervention for many of these professionals who had been mostly kept aside until then. Some GPs started to prescribe opiates (e.g. codeine, temgesic), not only to favour their patients’ survival but also to help them to feel in better condition to enter a process of treatment and to survive. These were the first approaches of substitution treatment which would be officially adopted later on, in the mid 1990’s.

The report of the commission for the reflection on drug and drug addiction, the so-called Henrion report (Henrion 1995b), delivered in 1995 to the Minister of Health evoked “a health and social catastrophe”: France reported at that time one of the highest prevalence of HIV infections in Europe. Getting aware of those consequences, government finally introduced harm reduction measures (syringe exchange programmes) in order to contain the AIDS epidemic. As France was quite late in offering opiate substitution to drug addicts and as public opinion was still shaken by the previous scandal of the HIV contaminated blood, the authorities had to react as quickly as possible to prevent further infections and deaths.

In 1995, specialised centres were authorized to provide methadone47. One year later, High Dosage Buprenorphine (HDB) was chosen as main substitution substance, despite its higher cost compared to methadone. France opted for this molecule since it could be prescribed in primary health care, which was considered as frontline system to respond to the important wave of demands (Escots, S. et al. 2004b; Escots, S., Fahet, G. 2004). This was quite naturally accepted among the general practitioners who started to prescribe HDB. The conversion was less simple among specialists, who were gradually organising methadone programmes (Coppel, A. 2004). In a way, HDB was left to general practitioners. This rapid and important shift in the French policy caused an animated polemics. They particularly issued from professionals who considered substitution seen like a setback for the therapeutic ambition. Questions subsisted about the GPs’ ability to take the change of direction towards substitution on. They rooted in the perception of their lack of training and of insufficient psychosocial care facilities to address drug addicted patients to (Bergeron 1999). At the time, the only directive from authorities concerned the maximum duration of any

47 Circulaire DGS n° 4 du 11 janvier 1995
prescription of HDB fixed at 28 days (versus 14 days for methadone). As the risk of overdose was not perceived yet and in the absence of any other specification, physicians were free to determine the dosage to prescribe. In the opposite, strict controls were imposed for methadone in order to prevent such accidents. But some of the first prescribers could work in a network, compare their practices and then fine-tune the pharmacological indications. The collaboration between GPs and the hospital sector could also rely on the specific so-called “ville-hôpital” network. The principles of the clinical practice, empirically conceived and tested, diffused via addictology networks (Coppel, A. 2004).

Few years later, the improved access to harm reduction and substitution cares resulted in a sharp fall in the number of fatal overdoses (184 in 1998 vs. 451 cases in 1994) and a decrease of the prevalence of HIV infections among drug injectors (10 % in 2007 vs. 30% in the early 90s). A major change had taken place in France and had demonstrated the efficacy of opioid substitution treatment. Faced with these incontestable outcomes, many drug specialised centres reconsidered their position and adopted the principle of substitution. Thus, the large diffusion of substitution treatment brought to the surface other issues like misuse and related health damages but also the apparition of a black market, in particular based on HDB. But those issues were not immediately handled, the priority being at first the consolidation of the still recent substitution policy (Coppel, A. 1998).

At the beginning of the 2000s, even though opposition still existed, substitution was entered in the clinical practices of the drug specialised and hospitals sectors and the GPs as well. However there was still a great heterogeneity throughout France regarding the accessibility to methadone programmes, the latter being very limited in many départements (sub-regional decentralised territories, 100 in total). In this context, France then entered in a phase of reflection characterised by the elaboration of the first formal guidelines on the drug use treatment.

In 2002, ministry of Health published the first recommendations aimed at improving the access to methadone. Two years later, the French federation of addiction (FFA) together with the ANAES (currently the HAS, High Authority for Health) organised a consensus conference with a special focus on HDB (ANAES 2004). On that occasion, most of the conclusions of the 2002 report were also reaffirmed. For the first time in this field, representatives of drug users have been associated to deliberations. For many professionnals, the 2004 consensus conference was marked by a strong feeling of acceptance, support and even enthousiasm: at the end of the conference, opposition to substitution had softened.

The year 2004 was also marked by the adoption of several measures aimed at curbing the misuse of substitution substances. The Law of 13 August 2004 relative to National Health Insurance (CNAMTS) imposes on any patient “to indicate to his attending physician, for each prescription, the name of the pharmacist who will be responsible for the delivery (of the medicine)” and imposes on any physician “to mention this name on the prescription that must be issued by the concerned pharmacist for acceptance of financial liability” (Article L.162-4-2). In addition, the National Health Insurance launched during the same year a National Action Plan on the Control of substitution treatments “to fight against fraud and abuse while preserving the right of patients to benefit with quality care”. Together with the Ministry of Health and the French Agency for Safety of Health Products (AFSSAPS), it also proposed clinical practice guidelines (CPG) focusing on the prescription of opioid substitution medication so as to reduce their potential misuse. These ones were published by the ANAES and the AFSSAPS in 2004 (ANAES 2004).

Later on, the HAS published two other guidelines to improve quality of addiction treatment. The raising concern about polyuse among drug users lead to the elaboration of the guidelines on the subject, in 2007 on the request of the French Federation of Addictology (HAS 2007). Faced with the sharp rise of the prevalence of cocaine use reported in France and the increase of treatment demands related to this product, the HAS studied the question. On the basis of the available international scientific works dealing with cocaine use

---

48 Circulaire DGS n° 29 du 31 mars 1995 (DGS/SP3/951°29)
49 Loi n°2004-810 du 13 août 2004 relative à l’assurance maladie. NOR: SANX0400122L
treatment, it supervised the development of specific guidelines, published in June 2010 (HAS 2010). At last, more recent guidelines taking over the involvement of drug users referred to medico-social addictology establishments were issued in April 2010 by the ANESM. But their ins and outs could not be analysed within the scope of this study.

**Characteristics of the definition and implementation patterns of the existing guidelines**

A synopsis of the studied guidelines is provided in Annex 1. It provides details on their objectives, the intervention or groups targeted as well as the contributors, the method applied for their elaboration (including quality control) and finally the implementation measures organised. The common points and relevant specificity of the development processes of these documents are also commented in this work.

A benchmarking chart offers a visual comparison of these features guidelines in respect to a theoretic ideal model (please see charts 11-1 and 11-2), according to the criteria noted hereafter. Nonetheless, it is important to mention that more detailed information was available regarding guidelines on opioid substitution (2004 consensus conference). Because of lack of information, the guidelines related to the misuse of opioid substitution medication (2004) are not included in this comparison.

**Definition process**

Four criteria were taken into account for the analysis of the process of definition of the selected guidelines:

- the multidisciplinarity of contributors;
- the evidence-based nature of the methods applied to define the guidelines contents;
- the evidence-based nature of quality control;
- the conciliation propensity of the whole process.

**Contributors**

In France, representative bodies of specialised professionals (federations, national associations) and public health authorities (ministry of Health, National Insurance, etc.) are the *sine qua non* protagonists of the elaboration process of guidelines related to drug addiction treatments. Guidelines can be produced at the instigation of any of these bodies. Any of them can be at the instigation of guidelines. For this purpose, they seize the public health agency that will suprervize works (HAS, former ANAES, which is the first producer of medical guidelines or AFSSAPS that specifically publishes recommendations on medications). In general rule, other categories of contributors are consulted: field actors, researchers, epidemiological data providers or even representatives of drug users. Their diversity and representativeness of profiles varied from one to another experience but in general the consultation mainly focuses on physicians. Pharmacists or nurses are more scarcely associated and sociologists, economists or jurists are even more rarely so. The authors’ notoriety contributes to legitimizing these guidelines and to promoting them towards professionals (Davis et al. 1997). In other words, the commitment of influential professionals (constituting a kind of leadership) allows the introduction of innovative clinical practices among peers.

**Definition methods**

The elaboration of the French drug treatment guidelines did not follow any imposed conceptual model. As a matter of fact, different methods were applied for the successive experiences: restricted work group, public hearing, audit or, more recently, the evidence-based method of clinical practice guidelines (CPG) (please see box below).

---

50 National Agency for the Evaluation and the quality of the social and medico-social establishments and services.
The clinical practice guidelines or CPG method usually involves promoters (initiators and funding providers), the steering committee (determining the subject, problems, contributors and handling logistics), the working group (that sums-up knowledge and prepares recommendations) and the reading group (validating outputs and providing with additional information and expert advice). It is based on three phases: the preliminary phase to define the method and objectives, the development phase including data collection (e.g. through literature review, surveys, etc.) and finally the dissemination phase including impact evaluation (ANAES 1999).

Although the deep reasons of these methodological choices could not be certified through this study, cultural or corporative preferences could certainly be invoked. For instance, the consensus conference has a good image in France and benefits from a good acceptance from professionals and public opinion (Durand-Zaleski I 1992).

When expectations for socio-political cohesion co-existed with scientific and deontological purposes, methods like consensus conference or public hearing were privileged. By allowing a conciliatory dynamic, these methods are liable to favour a better support towards conclusions by the majority of people. Another advantage is that these approaches also constitute a communication event.

This dimension is probably what was missing for the recent experience regarding guidelines on cocaine uses. As a matter of fact, although the scientific rigour of their definition has not been contested, their applicability was questioned by some professionals who did not find in them all the answers to their daily practical questions.

Quality control methods
In general, quality control rules applied while defining these guidelines could not be clearly described through the interviews. That suggests that they solely consisted in an on-going internal peer assessment. In 2009-2010, for the guidelines relative to cocaine use treatment, the HAS preferred to develop an ad hoc grading system on the quality of evidences.

Usually The HAS uses the AGREE criteria to evaluate the guidelines written under its responsibility, developed according to the method of clinical practice guidelines (CPG). Nevertheless it could not apply these evaluation criteria to the two guidelines dealing with the misuse of substitution medication (2004) and cocaine use (2010), both developed according to this CPG method.
The Appraisal of Guidelines Research and Evaluation (AGREE) questionnaire and its criteria were developed by scientists and health policymakers at the beginning of 2000s so as to assess the quality of clinical practice guidelines (CPG) developed by local, regional, national or international groups. This generic tool can be applied to any type of CPG regarding any health problem, medical intervention or type of care (AGREE Collaborative Group 2000)

Conciliation dynamic
The coordinators’ capacity to consider the whole positions expressed over the elaboration process supports the future acceptance of guidelines. This could explain for instance that, despite previous strong oppositions, the 2004 guidelines on the substitution strategy have had better echoes than most of recommendations issued till now in relation to addiction treatment (see Chart 11-1). At that time, the shared willing of improving therapeutic practices through the consensus conference on substitution has certainly contributed to the cohesion of the discourse. For many people, this frame of mind symbolized the “end of the war” and the official acceptance of substitution treatment.

Apparently, the conciliation dynamic potentially stirred up while defining guidelines may weight on the perception of their impact or their social utility to some extent.

Implementation process
The implementation process of treatment guidelines begins in fact as soon as the phase of their conception considering the persuasion strength and communication skills of influential contributors. However implementing guidelines covers specific and proper steps: the stages of adoption, publishing and active diffusion (like training, reminder systems, etc.) before the final phase of appropriateness.

The implementation measures organised in France are examined here against four criteria: the multidisciplinarity of promoters, as an indicator of their representativeness and legitimacy while sustaining the adoption of guidelines;

the accessibility of publications, in other words the operational and pragmatic nature, characterising a primary level of dissemination;

the existence of accompaniment measures, in particular for active information strategy (i.e. a second level of dissemination);

the used resources and means to support the application of guidelines.

Multidisciplinarity of promoters
In most cases, key figures (leaders) could promote guidelines introducing them to colleagues or other audience. Therefore, these personalities and the specific professional networks did play an important role in the communication in favour of guidelines. The involvement from these experts may take over more punctual diffusion and communication measures. But such assets could rarely be optimized by a clear promotion strategy, once guidelines achieved. Specific communication initiatives took place when a pharmaceutical company or professional associations got involved as it was the case for the 2004 guidelines on substitution therapeutic strategy. The place left to the economic actors directly interested in the substitution market raised some ethical questions. This is why, in that case, the communication and training sessions organized by the pharmaceutical laboratory were organized in collaboration with the ministry of health and/or representative of professional bodies. Given the very restricted public funding, the possible resort to private funding proved to be helpful.

Accessibility of publications
In all cases, the guidelines were published in medical reviews and on the websites of the involved institutions or associations. Most often, a short version was also produced in order
to facilitate the distribution of recommendations and an easier access for practitioners. On one occasion, the HAS announced the publication of new guidelines through newsletters to physicians. But it stopped these mailings given the difficulty of updating the addresses database. Other publication forms were produced, as brochures or letters to general practitioners, summing-up the recommendations that directly concerned them. After the 2004 consensus conference, reminder systems like doctor letters were diffused, but punctually.
Chart 0-1: Benchmarking of definition processes of the French drug treatment guidelines

<table>
<thead>
<tr>
<th>Categories of the benchmarking – Definition process</th>
<th>Benchmark</th>
<th>Multidisciplinarity of contributors</th>
<th>Evidence-based method</th>
<th>Conciliatory dynamic</th>
<th>Quality control</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Very low level</td>
<td>Policy makers, concerned professionals</td>
<td>Professional empirical expertise</td>
<td>Epidemiological identification of needs</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>2 Low level</td>
<td>Level 1 + final target population</td>
<td>Partial literature references</td>
<td>Level 1 + consulting the diverse existing stakeholders</td>
<td>Independent</td>
<td></td>
</tr>
<tr>
<td>3 Moderate level</td>
<td>Level 2 + researchers</td>
<td>Systematic review</td>
<td>Level 1 + active contribution of the diverse existing stakeholders</td>
<td>Cross independent</td>
<td></td>
</tr>
<tr>
<td>4 High level</td>
<td>Level 3 + other relevant professionals</td>
<td>Level 3 + standardized grading of evidence</td>
<td>Level 3 + consensus</td>
<td>Level 3 + process evaluation</td>
<td></td>
</tr>
</tbody>
</table>

Legend:
- GL 2001 Access to methadone 2001
- GL 2004 Substitution therapies
- GL 2007 Polyuse
- GL 2010 cocaine
- Ideal model
Chart 0-2: Benchmarking of implementation processes of the French drug treatment guidelines

<table>
<thead>
<tr>
<th>Categories of Benchmarking – Implementation process</th>
<th>Benchmark</th>
<th>Multidisciplinarity of promoters</th>
<th>Written Information tools</th>
<th>Active Information tools</th>
<th>Support resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Very low level</td>
<td>1 Very low level</td>
<td>Policy-makers</td>
<td>Written material, Internet (Online version)</td>
<td>Academic continuou s education</td>
<td>Legislative texts</td>
</tr>
<tr>
<td>2 Low level</td>
<td>2 Low level</td>
<td>Level 1 + Strategic change actors</td>
<td>Level 1 + short version of GL</td>
<td>Opinion leader and audit feedback</td>
<td>Level 1 + specific funding</td>
</tr>
<tr>
<td>3 Moderate level</td>
<td>3 Moderate level</td>
<td>Level 2 + Economic actors</td>
<td>Level 2 + targeted short version</td>
<td>Interactive workshops/ seminars/ trainings</td>
<td>Level 2 + prescription control system OR implementation unit</td>
</tr>
<tr>
<td>4 High level</td>
<td>4 High level</td>
<td>Level 3 +Final target population</td>
<td>Level 3 +Newslet ter, prescription reminder system</td>
<td>Durable combination of the aforesaid components</td>
<td>Level 2 + prescription control system AND implementation unit</td>
</tr>
</tbody>
</table>

---

52 Adapted from the SIGN work (SIGN: Scottish Intercollegiate Guidelines Network)
53 Corporations, experts, personalities
Accompaniment measures
Several studies from the Cochrane Effective Practice and Organisation of Care group (EPOC group) enabled to put into a hierarchy, according to their effectiveness, possible patterns of communication in relation to the implementation of policies (see table below). According to this classification, targeted and interactive surpass the other patterns of communication as for assuring an appropriate diffusion and facilitating the integration of information (ANAES 2000) (Grol, R. et al. 2003). Quite logically, the combination of these types of interventions appears more efficient than each one separately (SIGN 2008).

Table 0-1: Effectiveness of communication patterns for effective implementation of a policy

<table>
<thead>
<tr>
<th>Not effective (Mixed effects)</th>
<th>Low effective</th>
<th>Moderate effective</th>
<th>High effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Continuous medical education</td>
<td>- Opinion leader</td>
<td>- Audit-feedback</td>
<td>- Interactive training</td>
</tr>
<tr>
<td>- Conferences</td>
<td>- Mass media campaign</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In France, no accompaniment measures (such as training, workshop, seminars) were organised at national level to support the publication of drug treatment guidelines. They were often discussed but did not ever materialize on a national level. Whatever they were, they remained punctual.
In 2004 meetings and trainings for practitioners were locally organised by the pharmaceutical company distributing HDB. This laboratory also sponsored brochures for practitioners and drug users.
Some years after the publication of the 2004 consensus conference, academic modules of addictology were integrated in the initial medical curricula. Now, short modules of continuous training and diploma in addictology also exist. But overall, the integration of clinical recommendations in these curricula is not assessed.

Resources and support system
In France neither law nor any control body compels practitioners to apply the issued recommendations. The only control in force has been established by the National Health Insurance (CNAMTS) and concerns abusive or suspicious prescriptions (mean daily dose of HDB > 32mg). It aims at reducing the misuse of the substitution medication.
On the other hand, professional orders (physicians or pharmacists’ ones) can provide for clinical or technical advice. But there is neither local nor national administration overseeing the substitution treatment delivered. Except for the creation of the département committees for the follow-up of opioid substitution treatments (which finally disappeared), adequate resources were not developed so as to support the application of guidelines. No permanent resources unit (ex.: mediators, dedicated staff) liable to help practitioners to understand or to implement recommendations, could be set up neither locally nor nationally, neither by heath authorities, nor by professional organisations.
Through the reported experiences, gaps identified in respect to the implementation systems of guidelines seem to be largely imputable to the recurrent lack of funding, major obstacle to a structured, proactive and viable implementation strategy.

Available evaluation details
None of the reported experiences was evaluated. Nonetheless, with the passing of time, professionals have perceived that the diverse guidelines have had a limited impact, apart from the benefits attributed to the 2004 consensus conference regarding the social climate among professionals. The main criticisms refer to recurring weaknesses in the accompaniment of the guidelines.
A recent study carried out by the ANITeA (forthcoming publication) shows a great heterogeneity of substitution practices and knowledge on good practices among specialised treatment centres (CSAPA). These findings tend to confirm the perception expressed by the experts interviewed for the present study.

Literature reveals that the lack of visibility about the impact of guidelines is not exceptional, at least in the field of addictions. Although there are sufficient sources defending the implementation of evidence-based approaches, the latter are generally underused in drug addiction treatment (Institute of Medicine 2005).

The chart below sums up the influencing factors weighting on the production and implementation processes of French guidelines on drug addiction treatment as well as the main weaknesses.

Chart 0-3: Determining factors of the definition and implementation of drug addiction treatment guidelines in France

Possible paths of improvement
Some paths of improvement can be drawn from this analysis. However their budgetary weight has not been estimated in the scope of this study.
Involving from the beginning to the end of the process the different concerned publics, in particular opinion leaders, is essential in order to manage correctly all stakeholders’ expectations and to find realistic methods to sustain changes. The opinion leaders’ commitment and accountability prove to be important to achieve effective development and diffusion of guidelines just like appointed human resources and support conditions are necessary to sustain their viability.

As a matter of fact, the promotion of guidelines must be long-standing, beyond the simple phase of their publication, and proactive. A particular impetus must be put on communication and support systems. The gaps identified in these domains are bound to the absence of specific public funding.

An action plan would have allowed to structure the coordination of a cost-effective and sustainable implementation. If such an action plan is built in the future, it could deal with the following points:

1. Setting up a national network for reflection and exchange on experiences;
2. Continuous education and training, and specific lectures in academic curricula;
3. Establishment of a help service for practitioners (resource unit) for the application of guidelines;
4. Process formative evaluation; further researches on successful implementation experiences;
5. Research on drug users’ acceptance of the recommended approaches;
6. Regular review of guidelines;
7. Monitoring of drug treatment demands

The monitoring of treatment demands and the integration of academic lectures are the only aspects performed on a regular basis nowadays in France.

Conclusion
The French High Authority for Health (HAS) produced six treatment guidelines related to drug use. On the basis of literature review and key experts’ interviews, this study covers the production process (definition and implementation) of five of these guidelines (detoxification matter having been excluded). Most of the guidelines deal with opioid substitution that has become from the mid-1990’s the major treatment pattern in France.

The drug care system has been for a long time mainly dominated by the psychoanalytical approach. With the coming of HIV epidemic, especially among drug injectors, France adopted, though quite lately, substitution treatment in a risk reduction and harm reduction perspective. The large proportion of GPs committed or potentially concerned by drug related care has been one of the main reasons that made France opt for buprenorphine in the mid-1990s. But the advent of substitution was marked by important dissensions in the medical world. At the beginning of the 2000s, the need to pacify the debate on substitution was almost as important as the need of harmonizing practices. In this way, the production of guidelines has also been a field for reconciliation.

All formal recommendations were created in the 2000’s according to diverse methods: through restricted working group, public hearing, audit or Clinical Professional Guidelines (CPG) method. Quality assurance processes also varied from internal discussions to cross independent revisions. But the methods applied for the grading systems of recommendations and the evaluation criteria themselves are unclear.

Though the method of definition of guidelines and of quality control did not always follow the most recognized international standards, this absolutely does not allow any depreciation of the quality of recommendations. The most obvious gaps concern above all the diffusion of the guidelines which rarely went beyond a primary level consisting in their publication. Communication and assistance to professionals also lacked. Nowadays, the intervention of opinion leaders is a major asset in the production of guidelines, particularly when they defend innovative practices. It appears as a key ingredient not only so that guidelines contents gain
in consistency but also to favour their acceptance by professionals and finally the adoption of new practices.

Barriers such as the lack of financial and human resources and other organizational or ideological issues, restrain the integration of evidence-based approaches in routine practice. In France, incontestably, future endeavours must focus on support resources and means likely to strengthen the implementation of guidelines.

The relatively short period of time between the publication of guidelines and the identification of the option problems at their origin suggests that authorities more spontaneously resort to this type of tool in the field of addiction. Due to the high costs of their organization, the HAS, the main producer of medical recommendations in France, will probably not organize anymore consensus conferences. In the future, it has decided to refer more and more to evidence-based methods like Clinical Practice Guidelines (CPG).
### Appendix a: Synopsis of guidelines related to addiction treatment

<table>
<thead>
<tr>
<th>Guidelines (year)</th>
<th>Objectives</th>
<th>Targeted interventions</th>
<th>Targeted professionals</th>
<th>Actors</th>
<th>Method and quality control</th>
<th>Implementation resources</th>
</tr>
</thead>
</table>
| Access to methadone in France (2002) | To formalize, clarify and organise public health policy regarding substitution treatment  
  - To develop and to sustain what works, to assess and correct what does not work  
  - To improve the quality of care with substitution treatment in prisons  
  - To improve ease of use of methadone and to enhance adherence to therapy among drug addicts | Substitution treatment | Field health care providers<sup>54</sup> | Initiator and promoter: Delegated Minister of Health  
Contributors: Health professionals (Psychiatrist, Internist Pharmacist, GP) | - Report  
- Professional empirical expertise  
- Internal quality control | - Publication (92 pages)  
- Online version Sub regional committees to support opioid substitution treatment |

---

<sup>54</sup> Drug addiction specialists, Psychiatrists, GPs
<table>
<thead>
<tr>
<th>Guidelines (year)</th>
<th>Objectives</th>
<th>Targeted interventions</th>
<th>Targeted professionals</th>
<th>Actors</th>
<th>Method and quality control</th>
<th>Implementation resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic strategies for opiates addicts: place of substitution treatments (2004)</td>
<td>To determine goals and expected results for substitution treatment To identify the necessary modalities of support for implementation and follow-up of treatment To find ways for the adoptions of treatments in primary health care To promote good practices in the management of patients receiving treatment</td>
<td>Substitution treatment provided with methadone and high dosage of buprenorphine (HDB)</td>
<td>Field health care providers</td>
<td>Initiator: FFA Contributors: Health professionals[^55], ANAES, Representatives of drug users Promoters: ANAES, FFA, Pharmaceutical laboratories, Health professionals, Representatives of drug users</td>
<td>▪ Consensus conference ▪ Partial literature references ▪ Independent quality control ▪ Prescription control system</td>
<td>▪ Publication of a short and long versions of guidelines (15/40 pages) ▪ Online version ▪ Extra short version addressed to GPs ▪ Brochures ▪ Trainings/Workshops</td>
</tr>
</tbody>
</table>

[^55]: Psychiatrists, GPs, MDs specialized in Public Health or in Addiction, Pharmacists, Psychologists and others

[http://lesrapports.ladocumentationfrancaise.fr/BRP/024000177/0000.pdf](http://lesrapports.ladocumentationfrancaise.fr/BRP/024000177/0000.pdf)


<table>
<thead>
<tr>
<th>Guidelines (year)</th>
<th>Objectives</th>
<th>Targeted interventions</th>
<th>Targeted professionals</th>
<th>Actors</th>
<th>Method and quality control</th>
<th>Implementation resources</th>
</tr>
</thead>
</table>
| Reducing the misuse of opiate substitution medication (2004) | • To identify available substitution medication, their misuse and the determinant factors  
• To improve the prescription by monitoring and reassessing patient’s treatment and follow-up  
• To improve the organization of care | • Diagnostic according to DSM-IV or CIM-10  
• Prescription of medication | Field health care providers | Initiator: Ministry of Health, CNAMTS, AFSSAPS  
Contributors: Health professionals\(^{56}\), ANAES, Representatives of drug users  
Promoters: ANAES, AFSSAPS | Clinical practice guidelines  
Partial literature references  
Cross independent quality controls | Publication (15 pages)  
Online version  
Fact sheets for prescribing physicians as reminders for good practices  
Centres for Evaluation and Information on Pharmacodependence (CEIP)  
Prescription control system |
| Abuse, addiction and polyuse: strategies of care (2007) | • To educate all professionals involved in the management of various addictions  
• To provide these professionals with operational recommendations  
• To propose studies, programmes and trainings | • Application of the Addiction Severity Index (ASI)  
• Therapeutic care | Field health care providers, especially the ones in contact with the youth, pregnant women, elderly, inmates, precarious population, sportsmen  
Researchers | Initiator: Ministry of Health  
Contributors: Health professionals, HAS  
Representatives of drug users  
Promoter: HAS | Public Hearing  
Systematic review  
Independent quality control | Publication (36 pages)  
Online version |

\(^{56}\) Psychiatrists, GPs, MDs specialized in Public Health or in Addiction, Pharmacists, Psychologists and others
<table>
<thead>
<tr>
<th>Guidelines (year)</th>
<th>Objectives</th>
<th>Targeted interventions</th>
<th>Targeted professionals</th>
<th>Actors</th>
<th>Method and quality control</th>
<th>Implementation resources</th>
</tr>
</thead>
</table>
| Strategies of care for cocaine users (2010) | - To improve health care of cocaine users  
- To facilitate their identification and the cessation | - Counselling  
- Psychologic al follow-up  
- Detoxificatio n  
- Psychothera py | ➞ Field health care providers, especially the ones in contact with pregnant women and young people\(^{57}\) | **Initiator:** Ministry of Health  
**Contributors:** Health professionals, HAS  
Representatives of drug users, Researchers | Clinical prac- tice guidelines  
Systematic review and standardized grading of evidence  
Cross independent quality controls | Publication of a short and long versions of guidelines (28/148 pages)  
Online version |

---

\(^{57}\) In primary health care, hospitals or specialised centres.
## Appendix b: List of participants by alphabetic order

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Christine BARBIER</td>
<td>General Department of Health (DGS)</td>
</tr>
<tr>
<td>Henri BERGERON</td>
<td>National Centre for scientific research (CNRS)</td>
</tr>
<tr>
<td>Anne COPPEL</td>
<td>Public health sociologist specialised in the field of addiction</td>
</tr>
<tr>
<td>Jean-Pierre COUTERON</td>
<td>President of the association ANITeA</td>
</tr>
<tr>
<td>Patrice DOSQUET</td>
<td>National Authority for Health (HAS), Head of the guidelines department</td>
</tr>
<tr>
<td>Isabelle FERONI</td>
<td>National Institute of Health and Medical Research (INSERM)</td>
</tr>
<tr>
<td>Albert HERSZKOWICZ</td>
<td>General Department of Health (DGS)</td>
</tr>
<tr>
<td>Laurent KARILA</td>
<td>Hospital psychiatrist</td>
</tr>
<tr>
<td>Bertrand LEBEAU</td>
<td>Clinical physician in specialised drug addiction treatment centres</td>
</tr>
<tr>
<td>William LOWENSTEIN</td>
<td>President of the TSO group (addiction commission)</td>
</tr>
<tr>
<td>Michel MALLARET</td>
<td>President of National Commission on Narcotic and psychotropic Drugs (CNSP)</td>
</tr>
<tr>
<td>Alain MOREL</td>
<td>President of French Federation of Addiction (FFA)</td>
</tr>
<tr>
<td>Dominique MEUNIER</td>
<td>Association ANITeA</td>
</tr>
<tr>
<td>Fabrice OLIVET</td>
<td>President of the Association of self-help for drug users (ASUD)</td>
</tr>
<tr>
<td>Pascale REDON</td>
<td>Department of Health (DGS)</td>
</tr>
</tbody>
</table>
### Appendix C: List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFSSAPS</td>
<td>Agence française de sécurité sanitaire des produits de santé</td>
<td>French agency for safety of health products</td>
</tr>
<tr>
<td>AGREE</td>
<td>Appraisal of Guidelines Research and Evaluation</td>
<td></td>
</tr>
<tr>
<td>ANAES</td>
<td>Agence Nationale d'Accréditation et d'Evaluation en Santé</td>
<td>Agency for Accreditation and Evaluation of Scientific Evidence</td>
</tr>
<tr>
<td>ANESM</td>
<td>Agence nationale d'évaluation et de qualité des établissements et des services sociaux et médicosociaux</td>
<td>National Agency for the Evaluation and the quality of the social and medicosocial establishments and services</td>
</tr>
<tr>
<td>ANITEA</td>
<td>Association nationale des intervenants en toxicomanie et addictologie</td>
<td>National Association of Drug Abuse and Addictology Workers</td>
</tr>
<tr>
<td>ASUD</td>
<td>Auto-support des usagers de drogues</td>
<td>Association Self-help for drug users</td>
</tr>
<tr>
<td>CPG</td>
<td>/</td>
<td>Clinical Practice Guidelines</td>
</tr>
<tr>
<td>CNAMTS</td>
<td>Caisse nationale d'assurance maladie des travailleurs salariés</td>
<td>National Health Insurance of salaried workers</td>
</tr>
<tr>
<td>DGS</td>
<td>Direction générale de la santé</td>
<td>General Department of Health</td>
</tr>
<tr>
<td>FFA</td>
<td>Fédération française d'addictologie</td>
<td>French Federation of addiction</td>
</tr>
<tr>
<td>GL</td>
<td>Recommandations</td>
<td>Guidelines</td>
</tr>
<tr>
<td>GP</td>
<td>Médecins généralistes</td>
<td>General practitioner</td>
</tr>
<tr>
<td>HAS</td>
<td>Haute autorité de santé</td>
<td>High Authority for Health</td>
</tr>
<tr>
<td>HDB</td>
<td>Buprénorphine haut dosage</td>
<td>High Dosage Buprenorphine</td>
</tr>
<tr>
<td>InVS</td>
<td>Institut national de veille sanitaire</td>
<td>National Institute for Health Surveillance</td>
</tr>
<tr>
<td>MD</td>
<td>Médecin</td>
<td>Medical doctor</td>
</tr>
<tr>
<td>MILDT</td>
<td>Mission interministérielle de lutte contre la drogue et la toxicomanie</td>
<td>Interministerial Mission for the Fight against Drug and Drug Addiction</td>
</tr>
<tr>
<td>OFDT</td>
<td>Observatoire français des drogues et des toxicomanies</td>
<td>French Monitoring Centre on Drugs and Drug Addictions</td>
</tr>
<tr>
<td>WHO</td>
<td>Organisation mondiale de la santé</td>
<td>World Health Organisation</td>
</tr>
</tbody>
</table>
Appendix d: Comparison with the WHO guidelines

Guidelines are considered by the World Health Organisation (WHO) as an indispensable tool for promoting “best practices” in the treatment of drug addiction due to the great number of publications on treatment principles and guidelines (WHO et al. 2008). Considering this increased interest, the WHO recently published guidelines for psychosocially assisted pharmacological treatment of opioid dependence (WHO 2009). These guidelines were set up by an international expert group, in collaboration with the United Nations Office on Drugs and Crime UNODC. They respond to a resolution from the United Nations Economic and Social Council ECOSOC. They are based on a systematic review of available literature and consultation with experts from all relevant fields. A study carried out by the Centre for interdisciplinary addiction research (CIAR, Hamburg University) has shown a large diversity between the EU Member States regarding the number and contents of drug treatment guidelines (Zurhold et al. 2009). In this section, the French recommendations referring to opioid substitution are compared to the WHO guidelines. Further comments are provided below the table.
For each listed WHO recommendations, the following question is answered:
Do the present guidelines include this recommendation?

Name of Assessors: Tiphaine Canarelli (OFDT) & Stefanie Schütte (Public Health master)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
<th>Specify</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Choice of treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 For opioid-dependent patients not commencing opioid agonist maintenance treatment, consider antagonist pharmacotherapy using naltrexone following the completion of opioid withdrawal.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Opioid agonist maintenance treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1 For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2 During methadone induction, the initial daily dose should depend on the level of neuroadaptation; it should generally not be more than 20 mg, and certainly not more than 30 mg.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3 On average, methadone maintenance doses should be in the range of 60–120 mg per day.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4 Average buprenorphine maintenance doses should be at least 8 mg per day.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 Methadone and buprenorphine doses should be directly supervised in the early phase of treatment.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.6 Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.7 Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Management of opioid withdrawal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1 For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2 Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3 Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4 Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Pregnancy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1 Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2 Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Guidelines on closed settings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1 Do the present guidelines agree with the “Clinical guidelines for withdrawal management and treatment of drug treatment”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
For each listed WHO recommendations, the following question is answered:
Do the present guidelines include this recommendation?

Name of Assessors: Tiphaine Canarelli (OFDT) & Stefanie Schütte (Public Health master)

Further comments are furnished underneath, referenced according to the recommendation numbers used in the table.

1. Choice of treatment
The guidelines recommend opioid withdrawal and opioid agonist maintenance but no antagonist maintenance treatment. Therefore, pharmacotherapy-using naltrexone does not exist and opioid agonist maintenance treatment is advised in France.

2. Opioid agonist maintenance treatment
2.1 Two opioid agonist maintenance treatments exist: methadone and high dosage buprenorphine (HDB). None of those two treatments is more recommended than the other. However, the guidelines mention that methadone is more adequate for injecting drug users. On the other side, methadone can be only prescribed in a restricted way (specialised centres) whereas HDB can be given to the patient by every physician and in the primary health care.
2.2 The initial dose for methadone is between 10-40 mg per day and can be increased by 5-10 mg from 1 to 3 days per week without exceeding 50% of the initial dose. The daily initial dose for buprenorphine is 4 mg to 8 mg and can be increased by 1 to 2 mg from 1 to 3 days until the optimal dose.
2.3 The majority of patients treated with methadone are stabilized by a dose of about 60-100 mg per day but some people need higher doses. No maximum dose has been indicated for methadone.
2.4 For HDB, the majority of people are stabilized between 8 and 16 mg per day. However, some require higher doses of 16 mg per day (24 mg exceptionally). Maximum dosage authorized by the marketing authorization is 16 mg per day. So if higher dosages are expected it is recommended that the prescriber requires a specialist opinion (CSAPA, ES, addictologist, psychiatrist, etc.).
2.5 The initial treatment is prescribed for 1 or 2 days, with daily delivery, which requires the collaboration of the pharmacist. He must be contacted by the prescriber by telephone and must agree on the conditions. His details will be listed on the prescription secure. The contacts between prescriber and pharmacist must be regular.
   In the initial phase, it is recommended that consultations are done several times a week to adjust the dosage if necessary, to reassess the effect sought by the person, to estimate adherence, to investigate the association with other psychoactive substances and to deepen the therapeutic alliance. Therefore, the first weeks a therapeutic relationship has to be established, assessing the patient's situation and adapting treatment.
   For methadone, the regulation requires a urine test before starting treatment and a supervision.
2.6 No take-away dose has been specified in the present guidelines
2.7 Offering routinely psychosocial support in association with pharmacological treatment for opioid dependence is not mentioned in the present guidelines. However, cooperation between health care and social workers are highly recommended in the guidelines.
   Marketing authorization stresses on this global approach (medical, psychological and social).

3. Management of opioid withdrawal
Three different management methods of opioid withdrawal are recommended: prompt and progressive withdrawal and change of molecule in order to stop substitution treatment. None of these methods is more recommended than another.

Prompt withdrawal: Withdrawal is done in hospital with symptomatic treatment (central antihypertensives, BZD, hypnotics)

Progressive withdrawal: Withdrawal is done in outpatient with a gradual reduction of doses, for example from 1 mg to 2 mg for HDB and 5 to 10 mg for methadone

Change of molecule: It is recommended to reduce gradually the dosage of medication that the patient wants to stop before changing the molecule.

The transition from methadone to HDB requires a dose reduction at least up to 30 mg and free interval of at least 24 hours between the last dose of methadone and the first dose of HDB; the passage of buprenorphine to methadone requires also a free interval, lasting a little less (16 hours can be sufficient).

3.1 For the management of opioid withdrawal, tapered doses of opioid agonists are recommended but alpha-2 adrenergic agonists are not specified.

4. Pregnancy
The prescription of opioid agonist maintenance treatment is recommended, at best before a wanted pregnancy or in the first or the second quarter. However, the initialization of opioid agonist maintenance treatment in late pregnancy is controversial.
The perinatal effects of methadone and HDB are identical. Therefore, there is no preference given to one specific maintenance treatment.

5. Closed settings
The physician must ensure continuity of care in closed settings and prevent withdrawal syndromes, although the actual drug consumption in prison is not known.

A training of teams of health workers and of prison administrator is recommended to support treatment programmes including assessment and socio-psychological approaches in practice (misuse, traffic, lack of privacy, etc.).

Since the 30th of January 2002, any doctor practising in a health establishment is authorised to suggest a methadone-based substitution treatment to any opioid-dependent adult. Until then, this possibility was reserved for doctors working in specialised drug addiction treatment services (associations or hospitals), and operating in open or penal environments. The growth in the initial prescription of methadone in both hospitals and prisons has been included in the governmental plan to combat illegal drugs, tobacco and alcohol (2004-2008).
It is also recommended to develop a best practice guide (promoted by the General Department of Health, Prison Service and health and social actors) which would facilitate the establishment of opioid maintenance treatments and allow a surveillance of prisoners in better conditions.
ITALY

11. HISTORY, METHODS AND IMPLEMENTATION OF NATIONAL TREATMENT GUIDELINES

11.1. History and overall framework

In Italy, the problem of injecting heroin abuse had its origins in the 1970s. The problem grew progressively until reaching "epidemic" levels in the '80s and early '90s when, perhaps due to the spread of HIV and the deaths it was causing, the phenomenon entered a slow decline accompanied by an important change in abuse patterns. The injecting method was progressively displaced by less invasive use methods (via inhalation, for example) and heroin lost at least some ground to cocaine. As a result, the cultural reference models that had encouraged the spread of heroin use changed, the issue became less emotionally charged and it became less of a social emergency than in previous years. Along with the leveling off or lack of a rise in heroin use, there has also been, especially among the youngest age groups, a general "rejection" of tossicodipendenza (t.n. a term which means drug addiction in general but which has always been associated with heroin addiction specifically). The image of heroin addiction has progressively come to be perceived as corresponding to a rigid stereotype model of marginalization and social exclusion, characterized by enormous social stigma.

The social and healthcare intervention model proposed and then put together in the '80s and later perfected in the '90s was evidently among the factors that played a strategic role in the reduction of heroin demand in Italy. The intervention system made it possible, first and foremost, to adequately manage the health emergency at hand and thus ensure the necessary integrated interventions in the areas of prevention, harm reduction, treatment, rehabilitation and social reintegration. A specialized system (free and anonymous for its clients) was put together in Italy, specifically dedicated to fighting psychoactive substance abuse and addiction. This intervention system is comprised of 533 Public Drug Treatment Units (SerTs) under the authority of the National Health Service, and of 1,108 inpatient Therapeutic Communities, most of which are private, but funded, for the most part, with public money. This polyspecialized and multi-disciplinary system covers the entire nation and has become able, over time, thanks in part to a fair level of integration between public and private sectors, to ensure that the majority of social and healthcare needs of heroin-addicted patients are met and has made it possible to accumulate an enormous amount of important cultural and professional experience.

In the Italian National Report to Parliament on Drug Abuse for the year 2009, the Department for Anti-drug Policies (DPA) estimated the total number of heroin and cocaine users in need of treatment in Italy at approximately 393,000 (three-hundred and ninety-three thousand) nationwide, slightly less than 1% (one percent) of residents aged 15 to 64.

Up to now heroin addicted patients who attend any sort of therapy are about 178,000 (one hundred seventy eight thousand in Italy). 1.3% of the general population have used heroin at least once in their
lives, 4.8% have tried cocaine at least once and 22.45% have tried cannabis.
Among students aged fifteen to nineteen, the results are similar, with a percentage of 1.2% for heroin use and 22.3% for cannabis use, with a decrease in cocaine use, which stands at 4.1%. There is a trend towards a decrease in the use of heroin and cocaine in the youth population while the opposite is occurring in the older population. For the age groups below 20 years of age and younger, heroin and cocaine use is higher, as is cannabis use.
Two issues in particular are cause for great concern in Italy:
The first one is the increasing number of polydrug users – who often abuse alcohol as well - and the second issue is the long length of time that passes between the first use of any drug and the first request for treatment.
In 2008 about fifty-nine percent (54%) of opiates abusers attended a therapeutic program, among an estimated of two hundred sixteen thousand abusers who needed care.
Since the year nineteen ninety-six (1996) there has been a slight but constant decrease in new heroin treatment requests: In the past year we have had eighteen thousand (15,000) new requests for treatment.
In Italy, the age of initiation for heroin use is young, the latency period before entering treatment programmes is longer, less time is spent in treatment but, lastly, there has been a dramatic decrease in intravenous injection methods.
Among Italian students, heroin use is more prevalent among the female population than it was in the past, including the recent past. Zero point six percent (0.6%) of the youth population uses heroin frequently, but there is a higher prevalence of occasional use. The good new is the decrease in deaths by overdose, which have fallen from 517 in 2008 to 484 in 2009.
A strong commitment has been made to develop action plans aimed at the prevention of drug use. These plans target young people, families and schools through the introduction of training, peer education, counseling, etc.
11.1.1. Treatment of opiate addiction, in prisons as well as outside treatment for drug abuse, and specifically for heroin abuse, is available nationwide under the integrated multimodal model, which provides either “drug free” treatment and/or “abstinence oriented” treatments. Treatments are tailored to individual needs in terms of duration, quality and quantity.
Long term treatments are available, especially for patients with AIDS and psychiatric comorbidity, but also in the case of other clinical evaluation results.
Pharmacological treatments are available nationwide: they include opiate agonists, partial agonists, antagonists and anti-craving and symptomatic drugs.
Psychological treatment specifically for the drug addicted is available in all Italian SerTs and can guarantee individual and group counseling, individual and group psychotherapy and so on. The presence of social workers ensures social assistance.
About 67% of patients follow an opiate substitution therapy, mainly by methadone (49%), while other patients are in treatment undergoing psychosocial and rehabilitation programmes.
In general, substitution therapies are long term, but there is growing
evidence, -0.3%, of an increase in medium-term therapies, meaning pharmacological treatment ranging between 30 (thirty) and 180 (onehundred and eighty) days in length.

11.1.2. Treatment within the criminal justice system
The criminal justice and prison system in Italy has special legislation which takes into account drug addiction and related criminal offences. The Italian penal system applies severe sanctions in regard to trafficking in narcotic substances, with a maximum penalty of twenty years in serious cases. However, a drug addicted inmate may request to be admitted into treatment programs as an alternative to jail, with said treatment to be undergone either at home or within a public or private therapeutic community.
At the moment, there are nearly sixty-five thousand (65,000) inmates in Italian penitentiaries, plus about one-thousand eight hundred (1,800) juveniles. Foreigners are about one-third of the total. Approximately 30% of the prison population are drug addicts, but this number may be a gross underestimate because of some bias in the correct diagnosis, due to various factors. So we can consider that perhaps 50-60% of prison inmates are drug addicts. There is a large degree of variation between north and south, with more prison inmates in the north than in the south of the country.
As far as treatment is concerned, substitution therapy is available in all Italian prisons, for example with methadone, buprenorphine and GHB. Psychological treatment specifically for drug addicted inmates is available in all Italian prisons and can ensure individual and group counseling, individual and group psychotherapy, and so on. Social workers ensure social assistance is provided to convicts for the duration of their sentence. About 4% to 5% of prison inmates can benefit from “Attenuated Custody”, which consists of less surveillance and more intense therapy consisting of specific treatment. After almost one year of treatment, follow-ups show less relapses into drug use.
“Special projects for addicted inmates are numerous and are generally managed by the Ministry of Justice. Among these are projects related to the verification and treatment of mental illness in the prison population (“Dual Diagnosis” or psychiatric co-morbidity), which claim that more than 50% of these persons suffer from such disorders. On 31 December 2009, the number of addicted inmates in alternative treatment was established at 2,047.

11.2. Existing guidelines: narrative description of existing guidelines
Despite the existence of an organized system which appears to be decidedly effective and highly functional, there are currently no national guidelines for the treatment of heroin addiction. This strange lack is linked to the peculiar organization of the National Healthcare System and is, at least in part, compensated by the presence of a number of national laws and regulations, most of which are well structured and technically well-grounded, and which provide direction for treatment choices without, however, limiting them. The peculiarity of the National Health System is linked to the fact that the country is divided into twenty Regions, to each of which the central administration has delegated the management of public and private
healthcare treatment in this sphere. This system makes it more difficult to establish national guidelines, but makes it easier to lay down regional ones, and this is what, in fact, occurs on a local level in the majority of cases. Many regions have indeed established their own guidelines for dealing with heroin addiction which, nonetheless, base their policy and technical choices on a study of national technical regulations. The sets of guidelines which the different regions have drawn up do not differ noticeably from one another, just as they all exhibit similar scientific and practical parameters, all based on, among other elements, the significant amount of experience which Italy has accumulated in the field of heroin abuse.

It can therefore be concluded that, in Italy, despite the lack of national guidelines to deal with heroin addiction, adherence to WHO guidelines for heroin addiction treatment throughout the country is nonetheless quite high in terms of treatment choice, maintenance therapy with opiate agonists, opiate-abstinence therapy and the treatment of drug-addicted patients during pregnancy.
Chapter 11: History, methods and implementation of national treatment guidelines

History and overall framework

The year 2010 is marked by the development of the first drug treatment and prevention guidelines in Cyprus; as of 2010, a nationwide system assuring quality practices in this field exists. A brief historical overview of the social and political situation in this field, may assist in explaining the reasons for the lack of guidelines prior to 2010, justify the delay of the guidelines' development, and at the same time describe its process.

The lack of treatment guidelines until recently can perhaps be explained by (1) the medical approach having been the predominant drug treatment approach approximately up to the year 2004, (2) the lack of expertise in the field, (3) the lack of nationwide monitoring and evidence regarding the drug situation, and (4) the relative lack of an efficient coordinating body (due to shortage of human and other resources), and the lack of mention in any previous drug strategies (Symeonidou, 2010a, unpublished).

Until recently in historical terms, drug treatment was mainly offered by medical doctors (mostly GP's or psychiatrists) and nursing staff. Apart from psychiatrists, other mental health professionals (such as psychologists, psychotherapists, occupational therapists, drama therapists or substance abuse counsellors) were not involved in the treatment of drug addiction. Treatment mostly focused on handling withdrawal and / or overdose symptoms through pharmacology. Thus, since there was a common professional language, the general medical guidelines were perceived as adequate for substance abuse treatment.

The rise of drug abuse and its related problems is a recent social phenomenon in Cyprus (see also ch. 1), therefore there was a lack of public awareness and consequently a considerable lack of expert knowledge regarding all aspects pertaining to abuse and addiction. After the first drug-related deaths were made public; there was an urgent need for responding, mainly through developing treatment centres, and no time for developing and implementing a more holistic approach to treatment options and responses. The urgency of the situation resulted in the implementation of various programmes, each with a different structure, framework, and treatment approach, derived from programmes found in other countries.

Although the drugs phenomenon had already begun to affect the public perception of its consequences, the real extent of the situation was not clear due to the lack of pragmatic numbers and evidence. The drug situation was not monitored, and many drug-related problems such as deaths, crime and infections were not linked to drug use, until the establishment of the Cyprus NFP in 2004. By 2008, the NFP was able to reveal the increasing trend of drug use, and point out the need for appropriate responses.

The Cyprus Anti-Drugs Council (CAC), supreme coordinating body for drug policy, was established in 1992. In the first few years of its development, the CAC was not fully functional due to its structural synthesis and the lack of executive secretariat staff. The aforementioned obstacles did not allow the CAC to play an active role in this field, until its
reorganization and staffing, which led to the development of the first NDS 2004-2008. In the framework of this national strategy’s monitoring and evaluation, the CAC in cooperation with the University of Hamburg proceeded to evaluate the treatment system and existing programmes (Symeonidou, 2010a, unpublished). Among other observations, the evaluation suggested the need for ensuring the quality of the treatment services, offered by developing objective efficacy indicators, as well as by establishing minimum quality standards. The aforementioned suggestions were included in the second NDS 2009-2012, and hence in 2010 the country’s first set of national treatment guidelines were elaborated.

Existing guidelines: narrative description of existing guidelines

The first national treatment guidelines developed by the CAC, constitute a synopsis of other EU and international guidelines, mainly focusing on those of the UK and WHO, but modified to meet Cyprus’ specific needs and current situation.

Due to the lack of expertise and specialization in the drugs field, as well as the rapid need to respond and provide drug treatment, most of the treatment programmes which developed were not implemented following a thorough needs assessment, and neither were they based on evidence. Therefore, most units provided all types of treatment (except substitution), without really adhering to any specific intervention-type principles. For instance, some of the open therapeutic communities provided psychosocial services, without really adhering to TC principles.

The national treatment guidelines therefore attempt to limit confusion, and to gradually create a treatment system in which interventions can be distinguished and categorized, based on recognized European and international standards and quality services which can be offered (Symeonidou, 2010a, unpublished).

Framework, types of interventions

The basic guidelines for each intervention are presented in Annex IV. The guideline manual contains the basic principles that all drug-related programmes should follow, and the type of services appropriate to each intervention; namely, all drug-related programmes should:

- Be easily accessible
- Target sub-groups
- Provide individual assessment
- Provide treatment planning, coordination and case management
- Assist in treatment commitment and retaining
- Provide for continuous programme monitoring and evaluation
- Employ qualified personnel
- Follow a code of conduct
- Provide for appropriate building infrastructure
More specifically, the manual includes guidelines of good practice for 1) telephone help lines, 2) outpatient adolescent services, 3) adult counselling stations, 4) outpatient psychosocial rehabilitation services, such as structured day-programmes and open therapeutic communities, 5) inpatient psychological rehabilitation services, such as closed therapeutic communities, 6) inpatient detoxification services, 7) outpatient substitution services, 8) drop-in centres, 9) multi-functional outpatient drug services, and 10) treatment programmes within the prison system.

It seems fair to comment that the content of the guidelines reveals the readiness and effort of, and by, the country’s drugs professionals and services, for a) the development of evidence-based services and b) the improvement in quality of the drug services provided. The movement towards an evidence-based drug treatment service development is apparent in the guidelines’ encouragement of membership in antidrug accredited organizations such as the FESAT for the help lines and the World Federation of Therapeutic Communities (see: telephone help lines & TCs). The need for pharmacological evidence-based treatment provision is also encouraged by referral to the WHO guidelines for all pharmacologically-based practices (see: detoxification, substitution services & treatment within the prison system).

Furthermore, quality treatment provision is encouraged through the emphasis given to programmes’ duration, to the variety of treatment approaches, as well as the suggestions for individualized treatment and aftercare plans as part of a holistic treatment approach. Additionally, quality service provision is encouraged through providing specialized treatment; this is evident from the explicit recommendation for specific treatment approaches, which according to the scientific bibliography are more efficient when targeting specific target groups (see: adolescent services & closed TCs for problem drug users, and treatment within the prison system). The notion of case management is also introduced, as a necessity for improving quality service provision.

It is worth mentioning that the guideline manual not only defines the principles and guidelines, but it also includes a brief description of each type of approach, mostly based on European bibliography and practices, such as the systemic, cognitive behavioral etc. In addition, although a specific treatment modality is mentioned as the most efficient for specific target groups (e.g. systemic approach for adolescents, see: adolescent services), the manual encourages the use of a combination of modalities, and therefore promotes a pluralistic drug treatment system.

Substance of use

It is noteworthy that the guidelines do not mention or specify types of substances, but focus instead generally on all psychoactive substances causing abuse and dependence, including alcohol (CAC, 2010e, unpublished).

Target groups

In the guideline manual, special emphasis is placed on the professional credentials of the individuals employed in drug treatment units. Specifically, the guidelines suggest the specialization of each professional according to his / her duties, their specialization on assessment and other tools used, and their continuous training, education and supervision. Furthermore, the guidelines include a code of conduct which professionals in this field should follow (CAC, 2010e, unpublished).
Development of guidelines

The results of the evaluation of the NDS 2004-2008, as well as the results of the prevention and treatment programme evaluations by external evaluators, suggested the need for improvement in the quality of drug treatment services offered. Hence, as mentioned above, in the beginning of 2009, and in the framework of the 2009-2012 NDS, the CAC decided to develop the first prevention and treatment guidelines, which should also function as the minimum standards of all programmes requesting licensing under the L57(1)/92 Law. The guidelines were developed by a committee assigned by the CAC, and the resulting guideline development was monitored and coordinated by an officer of the Executive Secretariat of the CAC. The process included literature review, study of the WHO guidelines, as well as the reports of the prevention and treatment programme evaluations mentioned. Hence the end result was a product based 1) on scientific evidence, and 2) on the national situation (Symeonidou, 2010a, unpublished).

Implementation process

Guideline Implementation processes

The CAC is responsible for ensuring the implementation of the guidelines. All programmes are now required to abide by them, since licensure will be based on their implementation. The process began with the dissemination of the guideline booklet to all treatment services, and continued with their presentation at the next treatment network semi-annual meeting. It was also announced that by October 2010, all programmes are expected to comply. According to the CAC, all programmes are required to apply for approval, and only approved programmes will be considered legitimate, and will be eligible for funding (Kyprianou, 2010a, unpublished). In addition, again according to the CAC, the guidelines will be reviewed as needed (Symeonidou, 2010a, unpublished).

Comparison with the WHO guidelines

The aforementioned treatment guidelines do not specifically focus on opioid / substitution treatment, and no other guidelines exist. However, the current guidelines refer all programmes providing pharmacologically-assisted treatment to the WHO guidelines. The CAC requests that the WHO guidelines are followed when implementing detoxification, substitution and/or maintenance programmes, since there are no local pharmacologically-assisted specialized guidelines available (Symeonidou, 2010a, unpublished).

The lack of local pharmacologically-assisted treatment is evidence of possible lack of expertise in the field. However, it is also a case in point that the uniqueness of Cypriot culture in general, and its specific expression in the local drugs phenomenon, is not taken into consideration when following international guidelines. Furthermore, the WHO (best practice) guidelines cannot always be followed, since 1) there is no availability of all substances suggested by WHO (e.g alpha-2 adrenergic for withdrawal treatment) and 2) the legal framework does not allow the prescription of some substitution medicines by the private drug treatment services, or any other private clinics on an outpatient basis.
11. History, methods and implementation of national treatment guidelines

In Latvia, treatment processes are stipulated in the Medical Treatment Law, in which two terms are defined, which stipulate and regulate treatment processes and their quality, namely, "medical technologies" and "clinical guidelines". According to the Medical Treatment Law, "medical technologies" are defined as methods and medical equipment used in treatment, whereas "clinical guidelines" are defined as a systematised description of the treatment process for a specific group of patients, which are established, observing evidence-based medical principles, and in which are set out the necessary actions required, the order in which they are to be performed, and important criteria for selection of preferred treatment tactics to achieve the best treatment outcome.

A medical technology is a technical document, which addresses all the possible manipulations, essential equipment for the therapeutic process, medications to be used, and so forth. Latvia has 16 approved medical technologies that apply to the treatment of drug-dependent patients. Observance of medical technologies approved by the Cabinet of Ministers is mandatory in the treatment process and in the receipt of public funding.

Clinical guidelines are a broader document, which, according to the definition in the Medical Treatment Law, is based on scientific evidence. One set of guidelines may encompass a number of medical technologies. However, in contrast to medical technologies, clinical guidelines are recommendatory in nature, and their implementation in medical institutions is dependent on the financial capability of the relevant institution. At the same time, the Medical Treatment Law stipulates that treatment should be in accordance with clinical guidelines or assessment of therapeutic methods and medication usage safety and therapeutic efficacy performed in accordance with evidence-based medical principles.

This chapter overviews existing the Latvian treatment guidelines for drug dependence, their historical development, design and implementation process, and compares the Latvian guidelines for long-term pharmacotherapy of opioid-dependent patients with the pharmacotherapy guidelines developed by the WHO. As part of the guidelines analysis process, seven interviews were conducted with experts in the field who had participated in the guideline development process or are responsible for the approval and implementation of the guidelines.

11.1. History and overall framework

The development history of the Latvian clinical guidelines is not ancient. The Latvian Addiction Disorders Specialists’ Association (LADSA) working group of specialists developed the first Guidelines for the Treatment of Drug-Dependent Patients in 2005. A second set of guidelines: Guidelines for the Treatment of Misuse and Dependence on Sedative Medications was developed a year later, in 2006. However, the Long-Term Pharmacotherapy of Opioid-Dependent Patients using Methadone and Buprenorphine was developed in 2009. All the guidelines have been developed by the working group of the LADSA.
Historically, the specialty of addiction disorders was established in Latvia during the 1970s, when the first institution for treatment of addiction disorders was established. The specialty was created to reduce the growing prevalence of alcoholism throughout the Soviet Union. Even today, the addiction disorders sector encompasses the treatment of addiction to alcohol, drugs and psychotropic substances, tobacco, and gambling. Consequently, the first Guidelines include information not only about treatment for addiction to drugs and psychotropic substances, but also on alcohol and gambling addiction.

Like the addiction disorders sector during the Soviet era, the first guidelines developed for treatment of drug-dependent patients were also based on Russian practice, where the main role was focused on the treatment of withdrawal and the treatment of intoxication. Currently, experts in the field indicate that these guidelines should be redrafted with a greater focus on multidisciplinary teamwork, and psychosocial treatment, as well as specific treatment of different patient groups. At the same time, experts point out that although the first guidelines were not based on scientific evidence and international research, it is beneficial that they were developed, as supplementing and revising them now will be much easier than developing entirely new ones.

As recently as 2010, Latvia had no single procedure for how guidelines were to be developed, validated and implemented. All three Latvian existing treatment guidelines for drug-dependent patients were developed by the LADSA working group. The developed guidelines were presented at a meeting of the Association and disseminated to members of the Association, namely, addiction specialist physicians. Since in Latvia the guidelines are recommendatory in nature, their use is optional and therefore it is unknown how actively physicians are using them. The experts do hope that new Cabinet Regulations will form the basis for the guidelines to be taken into account in determining health care service charges and payment conditions in the future.

The specialists also unequivocally acknowledge that the existing guidelines should be redrafted to align with international practice. Furthermore, the development of new guidelines should involve a multidisciplinary panel of experts, consisting not only of addiction psychiatrists, but should also involve teaching staff. The specialists also point out that it would be much more appropriate to use guidelines already approved throughout the world, such as those already developed by the World Health Organization, and adapt those to the Latvian situation, rather than create something completely new.

It should be noted that the existing treatment guidelines for drug-dependent patients are very similar to medical technologies. Consequently, the need for such separate documents is unclear. The fact that the guidelines for long-term pharmacotherapy of opioid-dependent patients do not really correspond with the new World Health Organization guidelines, is also considered a negative feature.

According to experts, by late 2010, the Guidelines for the Long-Term Pharmacotherapy of Opioid Dependent Patients using Methadone and Buprenorphine will be revised, based on the World Health Organisation 2009 guidelines. Accordingly, it is also planned to develop new medical technologies for methadone and buprenorphine. In the future, it is also planned to revise the Guidelines for the Treatment of Misuse and Dependence on Sedative Medications, because new methods and medications are increasingly being used in the treatment of such patients, and renewal of the guidelines would be natural.
11.2. Existing guidelines: narrative description of existing guidelines

Latvia currently has three drug treatment guidelines, which have been developed and approved by the Latvian Addiction Disorders Specialists’ Association:

- Guidelines for the Treatment of Drug-Dependent Patients, 2005;
- Guidelines for the Treatment of Misuse and Dependence on Sedative Medications, 2006;

The existing guidelines are mostly informative material, which provides an overview of the treatment of drug-dependent patients. The guidelines mostly contain information on medicinal treatment, with particular emphasis on detoxification. Experts in the field indicate that the guidelines should be redrafted in line with global practice, as the first two guidelines were drafted the basis of Soviet practice, where the major focus is on acute treatment forms. Experts point out that in redrafting the guidelines, greater attention should focus on psychosocial aspects in the treatment of drug-dependent patients. Similarly, treatment for different patient groups and different substance addictions should be differentiated.

A more detailed analysis of each of the three guidelines follows.

Guidelines for Treatment of Drug-dependent Patients

*Guidelines for Treatment of Drug-dependent Patients* is a document in which attention is focused in condensed form on many addiction-related topics, ranging from addiction risk factors, pathogenesis, prevention, and clinical manifestations of addiction, to various forms of assistance: outpatient, inpatient hospital assistance, inpatient psychotherapy, rehabilitation, and anonymous movements (*State Addiction Agency, 2005*).

The chapter on outpatient assistance is dedicated to such topics as addiction-specialist advice on the use of or addiction to alcohol, drugs and psychotropic substances, tobacco, gambling and new technologies, when a decision is made on the need for addiction tracking and dynamic observation, as well as treatment of the withdrawal in mild and moderate consumption of alcohol, drugs and psychotropic substances. The guidelines precisely describe the symptoms of this condition and the appropriate medicinal therapies. Attention is also paid to medicinal assistance in cases of light and moderate withdrawal from opioid or psycho-stimulant substance addiction. Similarly, a brief insight is provided into the application of buprenorphine and methadone replacement therapy (when is it necessary to select methadone/buprenorphine, drug dosage).

Separate sections of the guidelines are devoted to gaming and new technology dependence and outpatient therapy, inpatient psychotherapy (motivational program, Minnesota 12-step program), rehabilitation, and anonymous movements.

The largest section of the guidelines is dedicated to inpatient assistance in cases of acute intoxication (acute intoxication from alcohol, opioids, cannabis, sedatives, cocaine, drugs and non-narcotic stimulants, hallucinogens, and volatile organic solvents), which describe in condensed form the symptoms, tests and required medicinal therapy, as well as inpatient assistance in withdrawal cases.

The Guidelines conclude with notes on inpatient assistance in cases of psychotic, mental, cognitive, and personality disorder following the use of psychoactive substances (symptoms, tests, therapy).
Guidelines for the Treatment of Misuse and Dependence on Sedative Medications

Guidelines for the Treatment of Misuse and Dependence on Sedative Medications is in its structure and substance similar to Guidelines of the Treatment of Drug Dependent Patients, but its target group is much broader (State Addiction Agency, 2006). If the former guidelines are intended more for professional addiction specialist physicians, then the Guidelines for the Treatment of Misuse and Dependence on Sedative Medications are intended for a wider range of professionals including family doctors and other specialist physicians. Experts indicate that these guidelines are more like informative material, rather than clinical guidelines, because the sedative and sleep medications are widely distributed throughout society, and these medications may be freely prescribed by any physician, they are often prescribed improperly or in excessive doses and for excessive periods, causing substantial harm to the patient’s health. Similarly, the use of sedative and sleep agents has always been prevalent among drug-dependent persons since Soviet times.

The Guidelines for the Treatment of Misuse and Dependence on Sedative Medications focus on several groups of sedative and sleep preparations i.e. barbiturates, benzodiazepines and GHB.

The guidelines describe the use of medications in the barbiturate group, phases of intoxication, acute intoxication (symptoms, examination and treatment), signs of overdose, clinical manifestations of dependency, developmental stages, the withdrawal state (symptoms, necessary examinations and applicable therapy), as well as possible complications.

Similarly, the guidelines provide the pharmacokinetics of benzodiazepines, a comparison of the most common benzodiazepines, information on the need for prescribing these drugs, indications for their use, adverse effects, and contra-indications. As in the section on barbiturates, the benzodiazepines are described in terms of acute intoxication (symptoms, tests and applicable therapy), benzodiazepine dependence and withdrawal state.

Similarly described is GHB intoxication, emergency assistance in case of intoxication and the principles of treatment in withdrawal cases.

The final section of the guidelines considers the psychotic, psychiatric, cognitive, personality and behavioural disorders following the use of sedative agents: acute intoxication with delirium, its symptoms, tests, and therapy; withdrawal state with delirium – its symptoms and available therapy. Attention is also drawn to the withdrawal state accompanied by delirium complications, psychotic disturbances, amnesic syndrome and psychotic disturbances, which begin long after the use of sedative and sleeping drugs.

The guidelines conclude by providing information on opportunities for receiving outpatient and inpatient assistance, rehabilitation facilities, anonymous movements and opportunities for consulting addiction specialist physicians.

Guidelines for The Long-Term Pharmacotherapy of Opioid-dependent Patients using Methadone and Buprenorphine

Guidelines for The Long-Term Pharmacotherapy of Opioid-dependent Patients using Methadone and Buprenorphine is intended for professionals in the field and is much more specific than the two previously-mentioned guidelines (Public Health Agency, 2009). It should also be noted that these are the newest guidelines, and are therefore more in line with international standards. The guidelines refer to international research and literature, and also take into account outcomes of the Latvian Pharmacological Evaluation of Opioid Dependence Treatment (Sile, Pūgule, 2008).
The guidelines briefly describe global practice in the use of methadone and buprenorphine in pharmacotherapy, epidemiological data, effectiveness and cost effectiveness of long-term pharmacotherapy, pharmacokinetics, and interaction with other medications, side effects and contraindications.

Further chapters in the guidelines are devoted to the description of long-term pharmacotherapy, defining examination of the patient, and indications, contraindications and precautions while using medications. Given the fact that the guidelines focus only on long-term pharmacotherapy using methadone and buprenorphine, they do not include information on the use of opioid antagonists in pharmacotherapy. The guidelines contain information on the commencement of treatment, using combinations of methadone/buprenorphine and buprenorphine – naloxone, the transition from methadone to buprenorphine or buprenorphine – naloxone combinations, and vice versa, discontinuation of those medications and overdosing. Guidelines also indicate criteria that determine a patient's exclusion from the therapy and the patient groups that are particularly important to involve in therapy (e.g. pregnant women and HIV/AIDS patients, patients with hepatitis B/C).

The final three chapters of the guidelines contain a short description of the work of pharmacotherapy in terms of organisation, the resources required and the evaluation methodology.

A detailed comparison of the Latvian guidelines for long-term pharmacotherapy of opioid-dependent patients with the WHO guidelines for long-term pharmacotherapy is given in the final chapter of this Selected Issue.

11.3. Implementation process

Until now, there has been no uniform procedure in Latvia for the manner in which guidelines were to be developed and implemented. Usually it was a matter of medical associations who developed the guidelines and subsequently also approved and distributed the developed guidelines to their members. However, the current procedure for the development, evaluation, authorization and arrangements for implementing clinical guidelines is stipulated in Cabinet Regulation No. 469 of 25 May 2010: Procedures for the Development, Evaluation, Registration and Implementation of Clinical Guidelines, which firmly and specifically defines the development and implementation process for clinical guidelines. However, given the fact that the state has not allocated additional funding for development of guidelines, and that guidelines are more recommendatory in nature, there is no present mechanism to motivate the preparation of guidelines based on scientific evidence. Experts do point out that one motivation could be that the guidelines will in future be taken into account in determining health care service charges and terms of payment.

The aim of the new Cabinet Regulation is to facilitate the development of evidence-based national guidelines based on common criteria, their application in medicine, medical education training programs, and the drafting of tariffs and payment terms for health care services from the state budget, as well as in the monitoring and quality control of provision of health care services.

The Cabinet Regulation stipulates that the medical staff of professional organizations, and medical institutions and universities which offers academic and second level professional programs in medicine shall have the right to develop draft guidelines and submit them to the Centre of Health Economics for registration in the Clinical Guidelines Database.

In order for clinical guidelines to be approved and registered in the database, the developer must submit a full text of the draft guidelines, a summary of the draft guidelines, together with a description of the development process for the guidelines, including
information on the developers and reviewers of the draft guidelines, their consideration by medical personnel in professional organizations, medical and scientific institutions, and in seminars or conferences. The developer must also provide information regarding the form of the draft guidelines, indicating whether they are original, adapted or translated. If the draft guidelines are adapted or translated, the developer is to submit a copy of the original guidelines.

The draft guidelines must include the following information:

- title of guidelines
- guideline developer;
- aim and objectives of the guidelines;
- intended users of the guidelines;
- benefits, side effects and risks that could occur by following the guidelines' recommendations;
- target group for application of the guidelines, indicating patient diagnoses or diagnosis groups and their corresponding codes, in accordance with the International Classification of Diseases, 10th edition endorsed by the World Health Organization;
- sources of evidentiary information and criteria for their selection;
- recommendations for medical treatment personnel for specific therapeutic activities, including diagnosis, prevention, treatment methods, observation tactics, rehabilitation and indication of which of the technologies mentioned in the guidelines (medications, medical equipment, methods, procedures) could be applied in Latvia;
- The evidentiary level for recommendations shall be in accordance with the following: 
  Level A - highly reliable evidence obtained from several good-quality randomized clinical trials which have been the subject of meta-analysis;
  Level B - evidence of moderate reliability, which has been obtained from individual good-quality randomized clinical trials or meta-analysis of several well-organized studies of control groups (unrandomized clinical studies, case-control studies, cohort studies);
  Level C - evidence having low reliability, obtained in separate trials of a control group (unrandomized clinical trials, case-control studies, cohort studies);
  Level D - insufficient evidence, obtained in a series of case observations, or which have received the unanimous recommendation of experts.
- Links between guideline recommendations and evidence, indicating specific references;
- funding source for development of guidelines.

Following submission of the draft guidelines, the Centre of Health Economics assesses the documentation submitted by the developer for conformance with the above-mentioned guidelines. If discrepancies are found in the documents, the Centre of Health Economics requests additional information from the developer.

After evaluation of the submitted documents for compliance, the Centre of Health Economics forwards the draft guidelines for evaluation by key specialists in the relevant health sector of the Ministry of Health, and by the health sector strategic council58. Besides the said institutions, the Centre of Health Economics may forward the draft guidelines for evaluation to other healthcare institutions, professional organizations, or experts who are

---

58 The Council is an advisory body for formulating and implementing health policy, and is comprised of representatives from health associations, as well as state and municipal institutions. The Council is established and its bylaws are approved by the Minister of Health.
specialists in a particular branch of health care, and who meet at least one of the following criteria: that the expert has a doctoral degree in medical science; is a university assistant professor, associate professor, professor, or a person authorised to train other persons, or is a senior researcher, and/or the expert has at least five years' experience in a relevant medical specialty.

If, after one month, the above-mentioned institutions and experts have not submitted any comments or corrections of the draft guidelines to the Centre of Health Economics, then the draft guidelines shall be deemed to have been approved. Conversely, if the above institutions and experts have expressed reservations or comments regarding the draft guidelines, the Centre for Health Economics shall inform the guideline developer who shall within the period of one month evaluate the objections and clarify the draft guidelines or reject the complaints, providing a reasoned written explanation to the Centre.

Once the guidelines are approved, they are registered in the database maintained by the Centre of Health Economics.

By contrast, treatment institutions introduce guidelines according to the medical institution's financial capability, which means that the introduction of clinical guidelines is not yet mandatory, but is of a recommendatory nature.

11.4. Treatment guidelines comparison with the WHO guidelines

In Latvia, the guidelines for long-term pharmacotherapy of opioid-dependent patients were drafted in 2009. The main reason for their development was the enlargement of pharmacotherapy at the national level, which was organized by UNODC as part of the project: HIV/AIDS Prevention and Care among Injecting Drug Users and in Prison Settings in Estonia, Latvia and Lithuania 2006-2010. Also undertaken within the framework of this project was the Pharmacological Evaluation of Opioid Dependence Treatment in Latvia (Sile, Pūgule 2008), resulting in a recommendation to develop common guidelines for professionals for the long-term pharmacotherapy of opioid-dependent patients, which will provide pharmacotherapy at the national level.

The national guidelines for the long-term pharmacotherapy of opioid-dependent patients are based on scientific evidence and international research; however, it should be noted that the guidelines are more descriptive rather than advisory or recommendatory. To be precise, the guidelines provide extensive information on long-term pharmacotherapy, its efficacy and cost effectiveness, interaction with other medications, side effects etc., but do not provide recommendations as to what should be the preferred choice in any given case. As indicated by experts in the field, the physician is concerned to select the best and most appropriate treatment method, whereas the guidelines essentially describe all the possible options.

It is important to note that the national guidelines for long-term pharmacotherapy of opioid-dependent patients are narrower than the WHO guidelines, as they describe only long-term pharmacotherapy using methadone, buprenorphine and buprenorphine-naloxone combinations, and therefore do not include information on the use of opioid antagonists in the treatment of opioid dependence.

The following Table 11.1., which was developed on the basis of methodology developed by the EMCDDA, compares the WHO guidelines, or the recommendations described therein, to the Latvian guidelines and the information they provide for the long term pharmacotherapy of opioid-dependent patients. In the explanation section below Table 11.1, explanation is provided for cases where the WHO recommendations are not included in the Latvian guidelines or are not appropriate for a particular situation.
<table>
<thead>
<tr>
<th>1. Choice of treatment</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2 For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 For opioid-dependent patients not commencing opioid agonist maintenance treatment, consider antagonist pharmacotherapy using naltrexone following the completion of opioid withdrawal. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2 Opioid agonist maintenance treatment</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2 During methadone induction, the initial daily dose should depend on the level of neuroadaptation; it should generally not be more than 20 mg, and certainly not more than 30 mg. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3 On average, methadone maintenance doses should be in the range of 60–120 mg per day. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4 Average buprenorphine maintenance doses should be at least 8 mg per day. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 Methadone and buprenorphine doses should be directly supervised in the early phase of treatment. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.6 Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.7 Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3 Management of opioid withdrawal</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2 Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3 Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4 Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4 Pregnancy</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2 Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered. Do the present guidelines include this recommendation?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Explanation

1.1. The Latvian guidelines apply to pharmacotherapy using methadone, buprenorphine and buprenorphine-naloxone combinations, and therefore the guidelines do not provide information on opioid antagonist (naltrexone) maintenance therapy. Similarly, the guidelines do not specifically indicate that opioid agonist therapy should be recommended for the majority of patients.

1.2. See 1.1 explanations

2.1. The Latvian guidelines do not specifically indicate that for the majority of opioid-dependent patients, adequate doses of methadone should be used rather than buprenorphine. The guidelines provide a wealth of information on both drugs, their effectiveness, cost effectiveness, etc. They also indicate in what cases a particular drug would be more appropriate.

2.2. The Latvian guidelines stipulate that in long-term methadone pharmacotherapy, the initial daily dose is 10–40 mg.

2.3. In long-term methadone pharmacotherapy, the initial daily dose is 10–40 mg, which is progressively increased. The average daily methadone dose is 60–120 mg. The maximum dose is 150 mg, but higher doses are also possible, following assessment of the patient's individual health criteria.

2.4. The initial daily dose of buprenorphine is 2–4 mg, with a maximum of 8 mg. The highest daily dose is 16 mg but the average therapeutic dose of buprenorphine is 8–12 mg per day.

2.6. The Latvian guidelines indicate that in cases where the patient has a medical certificate issued by a family physician certifying incapacity for work, it is possible to receive a methadone dose to take away, or the dose may be issued to family members after completion of issue/receipt documentation for the methadone received. Conversely, if the patient has an employment contract and a social worker has verified the place of employment, and if the patient has no history of offending during methadone therapy, it is possible to take methadone away at the physician's discretion.

3.1. The Latvian guidelines describe opioid withdrawal therapy and appropriate medications, but do not specifically state that it should be based on the use of opioid agonists in reduced doses.

3.2. The Latvian guidelines are oriented towards opioid agonist therapy, and thus do not indicate that in opioid withdrawal therapy, physicians should not regularly use opioid antagonists in combination with sedative preparations.
History and overall framework

May 3, 2002, the Minister of Health signed the Decree *On standards of dependence treatment and rehabilitation* (ref. No. 1), which listed and briefly described approved methods for outpatient and inpatient treatment of dependence disorders. These Standards were implemented in outpatient mental health care centres and medical dependence treatment centres (both outpatient and inpatient services). They include essential descriptions of withdrawal management, long-term pharmacotherapy and psychosocial treatment services for patients with dependence disorders.

The legal acts of the Ministry of Health assigned diagnosis of dependence disorders to psychiatrists (ref. No. 2). Outpatient medical treatment of dependence was assigned primarily to multidisciplinary teams of mental health specialists (which consisted from a psychiatrist, a nurse, a social worker, and a psychologist). State Patients’ Fund provided funding for a multidisciplinary team of mental health specialists on the community (primary health care) level for patients with health insurance. Patients without health insurance received medical treatment in 5 Centres for Addictive Disorders. Family physicians on a primary health care level according to legal acts could continue medical treatment of substance dependence after a psychiatrist initiated the treatment.

Long-term drug free inpatient treatment was provided by state and municipality Centres for Addictive Disorders as well as NGOs, which employed specialists (social workers and psychologists).

Existing guidelines for treatment and assessment

The requirements and process for development and adoption of medical Guidelines were regulated by Order No. V-1148, of November 26, 2008 (ref. No. 3), of the Ministry of Health. According this legal act, development of clinical guidelines could be initiated by medical professional associations, medical universities, and groups of medical practitioners. The Draft Guidelines should be reviewed and approved by the Vilnius University Medical Faculty and the Kaunas Medical University. Subsequently, the drafts should be submitted to the Ministry of Health, which should send for the reviews of the State Patients’ Fund, the State Medicines Control Agency, the State Mental Health Centre and/or other relevant agencies of the Ministry of Health. The final version of Guidelines not necessarily should be approved by the Ministry of Health, and could function as a document, endorsed by a professional association or university clinic.

The above mentioned legal act on the development of Guidelines required the uniform structure for Guidelines and also indicating in the text 1) the Level of Evidence for given recommendations and 2) the Class of the Recommendation. The Evidence level A of the recommendation meant that the recommendation was based on multiple randomized clinical trials or methanalysis; the Evidence level B meant that the recommendations was based on 1 randomized clinical trial or several non-randomized trials; the Evidence level C meant that the recommendation was based on expert consensus and/or small studies. The recommendation of Class I meant that the procedure/treatment, based either on evidence or on expert consensus, was beneficial for a patient and effective; Class II meant that there were controversial data on the usefulness/effectiveness of the procedure/treatment. Class II
included 2 subclasses: Class IIa meant that there was more evidence/opinions that procedure/treatment might be beneficial/effective and Class IIb meant that more evidence/opinions existed that procedure/treatment might be not beneficial/ineffective. Class III meant that there was evidence/opinions that procedure/treatment was not beneficial or ineffective, or in some cases could be even harmful to a patient.


The Guidelines of Treatment of Opioid Dependence with Naltrexone (ref. No. 4) was targeted primarily for psychiatrists and family physicians. It described the diagnosis of opioid dependence and assessment of a patient, indications for treatment with Naltrexone. The Guidelines provided recommendations for the initiation of treatment and administration of the first oral doses of Naltrexone (7-10 days after the last intake of heroin and 10 -14 days after the last intake of methadone), the average daily dose (recommended 50 mg), treatment of patients with concomitant illegal drug use, infectious disease management and psychosocial assistance. They recommended duration of treatment 6 months or longer, also described management of co-morbid mental health problems, evaluation of the effectiveness of treatment, remission criteria. The use of the injectable slow release naltrexone for opioid dependence treatment was attributed to Class II recommendation due to controversial data for the treatment of opioid dependence. Rapid Opioid Detoxification (ROD) for opioid withdrawal management was attributed to Class IIb recommendation (controversial evidence and opinions regarding usefulness/effectiveness of procedure/treatment) and opioid withdrawal management under heavy sedation or anesthesia was attributed to Class III recommendation (not beneficial/ineffective, potentially harmful).

Two guidelines for opioid dependence pharmacotherapy with methadone (ref. No. 5) and buprenorphine, buprenorphine/naloxone (ref. No. 6) were developed in accordance with legal requirements by Decree No. V-653, of August 6, 2007, On Approval of Procedural Profile of Administration and Delivery of Substitution Treatment for Opioid Dependence and Prescription, Dispensing, Storage and Stocktaking of Substitution Opioid Pharmaceuticals in Individual Health Care Institutions. This legal act set some important legal requirements for prescribing methadone and buprenorphine. According this legal act methadone and buprenorphine could be delivered through medical institutions only (not through pharmacies). Patients were allowed to take their medications to use at home maximum up to six days. The minimal age for prescription of methadone was established in this Decree as 18 years, and 15 years for buprenorphine (to be used in withdrawal management, as well as maintenance treatment). Both Guidelines were targeted primarily for psychiatrists and multi-disciplinary teams (nurses, social workers, psychologists) engaged in delivering pharmacotherapy for patients.

Guidelines of Treatment of Opioid Dependence with Methadone (2010) and Guidelines of Treatment of Opioid Dependence Buprenorphine and Buprenorphine/Naloxone (2010) recommended pharmacotherapy with long acting opioid agonists as preferable treatment of opioid dependence (Class I, evidence level A recommendation). Both Guidelines provided recommendations on indications and contraindications, pharmacokinetics and pharmacodynamics of medications, initiation of treatment and administration of first doses, prescription of maintenance daily doses (recommended 60-100 mg of methadone and at least 8 mg of buprenorphine), prescription of medications to use at home, duration of pharmacotherapy, side effects of medications and strategies to cope with them, social and psychological assistance, prescription of medications to special groups of patients (pregnant and breastfeeding women, patients with co-morbid mental problems, patients in prison settings or under custody), patients, which use other psychoactive substances, adolescents, those driving vehicles and operating machinery and suffering pain).
Both Guidelines included recommendations on treatment of opioid overdose, evaluation of the effectiveness of treatment as well as use of medications for opioid withdrawal management. Both Guidelines included detailed description on the management and prevention of infectious diseases among patients in pharmacotherapy (HIV, hepatitis B and C, as well as TB).

In 2009, the two national Guidelines were developed on treatment of children and adolescents, who used psychoactive substances. The Lithuanian Association of Child and Adolescent Psychiatry developed clinical Guidelines for Early Diagnosis and Treatment of Children, who Use Drugs, Psychotropic and Other Psychoactive Substances (ref. No. 8). These Guidelines included recommendations for children and adolescent psychiatrists, who work on the community level on the assessment (including urine screening) and counselling of children and adolescents who use drugs. They also included recommendations on the use of buprenorphine in opioid withdrawal management and maintenance treatment. Psychiatry Clinic at Kaunas Medical University developed Guidelines of Treatment and Pain Management of Children and Adolescents, who Use Psychoactive Substances (9), which provided recommendations on the use of buprenorphine for opioid dependence withdrawal management and pain management in children and adolescents.

Guidelines for long-term psychosocial treatment were developed in 2008 - Reintegration of Individuals, Dependent on Illicit Drugs into the Society and Labour Market (ref. No. 10). These Guidelines were recommended to be used by professionals (social workers and psychologists) in NGOs (therapeutic communities) and in Centres for Addictive Disorders.

In 2008-2010, a Lithuanian version of the Addiction Severity Index (ASI – UNODC version) with appropriate software was in the stage of development by Vilnius Centre for Addictive Disorders. The Addiction Severity Index was planned to be used in multidimensional assessment of a patient and individualized treatment planning.

Coherence of Guidelines: Comparison of national Guidelines of pharmacological treatment of opioid dependence with WHO Guidelines

1. Choice of treatment. The national Guidelines suggest that a physician and patient should discuss different types of available treatments, while pharmacotherapy with long acting opioid agonists should be considered as one of the first line options due to existing evidence on its effectiveness. The physician may prescribe pharmacotherapy with methadone, buprenorphine or buprenorphine/naloxone if a patient is diagnosed as opioid dependent, has an ID and is capable to sign an informed consent. There are no major discrepancies between the WHO and national Guidelines in regard to indications and contraindications for treatment. There are some differences on the recommendation on the minimal age, when methadone and buprenorphine could be prescribed (minimum 18 years for methadone, and 15 years for buprenorphine in Lithuania).

2. Opioid agonist maintenance treatment. There are no major discrepancies between the WHO and national Guidelines regarding the recommended pharmacotherapy induction and maintenance doses (which are recommended as average 60-100 mg for methadone, and average minimum 8 mg for buprenorphine). The treatment with long acting opioid agonists is recommended according to the individual needs with a recommended minimum duration of 12 months. The national Guidelines include recommendations on management and prevention of infectious diseases, driving vehicles and operation machinery, continuation of treatment in closed settings (prison, custody), treatment of patients with co-morbid disorders, dependence on multiple substances and are coherent with the WHO Guidelines.
3. Management of opioid withdrawal. There are no major discrepancies between the WHO and national *Guidelines* regarding the recommended schemes of withdrawal management with methadone, buprenorphine, buprenorphine/naloxone or adrenergic alpha2 receptor agonists (the latter were not registered in the country).

4. Pregnancy. There are no major discrepancies between the WHO and national *Guidelines* regarding the recommended treatment for pregnant women. According to the recommendation women, who became pregnant were recommended to start or continue pharmacotherapy with methadone or buprenorphine, while buprenorphine/naloxone was contraindicated. According to the *Guidelines* treatment with methadone or buprenorphine is generally indicated for breastfeeding women, if they are not HIV positive or use other psychoactive substances, including alcohol.

**Implementation of Guidelines**

The State Health Care Accreditation Agency under the Ministry of Health ensured that the health care institutions which provided medical dependence treatment were capable to provide services according the *Standards*, approved in 2002.

It was not clear to what extent and how widely the health care institutions implemented the national *Guidelines* on pharmacotherapy of opioid dependence and other. So far, the *Guidelines* were introduced through the Lithuanian Psychiatrists’ Association at annual conferences. The *Guidelines* were introduced on a regular basis in training of physician residents in psychiatry, regular continuous medical training courses for medical practitioners at the Vilnius University Psychiatry Clinic.

Since 2010 the “Intervision” sessions were introduced. These sessions were based on methodology of non-directive discussions and sharing of experience on problems in clinical practice, discussion of case studies in small groups of specialists without avoiding hierarchical relations (ref. No. 11). “Intervision” as a quality assurance methodology was introduced in the Baltic States (Estonia, Latvia and Lithuania) by the Regional UNODC project for the Baltic States in 2010, by adapting the Trimbos Institute (The Netherlands) experience. Sessions for multi-and mono-disciplinary specialist groups in a single health care institution or from different institutions seemed to have a promising potential in the implementation of the *Guidelines* and best practices in treatment of dependence.

Comparison of the national *Guidelines* for treatment of drug dependence in closed settings with the WHO *Guidelines* is presented in Appendix 1.

**References:**

1. Sveikatos apsaugos ministro 2002 m. gegužės 3 d., įsakymas Nr.204 "Dėl priklausomybės ligų gydymo ir reabilitacijos standartų patvirtinimo" (Žin., 2002, Nr 47-1824) / Decree No. 204, of May 3, 2002, of the Minister of Health of the Republic of Lithuania *On Approval of Standard of Treatment and Rehabilitation of Dependence Disorders*;


Procedural Profile Concerning Preparation of Methodologies of Diagnostics and Treatment and their application;


5. Subata E., Danilevičiūtė V., Adomaitienė V. ir kt. Priklausomybės nuo opioidų gydymo metodonu metodika; Lietuvos psichiatrų asociacija, UNODC, 2010 / Guidelines of Treatment of Opioid Dependence with Methadone


8. Karalienė V., Lesinskienė S., Subata E. Vaikų, vartojančių narkotines, psichotropines, kitas psichiką veikiančias medžiagas ankstyva diagnostika ir gydymas pirminės asmens sveikatos priežiūros įstaigose tvarkos aprašų patvirtinimo" (Žin., No.: 90 -3587) / Early Diagnosis and Treatment of Children, who use Drugs, Psychotropic and Other Psychoactive Substances


11. History, methods and implementation of national treatment guidelines

In the mid seventies the cooperation between state and NGOs working in the social field has progressively gained in structure. The first financing convention between the Ministry of Family and a series of NGOs, signed in 1975, was the starting point of what is known today as the ‘conventionned sector’. Progressively the collaboration schemes between State and NGOs evolved and have been extended to the Public Health sector.

In 1998 the so-called ASFT law\(^{59}\) entered in force, regulating the relationship between State and private organisations working in the social, family and therapeutic fields. Presently, most of NGOs involved in drug treatment have signed a financial and quality control agreement called ‘convention de collaboration’ with the Ministry of Health. A majority of these NGOs are financed entirely by the Ministry of Health and a few of them are financed on basis of regular subventions. The convention between the Ministry of Health and NGOs entitles the former to control the functioning and the financial management of each NGO via a governmental delegate within a management committee called ‘coordination platform’.

Since 2000 the coordination of drug demand reduction, risk reduction and drug related research is a competence of the Ministry of Health. The same year a national drug coordinator was appointed by the Minister of Health and has been mandated with the overall coordination in the domains of drug-related demand and harm reduction. The drug coordinator meets regularly with conventionned NGOs in order to share information and steer responses to emerging trends.

An evaluation of the national drug action plan (2005-2009)\(^{60}\) has been performed in the second half of 2009. Subsequently the third national drugs strategy and action plan (2010-2014) was presented by the Minister of Health and the National Drug Coordinator in April 2010.

Since 2004, the Luxembourgish Government has been elaborating a national action plan focussing on the improvement of healthcare with the respect of financial balance.\(^{61}\)

The objectives of the national strategy on health care are:
- implementation of an Health Observatory (sanitary policy and preventive medicine),
- promotion of health and active involvement of actors,
- coordination of healthcare,
- control of healthcare quality (amongst others, determination of hospital quality indicators for the EFQM model),


\(^{61}\) 2\(^{nd}\) Report on the national strategy on social protection and social inclusion 2008-2010
- reorganisation of social security (Caisse nationale de Santé - CNS),
- new hospital plan (main objectives: quality process including evaluation, documentation and quality guarantees; if indicated prefer ambulatory to stationary treatment, creation of a geriatric department, etc.).

11.1. History and overall framework

Description of the national situation

During the last decade, a range of national initiatives have been taken with regard to the hospital sector to promote quality and to sensitize and inform companies.

Government, chambers and professional federations, have been fairly supportive: legislative actions, conferences, further education, support for companies and representation at international level.62

The grand ducal decree of 10 May 2001 created within the Ministry of Economic Affairs a national accreditation, certification, normalisation and quality promotion council). This consultative body has the following missions:
- to advice the minister who is in charge of accreditation, certification, normalisation and quality promotion and to submit propositions on general orientations;
- to organize the collection, circulation and publication of information concerning activities of this domain;
- to follow the politics of European Community Law and International Law;
- to associate, if possible, each party interested in activities related to this domain;
- to elaborate propositions for the preparation of a national quality promotion plan.

The referred body also includes a delegate from the Ministry of Health.

The hospital and health care actors work towards a constant improvement of quality. The main objective is to guarantee the continuity of the provision of services. As a response to the changing operating environment, healthcare administrators have begun to implement modern management tools in their organizations to solve their financial problems while sustaining premium class services.

Concerning the hospital sector, actors involved in the (second) 2007-2009 national quality promotion plan are:
- hospitals and hospital actors,
- the Union of Health Insurance Funds (Union des Caisses de Maladie),
- the Public Research Centres,
- public authorities (Ministry of Health, Ministry of Economic and External Affairs, Ministry of Family, Ministry of Social security, etc.)

The 2007-2009 national quality promotion plan has the following objectives:

- implementation of the “EFQM” inside hospitals. This management model (EFQM) has been developed by the ‘European Foundation for Quality Management’ in 1988 and revised in 2002. In 2002, the alliance of Luxembourgish hospitals (EHL) and the Union of Health Insurance Funds have both decided its implementation. The EFQM

62 Ministry of Economy and Foreign Trade, National Plan for Promoting Quality (2007-2009)
model has been put in place inside national hospitals during 2004 to 2006. The EFQM can deliver each year three European Prizes, one of them dedicated to public administrations,
- since 2005, a progressive implementation of common performance, quality and result indicators to the EFQM approach has started. Each year, new common indicators are added to the list of indicators,
- integration of the “risk management approach” with the objectives of security, reduction of incidents, accidents, complaints, costs,
- hospital administrations continue to submit information concerning functioning and activities to the authorities in wardship (autorités de tutelle). These information are necessary to elaborate or revise the “sanitary card” (carte sanitaire), to determine resources and to evaluate quality of health care,
- in order to ensure a continuous quality and health care security improvement, each hospital establishment, besides EFQM procedures of auto-evaluation, has to undergo an external evaluation.

Hospital sector activities planed in the framework of the 2007 – 2009 plan:

- in the context of quality management: feasibility analyses of a standard contract of the relations between doctors and hospitals to clarify their role, missions and obligations,
- a system of activity surveillance of type "balanced score card" continues to be implemented. Balanced scorecard, a performance measurement and strategic management system, is one of the new tools adopted by management in hospitals. It translates an organization's mission and strategy into a balanced set of integrated performance measures.
- health care professionals are encouraged to analyse and compare service offers in the framework of the “peer review” model,
- the Luxembourg Medical Association (AMMD) and the alliance of Luxembourgish hospitals (EHL) will officialise a specific framework agreement regulating the attributions and missions of medical doctors, head of departments,
- activities of medical analyses laboratories will further be controlled by means of existing laws (e.g. guide of best practice).

In 2001, six foundation members (EHL, CRP Tudor, Chambre des Métiers, Chambre de Commerce, Fedil, Luxinnovation) created the Luxembourgish Quality Movement (MLQ) under the impulse of the Ministry of Economy. Today the MLQ counts more than 220 members. The MLQ has developed in 2002 the week of quality, in 2003 the Guide of Quality and in 2004 the Luxembourgish Prize for Quality (PLQ).

The grand-ducal decree of 13 March 2009 implementing the national hospital plan sets up in each hospital an evaluation and quality assurance committee. This committee has to follow the guidelines and recommendations of the national quality assurance coordination committee (e.g. patient’s rights guarantee, global evaluation of undesirable events and elaboration of recommendations). This national committee is composed of:
- a representative of the Ministry of Health and of the Ministry of Social Security,
- the director of Health or his representative and a delegate of the health insurance administration
- four representatives of hospital establishments,

63 Règlement grand-ducal du 13 mars 2009 établissant le plan hospitalier national et déterminant les missions et la composition minimales des structures d’évaluation et d’assurance qualité des prestations hospitalières et les modalités de coordination nationale de ces structures.
- two medical doctors from the hospital sector.

All the members are nominated by the minister of Health. This grand-ducal decree is of interest in the present context since drug detoxification treatment is mainly provided by regional hospitals.

Concerning specifically drug substitution treatment, a consensus expert paper was elaborated in 1998 by a working group of medical doctors (members of the AMMD association – the main national representative body of medical doctors) involved in substitution treatment. This document was admitted by the substitution treatment commission from the Ministry of Health and applied from then on in medical practice. These recommendations originate from a Belgium document issued from a “Methadone Consensus Conference” held in 1994 including guideline evaluation and complementary propositions (Sanitary Committee, Ministry of Social Affairs, Public Health and Environment, Brussels).

The grand-ducal decree of 30 January 2002 determines the modalities of the substitution treatment programme such as admission criteria, psychosocial follow up of patients, training requirements for prescribing MDs, etc.

11.2 Existing guidelines: narrative description of existing guidelines

Description of existing guidelines

The Neuro-Psychiatric Hospital (CHNP) runs a specialised department of addiction associated to an orientation centre situated in Luxembourg City called “Alternativ Berodungsstell”, an inpatient treatment centre called “Therapeutical Centre Syrdallschlass Manternach” (CTM) situated in the east of Luxembourg, a supervised housing programme (after-care) and a hospital rehabilitation unit called BU5 situated in the main hospital centre (CHNP).

The CHNP adheres to the national quality promotion plan. The CHNP is an active member of the EFQM (European Foundation for Quality Management) association and of the MLQ movement (Luxembourgish movement for quality) and promotes the development of centres of excellence. Since 1998, the CHNP participates in the “quality incentives programme” (measures of quality indicators).

Since 2004 a steering committee provides for the follow-up of projects in the framework of the EFQM principles and communicates their views to the committee of directors to optimize its organisation. In 2009, an evaluation of the EFQM model by two external experts has been performed.

In addition and since June 2009, the CHNP is a participant of the European exchange of practice and knowledge project in Mental Health “Leonardo VII”. Four countries (Belgium, France, Luxembourg, the Netherlands) with respective hospitals and psychiatric centres have initiated this project (e.g. comparison with international partners). Among the objectives of the “Leonardo VII” project are: exchange of best practices, quality evaluation, development of competencies and observation of practical professional knowledge.

The CTM has performed its third EFQM auto-evaluation in 2008. In 2010 the CTM has been campaigning for the “Recognized for Excellence” of the EFQM. Therefore the missions, visions and values of the CTM have been critically revised. Also the CTM has contacted other therapeutic centres from neighbouring countries to conduct a benchmarking process.
Medically supervised drug detoxification treatment is provided since 2005 regionally in 6 general hospitals. As stated above, one of the main objective of the 2007-2009 national quality promotion plan is to implement the “EFQM” inside hospitals.

The “Jugend-an Drogenhëllef” foundation (JDH) is the main specialised drug treatment agency at the national level. It is the most relevant national outpatient treatment facility and has regional antennas implemented in Luxembourg City, in the South and in the North of the country.

The national substitution treatment programme has reached national coverage since 1989 (JDH).

Until the beginning of 2001 there has been no genuine legal framework regulating drug substitution treatment. The law of 27 April 2001 modifying the basic drug law of 19 February 1973 introduces a legal framework for substitution and maintenance treatment. The grand ducal decree of 30 January 2002 regulates the practical modalities of substitution. The new law regulates drug substitution treatment in general rather than it legalises a single national substitution programme. The law does this by means of substitution treatment licenses granted to MDs and specialised agencies, the application of training requirements for prescribers and adequate control mechanisms of multiple prescriptions (i.e. centralised register of substituted patients). It should be stressed that following the application of the new legal framework, there still exists a structured substitution treatment programme provided by JDH and a lower threshold substitution treatment offer provided by freelance state licensed MDs.

11.3 Implementation process

Guideline implementation processes

In 2009 an external evaluation of the national drug action plan (2005-2009) was performed. The evaluators reported that national experts identified one of the following priorities with regard to quality control mechanisms:

- enhance quality of substitution treatment by using generally applied guidelines by implementing a national supervision and control system, with a national accreditation system for substitution treatment requiring specific training of involved doctors and offering social support to the clients. (Evaluation of the national drug action plan 2005-2009. page: 22).

The external evaluation results also underline that an assessment of the quality of the services provided should be taken into consideration. This would require a system of quality assurance applied to all prevention, treatment and harm reduction services. Such a system would involve a variety of elements, such as the formulation of quality criteria and standardized procedures, the development of checklists or protocols for different components of the work of the services and introducing supervision and/or intervision. Also the contracts between the Ministry and the services (the so-called conventions) could stipulate the required quality assurance measures. A first step could be to make an inventory of quality measures already undertaken and to exchange experiences between services.

In this context, a study on “Management and expertise in the public healthcare sector” with focus on “Quality management in Luxembourgish drug help services”, is currently being performed. The aim is to assess what quality dimensions have been implemented by specialized drug demand reduction agencies by means of quality management thus far. An
online survey/questionnaire addressed to all programme directors of specialized agencies financed by the ministry of Health has been performed. This study is the first one of its kind performed at national level and the outcome will be presented in the 2011 edition of the present report.

The Ministry of Health fully supports the approach of quality management and aims to discuss with all partners involved the outcomes of this survey in order to integrate quality improvement and quality assurance measures into the daily work plan of specialized agencies. This approach can also help to implement measures of the national drug action plan, enhance the planned implementation of a case management system and improve client health care provision in general.

11.4 For countries that have treatment guidelines: comparison with the WHO guidelines

**Comparison of national guidelines on pharmacological treatment of opiate dependence with WHO guidelines**

Concerning the **choice of substitution treatment**, neither the medical consensus paper (AMMD) nor the grand-ducal decree of 30 January 2002 include explicitly the recommendation on the preference of opioid agonist maintenance treatment as compared to other treatment options (e.g. opioid withdrawal, opioid antagonist treatment,...). In general, the existing guidelines do not include recommendations concerning the choice of treatment.

Concerning **opioid agonist maintenance treatment** the national guidelines do not include defined ranges of methadone, buprenorphine, etc. doses per day.

The medical consensus paper includes the statement that maintenance treatment only is effective if associated to adequate psychosocial support. Take-away doses have to be subject to an in-depth situation analysis of the patient and have to be clearly motivated (e.g. confidence, work place,...). Moreover, has the medical doctor to examine personally and regularly the patient. The grand-ducal decree in art.14 states that during the first two months of substitution treatment the patient has to take his daily dose within the accredited association or inside a pharmacy. A take-away dose only is permitted in specific and exceptional cases which have to be clearly motivated (e.g. health status, geographical or professional constraints).

Concerning the **management of opioid withdrawal**, medical doctors act in line with best medical, deontological and ethical expertise and practice.

Concerning **pregnancy** the medical consensus paper underlines that in the latter case medical and psychosocial support, if required, have to take place in a regulated framework where a multidisciplinary and professional follow-up is guaranteed. It is strongly recommended to admit pregnant women in a strictly regulated substitution programme. No medication specific guidelines are given as it falls under the responsibility of the prescribing MD.

**Comparison of national guidelines for drug treatment in closed settings**

Not applicable.
Overview

In Hungary two groups of the guidelines relating to the treatment of drug-related problems are distinguished: guidelines relating to healthcare and guidelines relating to social services. Healthcare and social services are determined in separate legal acts, they are financed from different funds and their quality assurance systems are also different. Because of all these, below the healthcare and social guidelines are described separately.

11.1. HISTORY AND OVERALL FRAMEWORK

Healthcare guidelines

In Hungary the methodological standardisation of addiction treatment was started in the years following the change of the political regime. In 1991 it became possible to take a specialised exam in addiction treatment, at the same time the National Institute for Addiction (hereinafter: OAI) and the National Advisory Board for Addictions was established. In 1995 the Advisory Board was terminated, and the professional work performed by it was then carried out by the specialised addiction workgroup operating within the National Advisory Board for Psychiatry. As a result of this, the professional representation of addiction treatment was passed on to the National Institute of Addictions until the institute was terminated in 2008. The first professional guidelines focusing on the treatment of drug users were elaborated between 2002 and 2007 under the coordination of the National Institute of Addictions.

Presently the tasks relating to the quality control of addiction treatment are primarily performed by the National Centre for Healthcare Audit and Inspection (hereinafter: OSZMK). Since 2005 the inspection and monitoring of the implementation of the guidelines has been performed by the ‘national inspector of addictions’ commissioned by OSZMK.

The healthcare guidelines (protocols, professional guidelines and methodological letters) are elaborated and updated, if necessary, by the so-called national advisory boards having the most expertise on the given special field. In 2008 the Institute for Healthcare Quality Improvement and Hospital Engineering (hereinafter: EMKI) was established, and the Ministry of Health referred the coordination of the elaboration and updating of healthcare guidelines within its sphere of action. Since April 2009 the re-established National Advisory Board for Addictions has been elaborating and updating the guidelines relating to addiction treatment, collaborating with the other advisory boards concerned in this field.

The advisory board submits the prepared/updated guidelines to the Ministry of Health for approval. EMKI also takes part in the process of granting approval to the guidelines by making a methodological evaluation about the new guidelines as a part of which the guidelines are evaluated from a professional aspect as well as from the aspect of their form and applicability. However, in the lack of finances a methodological evaluation is not made in respect of all materials.
On the basis of the professional guidelines of the Ministry of Health, Social and Family Affairs relating to the development of evidence based professional guidelines and on the basis of Regulation 23/2006. (V. 18.) of the Ministry of Health on the rules of procedure relating to the elaboration, compilation and professional harmonisation of examination and therapeutic guidelines, four different guidelines are distinguished (among which the local guidelines are beyond the issue dealt with in this chapter).

The professional guidelines are a series of systematically developed decision recommendations supported with available scientific evidence for determining the different treatment methods of a given group of diseases, the aim of which is to improve the quality, efficiency, successfulness of healthcare and provide help for doctors and patients in choosing the most suitable treatment.

Methodological letters include the descriptions of prevention, diagnostic, therapeutic or rehabilitation procedures, which are elaborated as directives for healthcare service providers by acknowledged personalities of the given profession on the basis of expert opinions. Generally methodological letters do not contain alternative recommendations, they do not provide information in connection with the negative effects of the recommended procedures or the probability of the occurrence of such effects, they do not contain a cost analysis, and they provide help only for healthcare service providers.

The professional protocol, in respect of a certain group of diseases and a certain treatment level, is a systematic list of activities relating to the treatment process of a disease or condition – including preventive, diagnostic, therapeutic, treatment, care and rehabilitation process supported with accessible scientific evidence –, which forms the basis of the professional inspection and financing of healthcare services, and the aim of which is to ensure the safety and even standards of the healthcare services.

The local guidelines include the description of the local practice applied at the given healthcare service provider and at the given healthcare service level, based on professional guidelines and professional protocols, or in the lack of these on the practice of the given healthcare service provider, relating to the treatment of the given disease or condition.

Social guidelines

The Ministry of Social Affairs and Labour ordered and financed the elaboration of the currently valid three guidelines relating to the treatment of addicted clients. The three professional guidelines were published in 2007 in Kapocs füzet (booklet) No. 5 of the Institute for Social Policy and Labour (hereinafter: SZMI). Although this booklet was published as a result of the collaboration between the Ministry of Social Affairs and Labour and the Specialised Workgroup of Addictions of the National Institute for Family and Social Policy (presently SZMI), up until the present the guidelines have not been issued in the Social Gazette, which is the ministry's official gazette. At the same time Government Regulation 191/2008 (VII. 30.) on the financing of helping services and community services refers to them as professional recommendations.

At an operative level, the social professional guidelines – including the three guidelines dealing with the treatment of addicted clients – are registered by the Employment and Social Office (hereinafter: FSZH).

---

64 Its term of validity has expired, but it can still be used for preparing guidelines.
65 Source: Regulation 23/2006. (V. 18.) of the Ministry of Health on the guidelines relating to the elaboration, compilation and professional harmonisation of examination and therapeutic guidelines
66 Source: professional guidelines of the Ministry of Health, Social and Family Affairs relating to the development of evidence based professional guidelines
67 Source: Regulation 23/2006. (V. 18.) of the Ministry of Health on the guidelines relating to the elaboration, compilation and professional harmonisation of examination and therapeutic guidelines
68 Source: Regulation 23/2006. (V. 18.) of the Ministry of Health on the guidelines relating to the elaboration, compilation and professional harmonisation of examination and therapeutic guidelines
The elaboration and updating of the guidelines, standards and service protocols is within the sphere of action of the SzMI\(^{69}\), but presently there is no standardised system of these processes. The content of the three guidelines published in 2007 has not changed since.

11.2. ADDICTION CARE GUIDELINES IN HUNGARY

Healthcare guidelines

Currently there are 3 protocols and one methodological letter in force in connection with the treatment of drug users:

- The methodological letter of the Ministry of Health – The methadone treatment,
- The professional protocol of the Ministry of Health – On the treatment of diseases related to opioid use,
- The professional protocol of the Ministry of Health – On the treatment of clinical conditions associated with amphetamine use, and
- The professional protocol of the Ministry of Health – On disorders related to cannabis use.

All three protocols were elaborated by the National Institute of Addictions primarily for specialists in psychiatry and addiction treatment. They are based on evidence and on professional consensus. The protocols contain the description of the disease, the process and recommended methods of diagnosing, treatment, rehabilitation and care and partly the indicators of efficiency. They need to be updated every two years.

The methodological letter is a guideline, which is much more specific than the protocols, it exclusively describes the diagnostic and treatment processes and the indicators of efficiency.

Social guidelines

Presently there are three professional guidelines dealing with social services provided for addicted patients:

- the “Daytime care for addicted persons – Professional recommendation”,
- the “Low-threshold services provided for addicted persons – Professional recommendation”
- and the “Community social care provided for addicted persons - Professional recommendation”.

The social guidelines were elaborated by the Specialised Workgroup of Addictions. The guidelines have no designated target group, their content is based on professional consensus\(^70\). They describe the aims and guiding principles of the service, its quality assurance conditions and the activities covered by the service.

Other guidelines

Besides the healthcare and social guidelines, in 2009 the draft of the guidelines entitled “The professional guidelines relating to school-based health promotion programmes aimed at the prevention of drug use” and the preparatory material entitled “Study for the guidelines relating to interventions aimed at the prevention of alcohol consumption and illicit drug use in settlements and communities (except for workplaces and schools)” was also elaborated on

\(^{69}\) Based on “Regulation 3/2008. (IV. 15.) of the Ministry of Social Affairs and Labour on the designation and tasks of social methodological institutes and on the expert fee of the licensing procedure of social service providers and institutes”.

\(^{70}\) The draft guidelines were harmonised with the representatives of the field in the scope of a consensus conference.
behalf of EMKI. The draft and the preparatory study includes recommendations in connection with the prevention relating to the formal components and intervention elements, which have proved to be efficient in prevention at schools, in settlements and in communities on the basis of the literature reviews and meta-analyses.

11.3. IMPLEMENTATION PROCESS

Healthcare guidelines

If the ministry grants its approval to new or revised guidelines, they are published in the official gazette of the Ministry of Health, in the Healthcare Gazette and on the ministry’s website. At the same time the new guidelines are also published on the website of EMKI.

In accordance with Regulation 23/2006. (V. 18.) of the Ministry of Health, healthcare service providers, in their organisational and operational rules, must determine measures needed for the implementation of the professional protocol, furthermore the professional control and financing of the healthcare services are also based on the professional protocol.

Consequently, it is the healthcare service providers’ obligation determined in the legal act to implement the guidelines. OSZMK is responsible for controlling the quality of the services – and the compliance of the practices with the guidelines – in the scope of planned or ad hoc auditing. The conditions of auditing have been created since the first addiction inspector was appointed in 2005, so no audit has been carried out in this field yet. With regards to the fact that in many places addiction treatment is realised within psychiatric treatment defined in a certain number of hours, it was very difficult to identify the units providing addiction treatment. At the same time the professional protocols of addiction treatment were elaborated (concerning the treatment of opiate, amphetamine and cannabis use related problems).

In 2009, under the coordination of the National Centre for Addictions, the system of indicators needed for the evaluation of the process and results of the services was elaborated in the fields of addiction with a treatment protocol (cannabis, amphetamine, opiate, substitution). In the individual service fields the indicators determined will be directly suitable – after professional legitimation (that is the approval of the advisory board) is granted – for starting to prepare the implementation in respect of the individual service providers. On the one part, in the long run it provides help for addiction service providers in modifying their own internal monitoring and documentation system accordingly, on the other part it enables addiction inspector chief physicians to start the auditing of the individual service providers.

It was a problem in the course of the preparation of quality control when the financing system changed from fixed financing to performance-based financing.

On the basis of the specialists’ experience gained so far, the main barriers for adapting healthcare guidelines to the practice of addiction treatment is the disharmony between the guidelines and financing. This problem occurs in the deficiencies of the financing of the medicines and procedures recommended in the professional protocols, and in the lack of expertise, which is also due to financing problems.

---

71 Task entitled “Organising and holding training courses needed for handling the drug problem” in the framework of the sub-task entitled “Quality training for addiction healthcare service providers”.

72 For further details see National Report 2008 and 2009, chapter 5.
Methodological letter and practice in opiate substitution with methadone

The survey (Rácz et al. 2009) relates to the practical implementation of the healthcare guidelines; in this survey they examined how much the practice of opiate substitution with methadone complies with the content of the methodological letter. During the survey 150 clients participating in methadone maintenance treatment at the time of the survey and 16 professionals controlling the treatment programme and handing out methadone were asked to fill in questionnaires.

The client questionnaire examined issues such as the accessibility of the location of the programme, handing out methadone (dose, taking it home), the attitude of the treatment staff, the protocol, sanctions, criminality, fear, subjective changes. The respondents were also asked to make recommendations relating to the further development of the service. Besides this questionnaire, the TDI questionnaire was also recorded in order to describe the socio-demographic situation and drug use habits of the sample. 10 of the professionals included in the sample represented treatment units outside of Budapest, and 6 of them represented treatment units located in Budapest. The questionnaire covered issues such as the characteristics of the organisation operating the treatment unit, the special features of the content of the service, the professional staff, the criteria of success and the professional methodological letter. Apart from the data deriving from the questionnaire data recording, the secondary analysis of the data of an earlier survey concerning the efficiency of the methadone treatment was also performed (Demetrovics 2005).

One of the problems identified as a result of the survey was that the methodological letter did not define the exact aim of the substitution treatment, consequently it is difficult to determine indicators for monitoring the efficiency of the treatment.

The results of the survey indicated that the methadone dose given to the patients is not high enough. The reason for this — according to the authors — is that although in respect of doses the methadone protocol determines exact numbers, it does not extend to when, how and under what circumstances the dose must be, can be or should be changed.

The survey showed that in many cases the clients are not provided with sufficient information. The methodological letter contains prescriptions relating to this, but as there are no consequences, many treatment units do not observe the instructions.

Social guidelines

The survey was performed by the Hungarian Academy of Sciences, Institute for Psychology, with the support of the National Institute for Drug Prevention. The survey was carried out in two target groups: among clients in substitution treatment and among professionals leading the substitution programmes and handing out methadone. The group of clients was selected from the clients of 3 treatment units located in Budapest and 5 treatment units outside of Budapest, on the basis of the gender distribution observed in the 2008 national substitution data collection. A total number of 150 persons were included in the sample (115 men, 35 women). The professionals were selected from the same treatment units, two professionals per treatment unit were included in the sample, a total number of 16 persons. In both target groups anonymous questionnaire data recording was carried out using face-to-face technique at the given treatment unit.

In the scope of the survey they compared the TDI questionnaire filled in during data recording with the TDI questionnaire filled in when the client entered substitution treatment, in order to identify the changes occurring since then. In 199 cases the questionnaire filled in upon admission was available.
After the publication of the guidelines (2007) until the end of 2008 the three guidelines were accessible only in the booklet entitled Kapocs füzet, in return of payment. During this period the use of the guidelines in professional practice was not a direct condition of issuing the operation licence or financing the operation.

Since the end of 2008 the guidelines as professional recommendations have been accessible on the internet, on the website of the Employment and Social Office (FSZH). On 1 January 2009, in the social field normative financing was replaced by a system of state supports granted via applications, since then the guidelines have formed a part of the tender documentation, which also means that partly represent a condition of financing.

At an official level FSZH, while at professional level – at the request of the Public Administration Office – the so-called Social Methodologies control whether a given service provider provides its services in compliance with the guidelines.

11.4. PHARMACOLOGICAL TREATMENT OF OPIOID DEPENDENCE – COMPARING NATIONAL AND WHO GUIDELINES

In Hungary there are two different treatment guidelines relating to the pharmacological treatment of opioid dependence. One of them is the professional protocol of the Ministry of Health on the treatment of diseases related to opioid use (hereinafter: opioid protocol), and the other one is the methodological letter of the Ministry of Health on methadone treatment (hereinafter: methodological letter). The opioid protocol provides a review of the possibilities of the non-pharmacological and pharmacological treatment of opioid dependent patients, while the methodological letter deals exclusively with methadone and with the process of the substitution treatment itself.

Choice of treatment

The two relating national guidelines partly contain the WHO recommendation, according to which “For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment.” The listed treatment possibilities are all included in the opioid protocol, but in the lack of a sufficient number of high-quality evidence, it does not contain a recommendation in respect of which treatment possibility should be used first of all.

The two relating national guidelines contain the WHO recommendation, according to which “For opioid-dependent patients not starting opioid agonist maintenance treatment, consider antagonist pharmacotherapy using naltrexone following the completion of opioid withdrawal”, but naltrexone is stated only as a possibility and not as a preference, as the use of the pharmaceutical preparation is not supported by the National Health Insurance Fund, and it is not widely used in practice.

Opioid agonist maintenance treatment

Guidelines relating to low-threshold services and community services.

This tendering system is handled by the FSZH on the basis of Government Regulation 191/2008 (VII. 30.).

Guidelines relating to low-threshold services and community services.

In this part of the chapter the questions of the EMCDDA questionnaire are dealt with.
The two relating national guidelines do not contain the WHO recommendation, according to which “For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine.” One of the reasons for this is that at the time of elaborating the protocol buprenorphine (which is accessible in Hungary even presently exclusively in a combination with naloxone) was not available. Furthermore, the opioid protocol simply provides a list of the preparations that can be used during pharmacological treatment, but it does not make recommendations or preferences in respect of the different preparations. Several of the listed preparations and therapies are still not available in Hungary.

The two relating national guidelines mostly comply with the WHO recommendation, according to which “During methadone induction, the initial daily dose should depend on the level of neuroadaptation; it should generally not be more than 20 mg, and certainly not more than 30 mg”, still the initial dose is set between 10-40 mg.

The two relating national guidelines determine the range of the recommended daily dose in compliance with the WHO recommendation, according to which “On average, methadone maintenance dose should be in the range of 60–120 mg per day.”

As opposed to the WHO recommendation – according to which “Average buprenorphine maintenance doses should be at least 8 mg per day” – the opioid protocol recommends 8 mg as the most efficient dose, and it does not determine the minimum dose.

The WHO recommendation, according to which “Methadone and buprenorphine doses should be directly supervised in the early phase of treatment” appears in the national guidelines only in the case of methadone.

The two relating national guidelines contain the WHO recommendation, according to which “Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review.” In the national methodological letter it is recommended to provide take-away doses for several days in a justified or especially justified case.

The two relating national guidelines contain the WHO recommendation, according to which “Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence”.

**Management of opioid withdrawal**

The two relating national guidelines contain the WHO recommendation, according to which “For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used”. But in this case too, it is only listed among the recommended treatment methods, and no preferences are determined.

The two relating national guidelines do not contain the WHO recommendation, according to which “Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal”.

The two relating national guidelines do not contain the WHO recommendation, according to which “Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal”.

136
The two relating national guidelines contain the WHO recommendation, according to which “Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal”.

Pregnancy

The WHO recommendation relating to pharmacological treatment during pregnancy – according to which “Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy” – is not included in the national guidelines. In the application order relating to methadone pregnancy is regarded as an absolute contraindication, application is recommended only in exceptional cases, after careful consideration of the advantages and risks. This may be the reason why it is not stated separately in the protocol. Nevertheless, cooperation has started between the National Advisory Board of Gynaecology and the National Advisory Board of Addictions in the interest of elaborating recommendations relating to the treatment of drug user / opioid dependent pregnant women.

The WHO recommendation, according to which “Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered”, is not included in the relating two national guidelines, for the reasons described above.

Conclusions

Presently there are 7 guidelines / protocols / methodological letters in the field of addiction treatment, 3 of them cover social service forms and 4 of them cover healthcare service forms. In the interest of the standardisation and development of addiction treatment the first guidelines were elaborated in 2002, so quality assurance in the field does not have a long history.

Guidelines are elaborated differently in the two fields: the social guidelines are based on professional consensus, while the healthcare guidelines are based on professional consensus and on evidence. While the healthcare guidelines are revised every 2 years, in respect of the social guidelines the term of validity is not restricted.

In connection with the adaptation of the guidelines, no comprehensive and reliable data is available in either field. At the same time, on the basis of the professional experience it can be said that the main barriers for their application in practice is the lack of harmonisation with financing.

---

79 It is because the manufacturers did not examine the applicability of methadone in the case of pregnant women.
MALTA

No information.
11 History, methods and implementation of national treatment guidelines

11.1 History and overall framework

11.1.1 Brief introduction on the role of guidelines in improving quality in addiction care in the Netherlands

The role of guidelines in improving the quality of care is considered important, but the literature on implementation and health policy measures shows that guidelines in itself are insufficient to realize this goal. “Guidelines are a way to translate research results and clinical experiences in practice into recommendations about care procedures. They work as an intermediary in the implementation process.” (Grol 2009b). For instance, besides guideline publications that tell professionals what to do in daily practice, other publications are needed that present guidance how to do it, for example protocols, manuals, and modules. Initial studies on the implementation of guidelines in Dutch addiction care showed some advantageous results, but the consequences for the quality of care in the longer run have to be evaluated yet.

To gain more insight into developments of the quality of addiction care, additional mechanisms have been or will be introduced in the Netherlands. Examples are the routine monitoring of the outcomes of care, performance indicators, and an elaborated administrative schedule of diagnosis-treatment combinations. The aim of these combinations is to structure treatment allocation arrangements and to structure the decision making of the insurance companies about funding arrangements. These mechanisms may have both advantageous and disadvantageous effects, which will also briefly be referred to in this selective issue.

11.1.2 Historical, cultural and institutional contexts that contributed to the development of guidelines

Below, some important and partly simultaneous developments and activities for guidelines in general health care, mental health care, and addiction care in the Netherlands are presented. Earlier developments were the consensus statements, initiated in the 1970s, of the National Institutes of Health (NIH) in the United States. These are reported to be the first examples of systematic guideline development. This movement was paralleled and supported by methodological advancements in reviewing the research literature during the period 1975 to 1995. For the social sciences this started with the publications of Glass (Glass 1976;Glass et al. 1981). The growing sense of importance among scientific researchers of conducting systematic reviews and meta-analyses for determining the effectiveness of interventions gradually became prominent. And on its turn, the international movement of evidence-based medicine, that started in Canada and the United Kingdom in the 1980s, has been fundamental for evidence-based professional guideline construction.
During the 1980s, general practitioners (GPs) in the United States started to construct guidelines and standards for professional practice. The function of these guidelines was to support GPs in their professional practice, to restrict unnecessary differences in professional practice, to offer a basis for evaluation and training, and to support medical task agreements between GPs and medical specialists (Theuvenet et al. 2004).

The international movement of evidence-based medicine that started in Canada and the United Kingdom in the 1980s has been directive for a similar movement in the nineties in the Dutch health care, the mental health care, and addiction care (Swinkels et al. 2008).

**General health care**

The first guideline for GPs was introduced in the Netherlands in 1989 by the Dutch Association for General Practitioners (NHG). Guidelines from this period were predominantly consensus based. From 1996 the guidelines became more evidence based, under the supervision of the Dutch pioneer in evidence-based medicine, the Institute for Quality in Health Care (CBO). In the same decade, foundations for medical specialists became also active in guidelines construction (Theuvenet et al. 2004).

In medical sciences, the Cochrane Collaboration started in 1992 and its Dutch sister organization, the Dutch Cochrane Center, started two years later. In the Netherlands, the growing availability of scientific evidence for effectiveness has fuelled the development towards more evidence-based guidelines instead of only consensus-based guidelines.

In the Netherlands, at the end of the nineties several developments and activities were initiated by the Ministry of Health, Welfare and Sport, all pointing in the same direction, namely supporting the process of improving the quality of care. Later in the nineties the costs of care, and thus the discussions about choices in care, also became a part of guidelines construction. The Ministry of Health, Welfare and Sport funded a program of cost-effectiveness analyses that was realized by several organizations, for example the Institute for Quality in Health Care (CBO), the Order of Dutch Medical Specialists, the Institute for Medical Technology Assessment, the Working Group on Research and Quality (WOK), and the Dutch Cochrane Centre. Improving the quality of care has become increasingly related to the quest for increasing the efficiency in health care expenditures, which is due to the steadily rising national costs of health care. The target is to reach for high-quality health care for the patient at the lowest price. Among the initiatives that were started are not only the guidelines, but also quality standards, protocols, benchmarking including routine outcome monitoring, performance indicators and Diagnosis Treatment Combinations (Casparie et al. 2004; Pijnenborg et al. 2004). The importance of these endeavours has currently grown due to the general quest.

**Mental health care**

During the nineties, the need for research reviews of the effectiveness of interventions was also felt in the field of mental health care, which resulted in several systematic review reports about different mental disorders (Arends et al. 1996; Donker et al. 1996; Van Gageldonk 1996). In 1999 the National Steering Group for the Development of Multidisciplinary Guidelines for Mental Health Care was initiated. This Steering Group was supported by
several professional and client organizations in the field of mental health care. Under this Steering Group, several commissions were inaugurated, meant for producing guidelines for specific classes of mental disorders. Until now ten guidelines have been published and disseminated, in hard copy and on the internet.

Addiction care

The developments and activities described above were in another way also introduced in the Dutch addiction care. The first research review on the effectiveness of the Dutch addiction care was published in 1997 (Van Gageldonk et al. 1997) and since then many other reports followed (Cuijpers et al. 2006; Rigter et al. 2004; Van Gageldonk et al. 1998). Also in 1999, the program Scoring Results started its activities for the improvement of the quality of the Dutch addiction care. This program would last until 2009. Actually, this program was initiated by the Ministry of Health, Welfare and Sport, because there was a broadly felt dissatisfaction with the quality of the Dutch addiction care. As an active reaction to the dissatisfactory situation, several directors of institutes for addiction care designed a program for quality improvement, the so-called program "Scoring Results" (Walburg et al. 1998). They phrased three main program goals. A first goal was to redesign the supply of interventions in the addiction care towards a more evidence-based care and to follow the 'stepped care' principles. A second goal was to apply routine monitoring to evaluate the outcomes of the care given by individual professionals and teams, this in order to arrive at permanent professional improvement. Finally, a third goal was to build a supportive system, starting with a redesigned training and (re)schooling system for professionals (Rutten et al. 2009). Apart from many other publications like literature reviews, manuals, handbooks, and working books, the program Scoring Results has now published several guidelines for professional practice in the addiction care. Several other guidelines have been published by other organizations and were funded by the Netherlands Organisation for Health Research and Development (ZonMw).

Finally, in their advisory report to the Minister of Health, Welfare and Sport, the Commission on Medical Interventions for Drug Dependence from the Health Council of the Netherlands (Gezondheidsraad), supported the targets and activities of the program Scoring Results. The advisory report stressed the importance of evidence-based medical and psychosocial interventions for drug dependent people. Knowledge about evidence should be incorporated in professional guidelines for the professional practice in order to improve the quality of the Dutch addiction care (Health Council of the Netherlands 2002).

11.2 Existing guidelines: framework and content per guideline

The descriptions below of the separate Dutch guidelines for addiction care (see § 11.2.1 to § 11.2.9) include the framework and the content of the guideline. The framework includes background, development, coordinating bodies and participants. The content describes interventions, targets of the guideline and the chapter subjects. Reports on and experiences with the implementation of these and other guidelines are presented in § 11.3.
Up to now nine guidelines for addiction care have been published in a period of eight years (see table 11.1). Two guidelines are forthcoming (one on methadone treatment, and one on treating drug problems in general). Unlike the former guidelines, the forthcoming two are using the methodology of evidence-based guideline development (EBRO) that is also used for medical guidelines in the Netherlands (Van Everdingen et al. 2004).

Table 11.2.1  Published Dutch guidelines for addiction care*

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Publication year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Comorbidity: diagnosis and treatment</td>
<td>2003</td>
</tr>
<tr>
<td>2. Compulsory discharge from treatment</td>
<td>2004</td>
</tr>
<tr>
<td>3. Inpatient and outpatient detoxification</td>
<td>2004</td>
</tr>
<tr>
<td>5. Case management</td>
<td>2007</td>
</tr>
<tr>
<td>6. Client profiles</td>
<td>2007</td>
</tr>
<tr>
<td>8. Treatment of cannabis problems in youth and young adults</td>
<td>2009</td>
</tr>
</tbody>
</table>

*Protocols, manuals and modules are not included. Source: National Branch Organization for Mental Health Care and Addiction Services (GGZ Nederland).

Six of the nine Dutch guidelines for addiction care are initiated and/or (co-)funded by the ten-year program Scoring Results, while the guidelines for mental health care were all the result of the organizational activities of the National Steering Group Multidisciplinary Guideline Development in Mental Health. The guideline for compulsory discharge from treatment was realized by the Coordination Group Guideline Development in Addiction Care. A second guideline on pharmacological treatment for drug dependent prisoners was supported and funded by the Ministry of Security and Justice (see § 11.2.5), and a second one on disorders in alcohol use was supported by the National Steering Group Multidisciplinary Guideline Development in Mental Health (see § 11.2.7).

It is observed that the sequence of guideline construction is presumably not guided by the prevalence rates of specific drug problems or disorders that cause most public nuisance or costs. Contrary to the Netherlands, the centralized guideline construction in the United Kingdom by the National Institute for Clinical Excellence (NICE) focuses both on mental health care and addiction care. It should be noted that in the United Kingdom a mean amount of £ 480,000 is spent per guideline. This is substantially more than the money spent on the Dutch guidelines.80

11.2.1 Comorbidity: diagnosis and treatment

---

80 Tim Kendall. Joint Director, National Collaborating Centre for Mental Health, UK. Presentation on NICE guidelines at the Big Guideline Conference in Amsterdam, Dec. 8th 2009.
The first Dutch guideline in addiction care deals with comorbidity. The publication was the result of a project conducted in a research department of one institute for addiction care (Posthuma et al. 2003). It presents guidelines and instruments for screening and diagnosis of comorbid problems. Manuals and specified recommendations are presented for professionals in both addiction care and mental health care. Guidelines for professional treatment practices are not described.

In the first chapter the concept "double diagnosis" is defined, epidemiological data are presented, and the aetiology of this phenomenon is presented. Chapter two presents the results of the literature review and the pilot studies, the guidelines and recommendations. Included are also limiting factors and recommendations for the implementation of the guidelines. A limiting factor is for instance the existing treatment climate in the organizations of mental health care that may hamper the treatment of drug problems. For example, there may be a climate in which drug use is considered a contra-indication for psychiatric treatment or is simply ignored. The recommendations given in the guideline not only stress the importance of education and training (mutually in psychiatric and addiction problems), but also stress discussions about prevalent professional attitudes. Furthermore, a lack of time and capacity (money and expertise) are considered limiting factors. An implementation plan is recommended in order to structure the process.

The last chapter gives an overview of instruments for screening and assessment. In the appendices a thorough description is given of the pilot studies and the literature reviews, for example instruments for measuring motivational enhancement, several screening instruments for substance use among psychiatric patients, instruments for screening and assessment of psychopathology among drug dependent patients, and an overview of evidence-based treatment for double diagnosis patients, which is specified for several psychiatric disorders.

11.2.2 Compulsory discharge from treatment

The second guideline has been realized by a group of experts from professional organizations in addiction care and psychiatric nursing (Regiegroep richtlijnontwikkeling in de verslavingszorg 2004). The group was funded by the Ministry of Health, Welfare and Sport. The guideline targets the organization of medical treatment and nursery care (in- and outpatient), and targets decision making for patients who are treatment-refractory or are seriously misbehaving during treatment or care. Examples of these behaviours are breaking the house rules, disobeying the treatment plan, or behaving dangerously. A more specific target is to guide the decision making process towards discharging patients from treatment and care, in case several earlier corrective measures were not successful. The guideline should offer more guarantees for maintaining the safety for other patients and professionals, and for maintaining a care environment that remains workable for both. Its purpose is that members of patient organizations and professionals will use this guideline for constructing a more specified local or regional protocol for compulsory discharge.

The guideline first describes important concepts concerning circumstances in treatment and care related to compulsory discharge. It also describes generally accepted points of departure or rules related to treatment and care. It continues with describing the processes and examples of breaking those rules, of acute danger and possible actions to be taken in those circumstances. In some chapters case descriptions are added for further
illustration. Decision steps and actions are summarized in two decision trees for both the organization and the patient. Finally, the ways of terminating the treatment contract and the process of discharge are described.

11.2.3 Inpatient and outpatient detoxification

The third Dutch guideline in the field of addiction care was composed by a working group of experts from two Dutch institutes of addiction care (De Jong et al. 2004). The fundament of this guideline was given by a literature review on the pharmacological treatment of withdrawal symptoms and by criteria that are important for the decision to choose outpatient or inpatient detoxification. Based on the results of this review, a draft protocol was written and evaluated during meetings with physicians and nurses. Both professional organizations and patients were asked to comment on this draft. The guideline has finally been tested in two pilot studies on its feasibility.

The guideline mainly describes the medical-biological process of detoxification that takes around two to three weeks, and supports the choices to be made during that process. The results of the two pilot studies showed that this process needs support, especially in outpatient detoxification treatment. Other activities, for instance psychosocial support and motivational enhancement, are not included in this guideline. It represents an evidence-based description of the pharmacological treatment possibilities for detoxification specified per psychoactive substance. The important role of the patient with regard to withdrawing symptoms and craving, and the important role of a systematic registration as a basis for evaluation and improvement are stressed.

The content of the chapters covers the main aspects of detoxification, information on several psychoactive substances (alcohol, opiates, benzodiazepines, cannabis, cocaine, polydrug use), guidelines/instructions for physicians and for nurses separately, and for both professional groups together. The guideline also presents standards for substance-specific detoxification treatment, and patient data registration issues (treatment plan, treatment agreement, measurement instruments, and an illustrative example). The last part describes a literature review on this subject.

11.2.4 RIOB: Methadone maintenance treatment

The RIOB guideline was developed by two institutes of addiction care to tackle existing problems in maintenance treatment. Methadone maintenance treatment already existed in 1968 in the Netherlands. During the nineties, the target of maintenance treatment changed from abstinence to the more realistic target of stabilization. In later years the target mainly changed toward reducing public nuisance (Driessen 2004). Partly due to this last target, the practice of methadone treatment was reduced to merely methadone dispensing. Since 2004 this change was increasingly criticized by individual authors (Loth, 2003 238 /id;Loth, 2009 3041 /id), by professional organizations, by the Health Care Inspectorate (IGZ 2004), and by the Netherlands Court of Audit (T.K.29660-1-2.Tweede Kamer der Staten-Generaal vergaderjaar 2003-2004 publicatienummer 29660 nrs.1-2 2004). The RIOB targets physicians and nurses separately. It stresses the necessity of adding nursery care to methadone dispensing practices. It also describes the requirements for the setting, organization, and management of this treatment.
The RIOB has been developed via several pilot studies. During these studies, both the managers and the professionals learned to reflect on their daily professional behaviors and learned to change it when necessary. The management should, for instance, enable nursing professionals to include nursing practices and psychosocial care in their daily tasks, by changing the system for time management.

The RIOB guideline (Loth et al. 2005) first describes different profiles of the opiates dependent client with special attention for women and cultural minorities. Secondly, the systematic collection of client data is considered, both for the physician and the nurse. A third subject is how to reach an adequate medication regime for methadone or for buprenorphine. Attention is paid to special patient groups, namely pregnant women, double-diagnosis patients, the young and older addicts, and polydrug users. Special circumstances are also highlighted, for example holidays and detention. Finally, attention is paid to multidisciplinary diagnosis and support, based on so-called "categories of intensity of care" (in Dutch: zorgzwaartecategorieën). These categories were based on a guideline on client profiles (see § 11.2.6). Furthermore, guidelines were formulated for the organization of maintenance treatment, including registration, funding, and the composition of a professional team. Next, attention was paid to national registration requirements, cooperation with general hospitals, mental health care organizations, judicial organizations, and institutions for mentally retarded people. At the end of each chapter, appendices are added about many subjects, for instance about the necessity of information transfer between physicians and nurses, about the DSM-IV- and ICD-10 criteria for substance dependence, and about urine testing. Finally, the reports of four literature reviews are added, two on maintenance substances, and a third and fourth review on maintenance treatment for patients with comorbid psychiatric disorders and polydrug use.

11.2.5 Case management

Two publications preceded the guideline for case management: a literature review (Wolf et al. 2002) and an 'assistance document' (handreiking) (Wolf et al. 2003). The review presents an overview of the results of effect studies on case management for chronic drug dependent patients. The assistance document is meant to support the professional work of case managers with regard to what should be done.

The guideline for case management has been produced by four institutes for addiction care. It describes how case management can best be realized, what methods and interventions can be used, and how an effective relationship of the case manager with the patient should be built. It is written from the perspective of the individual case manager (Tielemans et al. 2007). The authors assume that case managers should be part of a multidisciplinary team. They further state that basic conditions within the organization should be met in order to enable working with target groups with complex problems. These target groups not only have addition problems.

Chapter one of the guideline briefly describes the theoretical backgrounds, the points of departure (important targets), and the models of case management. The second chapter describes the target group and the inclusion- and release criteria for case management. In the following chapter the six-phases model of case management is described, offering support for the decision making by the case managers. These six phases are:
1) entry phase: sharing information, building a working relationship, and registration;
2) inventory phase: focusing on urgent problems, network analysis, description of life course;
3) analysis: planning an individual program of care;
4) execution of the individual case management program;
5) evaluation: regular evaluation of quality of life and;
6) release phase: reducing case management activities, transfer of activities to other professionals and determining types of after care.

In the final chapter of the guideline several areas of attention are specified and worked out, for example psycho-education and medication, self care, social contacts, daily activities, coping skills related to housing and living, and financial and judicial problem solving. A Compact Disk is added with the data from the literature review, an education module for case managers in the addiction care and measurement instruments.

11.2.6 Client profiles

The guideline for client profiles is based on an instrument for setting up profiles, especially for clients with chronic addiction and many other problems (Wits et al. 2007). This instrument was developed by the Rotterdam addiction research institute IVO in collaboration with three institutes for addiction care. The guideline construction was funded by the Netherlands Organisation for Health Research and Development (ZonMw).

The main target of the guideline is to improve the fit between the supply of care and the need of care among the patients. Target group analysis is considered fundamental for the programming of (often long-term) care for addicted patients with complex problems. The guideline presents suggestions for a target-group analysis when different types of care are considered for patients with complex problems. The basic subjects for such an analysis are patient needs, access to patients, and linking a care program to these needs. The use of this guideline is considered to be improved by a brief additional training of professionals.

Chapter one of the guideline contains four subjects:
1) a description of the usefulness of patient profiles: how to increase the response rate, how to reduce drop-out rates, and how to increase the effectiveness of treatment or care;
2) steps to be taken toward such a profile: management support within the organisation, sketching the context, data collection, determining the need of care, constructing a patient profile, organizing feedback, and a specified description of the best fit of care supply;
3) information on target group analysis: by a multidisciplinary working group inside an organization, if necessary supplemented by external expertise; and
4) reflections on the time and man power needed to realise this analysis: 10-30 days for 2-3 professionals, working group time some six months.

In the second chapter of the guideline the constituent steps are described for the analysis of the target group. Working schemes and elaborated examples are described in the last part of the guideline.

11.2.7 Pharmacological treatment for drug dependence among prisoners

The guideline for pharmacological treatment among prisoners was issued by the Ministry of Security and Justice and the Institute for Quality in Health Care (CBO). The guideline was
supported by a consensus working group with members from different professional departments: 1) professionals from the forensic medical, psychological and psychiatric circuit; 2) nurses and medical specialists in prisons; 3) pharmacists, and 4) physicians, specialized in addiction. The initial target was to construct a guideline for methadone treatment in prisons, but the target population very often has more problems besides substance use. These other problems (e.g. comorbidity) forced the working group to cast the net much wider, including other medical interventions. Still, the impetus of this guideline lies on opiates dependence.

The Department of Judicial Institutions (DJI) of the Ministry of Security and Justice endorses the following explicit points of departure or principles. Prisoners should receive efficient health care with comparable quality as in general health care, they should also be treated with the same evidence-based interventions as people outside prison, and continuity of care should be guaranteed when addicted prisoners need it.

The guideline consists of ten chapters, covering the following issues: the effectiveness of pharmacological treatments for substance dependent prisoners; epidemiological data on drug dependence in prisons, the state of the art of pharmacological treatment of opiate dependence in general; criteria for the eligibility of prisoners for methadone treatment, suggestions to cope with comorbid problems among prisoners when they receive pharmacological treatment (e.g. infectious diseases, somatic disorders, psychiatric disorders, pregnancy), criteria for decision making concerning the use of benzodiazepines among opiate dependents in prison, decision making criteria targeting the use of other medication by target group members (e.g. naltrexone, tranquilizers), the organization of methadone treatment, and guidelines for registration and for cooperation with external organizations and with other levels within the judicial circuit (DJI 2008).

11.2.8 Treatment of cannabis problems in youth and young adults

The guideline annex protocol for the treatment of cannabis problems deals with the outpatient treatment of cannabis problems among young people from 12 up to including 23 years (Ivens et al. 2008). At the same time a working book was published for homework for the clients (Ivens 2008). Both were written by an expert affiliated with one institute for addiction care. During the coming years, comparable publications for problems with other drugs than cannabis are foreseen for this target group.

For the cannabis guideline a supportive literature review was conducted, presenting the following topics: 1) epidemiological data on cannabis use among the target group, 2) the effects of cannabis use on young people, 3) the use of classification systems, instruments for screening and diagnosis, main results of treatment effect studies, and 4) the usefulness of client profiles for determining the most adequate treatment options (Wittenberg 2006). The guideline briefly mentions several principles for treatment, for example the targets, criteria for inclusion, comorbid problems, the role of significant others (family, friends), the flexible role of phases of behaviour change, the materials to be used, and guiding principles of the treatment process. Principles are for example: clients first, start with motivational enhancement, give homework, building a therapeutic relationship, tackling patient compliance, urine tests, relapses, and prevention of drop-out. Finally, some background information is presented for the professional about types of cannabis use among young people, existent treatment options, and methods and techniques.
Two intervention types are mentioned: lifestyle training 1 and 2 for adults (based on cognitive-behavioural principles) and the Cannabis Youth Treatment Series (Webb et al. 2002). The interventions focus on correcting inadequate coping strategies and dysfunctional cognitions via motivational enhancement techniques, self control, cue exposure, behaviour skills, and relaps prevention. The number of sessions depends on the need of the client.

11.2.9 Disorders in alcohol use: diagnosis and treatment

The last guideline for dealing with disorders in alcohol use was produced by a special working group of the National Steering Group Multidisciplinary Guideline Development in Mental Health (see § 11.1). It was done with the accordance of several professional organizations (e.g. for physicians, nurses, psychologists, psychiatrists) and was supported by the Trimbos Institute and the Institute for Quality in Health Care (CBO) (Trimbos-instituut/CBO 2009). The guideline was initiated by the Dutch Foundation for Psychiatry and funded by the Order of Medical Specialists.

In general, alcohol dependence is traced when it exists already for a long time. The target is to improve (early) diagnosis and treatment for one of the biggest problems in health care. This guideline has 15 chapters and gives recommendations and advice for 1) the diagnosis of alcohol problems of adult patients, 2) criteria for choosing in- or outpatient detoxification, and 3) recommendations for treatment. The guideline further describes instruments for case finding in the general medical practice, and laboratory tests that determine acute and chronic alcohol abuse. Other subjects are 1) the effectiveness of pharmacological treatments (e.g. acamprosate, naltrexone and disulphiram in targeting abstinence or reduction of use), 2) the effectiveness of psychosocial interventions for this patient group (e.g. motivation enhancement, brief interventions, selfhelp groups, the 12-step approach, cognitive-behavioural therapy), and 3) combinations of both types of interventions.

Brief attention is paid to the up to now insufficient evidence for the effectiveness of alternative treatment, e.g. transcendental meditation, biofeedback, and acupuncture. The guideline also covers recommendations for treatment in case of comorbid psychiatric disorders. Furthermore, the guideline pays attention to the causes of and risk factors for somatic complications of alcohol abuse and the role of general practitioners for the case finding and diagnosis of alcohol problems. Next, existing legal arrangements for quasi-compulsory treatment are described, as well as options for interventions in the work place. Finally, recommendations are formulated for enhancing the implementation of the guideline. The recommendations and advice are meant for professional use in the mental health care and the addiction care, but also for general medical practice and other professionals involved with the care of individuals with alcohol problems. The guideline is also expected to be of supportive value for the decision making for patients and their families.

As mentioned in the introduction of § 11.2, two multidisciplinary guidelines on (problem) drug use are in development.

11.2.10 Final remarks

The program Scoring Results is constructing a ‘new generation’ of guidelines (addenda) for the treatment of patients with comorbid disorders. These guidelines will be addenda to the existing multidisciplinary guidelines for mental health. The first addendum will be the
Guideline Anxiety and Addiction (Snoek et al. 2009). Separate guidelines will be constructed for patients with substance use disorder and other disorders like depression, schizophrenia, or borderline personality disorder.

In recent years, the treatment demand for GHB addiction has increased at a number of institutes for addiction care in the Netherlands (Van Laar et al. 2010). This far, no evidence-based guideline has been developed yet for the treatment of GHB-addiction. The institute for addiction care Novadic-Kentron was the first in the Netherlands to apply medical GHB for detoxification purposes. At Novadic-Kentron, scientific research is now being conducted to establish an evidence-based guideline for the treatment of GHB-addiction (Willemen 2010).

11.3 Experiences in the Netherlands with the implementation of guidelines

The experiences with the implementation of guidelines in the Netherlands will now be described. Lessons from more general implementation evaluation reports will be described first. These reports deal with the experiences with guidelines in the health sector in general, the implementation of guidelines in the mental health care (see § 11.3.1), and experiences with the implementation of guidelines and other 'products' of the program "Scoring Results" (see § 11.3.2). Finally, the results of two guideline-specific implementation reports will be described (see § 11.3.3 and § 11.3.4).

11.3.1 Implementation of guidelines in mental health care

Many factors may influence the implementation of guidelines. Grol and Wensing (2006) refer to characteristics such as the content (e.g. consensus based or evidence based), the form (e.g. digital or written), the formulation (e.g. easy to understand and accessible) and the layout (bad- or well-organised) (Grol et al. 2006). The actual implementation of a guideline will also depend on the circumstances and the clinical settings, that is the context in which the implementation is supposed to take place (Rycroft-Malone et al. 2010). Therefore, successful implementation will often require "building context" (Rycroft-Malone et al. 2009).

One study tried to gain insight in factors that influence the development, introduction and evaluation of six preselected guidelines (on prevention, cure and care) in somatic and mental health care (Fleuren et al. 2009). The authors constructed an instrument called the "Quality of Guideline Development, Introduction and Evaluation" (abbreviated in Dutch as KRIE). This instrument was applied to systematically compare the guidelines on three parts of the innovation cycle. The report mentions several conclusions:

- Although guidelines are developed systematically, some limiting bottlenecks occur:
  - Methodological knowledge for performing a systematic literature review is often restricted;
  - Patients and other stakeholders are insufficiently involved;
  - Bottlenecks are not systematically scrutinized;
  - Consensus-seeking strategies result in guidelines that are phrased in terms that are too general;
  - The development process takes too much time.
• Attention for the perspectives of patients and relatives is not self-evident.
• Guidelines do not include special versions for patients and management of care.
• The implementation of guidelines is considered in the final phases, not from the beginning.
• An analysis of determinants (limiting and facilitating implementation factors) is rarely done in advance.
• Implementation strategies that fit the results of a determinants analysis are rarely used.
• Evaluation of the implementation of guidelines is rarely done.
The authors finally conclude that the KRIE-instrument seems adequate for a comparative analysis of the development, introduction and evaluation of guidelines in general.

A second study showed that the accessibility of the multidisciplinary guidelines for anxiety and for mood disorders appears to be hampered by the following factors. Firstly, the decision trees presented in the guidelines are said to be insufficiently clarified. A similar conclusion is drawn for the sequence of working with several pharmacological treatments. Other factors mentioned are the recommendations not being specified for separate professional disciplines, the content being co-determined by the pharmacological industry, and guidance being given only for treating symptoms and not for underlying psychological problems (Smolders et al. 2006).

A third study was published to trace factors that hamper the implementation of the seven multidisciplinary guidelines for mental health care and the two addenda\textsuperscript{81} that were published in the Netherlands from 2000 to 2008 (Sinnema et al. 2009). This study was based on a literature review, interviews by mail and interviews by telephone. The mean response rate was low (27%), that is 406 interviews by mail from a total of 1,526 that were sent to selected professionals. The response was the highest among nurses and psychologists, followed by psychotherapists and psychiatrists. Very low response rates were reported for general practitioners, managers, and social workers. Interviews by telephone were held among directors of professional organizations who were or are active with guideline construction for mental health care. These interviews targeted 1) the use of these guidelines within their own organization, 2) the way they have tried to stimulate this use, and 3) their opinion about the best way of stimulating the use of guidelines in the future. Although the non-response rate was considerable, both the literature review and the two interviews largely revealed the same factors that influence the implementation of the guidelines.

Sinnema et al. (2009) concluded that the guidelines were used by only a minority of the professionals (28%). The use was the highest among psychiatrists (somewhat less than 50%), followed by the psychologists (around one third), the psychotherapists, general practitioners, and nurses. The use of the guidelines was the lowest among social workers and psychotherapists. A clear cut implementation policy and organised support within the organization are considered the most important factors for stimulating the use of these guidelines. On the other hand, the results showed that especially psychiatrists and psychologists feel unsatisfactorily pressed by measures taken by health insurance companies and the National Health Inspectorate to use guidelines. According to the

\textsuperscript{81} Addenda present adaptations to existing guidelines for specific subgroups, e.g. the younger and the elderly.
experience of psychiatrists and psychologists these pressures mainly result from economic motives and are not concerned with the content and the quality of care.

A general conclusion is that the energy during the past decade was mainly focused on developing guidelines. This conclusion is also drawn by Fleuren et al. (2009). According to the authors, the impetus of the energy spent during the coming years should be redirected toward an increased implementation rate of these guidelines. The study recommends the use of computer software programs for increasing the efficiency of care processes and for advice, evaluation and feedback. A second recommendation advocates brief summaries and overviews that are easy to read for the different professional user groups, and present clear guidance in which professionals should do what and when. Another important point of attention is investing in (accreditation) training in interactive workshops for professionals in using the guidelines, for example in using specific measurement instruments. Furthermore, not only scientific knowledge should guide the updating of existent guidelines, but also knowledge about daily experiences should be collected and reviewed for this purpose. The patient should be more involved in the decision making about diagnosis and treatment options (shared decision making) because until now this is rarely done. It is finally recommended to connect the Dutch guideline trajectory to another trajectory running in (mental) health care, namely the development and implementation of performance indicators. It is assumed that this will enhance a more stimulating environment for improving the quality of professional practice (Sinnema et al. 2009).

In mental health care the so-called "break through series" (doorbraakprojecten) have been realized to accelerate improvements in patient care for specific disorders or problems. Break through series were developed some fifteen years ago in the USA by Don Berwick, a pediatrician who was inspired by Total Quality Management and wanted to reduce existing resistances among fellow physicians against new (evidence-based) developments in medical care. The method has been introduced in the Netherlands by the Institute for Quality in Health Care (CBO). It mainly consists of a systematic and stepwise strategy for reducing limitations and enhancing stimulating factors for the implementation of new working methods. Setting SMART targets and continuously measuring indicators of outcomes are essential ingredients in this method. Until now the outcomes of this method showed modest advantages in health care (Schouten et al. 2008). In primary health care for mood disorders in the Netherlands the results of the evaluation literature were mixed or unclear (Franx et al. 2006; Franx et al. 2009). Until now the break-through method has not been used for the implementation of guidelines in the addiction care.

Several (potential) burdens of the introduction of guidelines in Dutch (mental) health care have also been reported and these coincide largely with earlier reported pros and cons of guidelines in general (Burgers et al. 2009).

A first type of argument against guidelines considers the reduced freedom of professional practice. Effective care cannot always be realized due to an overdose of rules, protocols and administrative duties (Van Os et al. 2004). Related criticisms point at the danger of overeager managers, superficial scientific support, and cost-effectiveness-based decisions by health insurance companies (Asmus 2005). The genesis of standardization of

---

82 www.trimbos.nl/verbeterdezorg
health care during the past decade is said to have created unease and discontent and to have increased the number of professionals that leave their work (Van de Brink et al. 2005).

A second type of argument is that after the introduction of the mechanisms of a free market economy in the national health care, the professional autonomy for creating a higher quality of health care has been challenged. The reason is that the government, the insurance companies (and the patients) increasingly want to use guidelines for their own targets. Implementation of guidelines is - without any piloting - enforced by a combination of formal measures, e.g. re-registration, accreditation, certification, and legal measures (Goudswaard et al. 2010; Grol 2010). In the Netherlands, the system of fixed combinations of diagnosis and treatment has been worked out and is currently evaluated to facilitate a new care funding system by means of these Diagnosis Treatment Combinations (Van Hoof et al. 2009). It is still unclear if these measures are effective for raising the quality of mental health care and addiction care.

A third argument concerns the cost-effectiveness of guidelines. It has been noted that the 'circle' of guideline construction, dissemination, implementation, evaluation and updating, has become an 'industry' with its own interests. The costs are high and should be maintained, while the effectiveness is still suboptimal and future perspectives are uncertain, unless all participants see the importance of this endeavour and will maintain the funds for realizing these activities in future. The cost-effectiveness of an implementation strategy can be considered as an amalgamation of: 1) cost-effectiveness of the desired medical actions; 2) the degree to which these actions already take place; 3) the costs of an implementation strategy; and 4) the effectiveness of an implementation strategy (Grol et al. 2004; Grol 2009b; Grol 2010). Reconsidering these factors suggests that a successful implementation is by no means easy or cheap, and it should be carefully guided by evaluation and adaptation.

11.3.2 Evaluating the implementation of the products from the program Scoring Results

The concept of "implementation" is often not clearly described and is confused with related concepts such as "dissemination", "diffusion", or "adoption". “Implementation can be described as a planned process and systematic introduction of innovations and/or changes of proven value; the aim being that these are given a structural place in professional practice, in the functioning of organizations or in the health care structure.” (Grol 2009a). The implementation process consists of five phases. The first phase is orientation, i.e. the promotion of the awareness of the innovation and stimulating interest and involvement. Insight is the second phase, creating understanding and developing insight into the own routines in daily work. In the third phase, the acceptance phase, a positive attitude is developed, motivation is enhanced, positive intentions are created, and decisions to change are initiated. The fourth phase concerns the change itself by promoting actual adoption in practice and confirming the benefits and value of change. The fifth and last phase is maintenance. In this phase new practices are integrated into new routines and into the organization (Grol et al. 2004).

The implementation of the diverse products of the program Scoring Results (not only guidelines but for instance also manuals and protocols) has been evaluated three times, namely in 2003, in 2005, and in 2008. The results of these evaluations are not one-to-one
comparable, but still give a rough picture of the state of the art in guideline implementation in the Dutch addiction care. The evaluation results are given in table 11.2.

Table 11.3.1  Percentage of institutes for addiction care that reported using (routinely) a guideline or having adapted it

<table>
<thead>
<tr>
<th>Guideline</th>
<th>2005* (N=12)</th>
<th>2008** (N=11)</th>
<th>2008 % that changed (adapted) guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comorbidity: diagnosis and treatment</td>
<td>50.0%</td>
<td>63.6%</td>
<td>18.0%</td>
</tr>
<tr>
<td>Compulsory discharge from treatment</td>
<td>41.7%</td>
<td>45.5%</td>
<td>18.0%</td>
</tr>
<tr>
<td>Inpatient and outpatient detoxification</td>
<td>41.7%</td>
<td>63.6%</td>
<td>9.0%</td>
</tr>
<tr>
<td>RIOB: methadone maintenance treatment</td>
<td>n.a.***</td>
<td>90.9%</td>
<td>n.a.</td>
</tr>
<tr>
<td>Case management</td>
<td>n.a.</td>
<td>63.6%</td>
<td>n.a.</td>
</tr>
<tr>
<td>Client profiles</td>
<td>41.7%</td>
<td>36.4%</td>
<td>9.0%</td>
</tr>
</tbody>
</table>

*Percentage of the organizations that used the guideline. **Percentage of the organisations that used the guideline routinely or that changed/adapted the content of it. *** Not included in the 2005 evaluation. Source: (Spits et al. 2009b).

The first evaluation in 2003 showed that data about the implementation rate of the products from Scoring Results were still scarce. This was partly due to the fact that the program did not start until 1999. Another reason was that in most organizations an implementation plan was lacking. Other factors that limited the implementation were the critical attitude of the professionals in the field towards a product (e.g. a guideline), the instability of the implementation team, and a weak management of the implementation process. The conclusion was that the implementation process of the program products needed to be enforced (Spits et al. 2009b).

For most guidelines, the rate of implementation (i.e. percentage of organizations that use these products routinely (in most cases without adaptations) increased when comparing the outcomes of the 2005- and 2008-evaluation. Table 11.2 shows that, for the early published guideline on comorbidity, the implementation rate increased from 50% in 2005 to 64% in 2008. For the guidelines on compulsory discharge and on detoxification there was an increase from 42% to 46% and from 42% to 64% respectively. Finally, for the later published guidelines on methadone maintenance treatment and (intensive) case management, only 2008 data were available showing implementation rates of 91% and 64% respectively. The implementation rate of the client profiles guideline decreased between 2005 and 2008, namely from 42% to 36%, possibly indicating a lack of interest or usability.

According to the authors, the implementation of the guidelines on comorbidity and detoxification still needed reinforcement in 2008. Suboptimal implementation rates are reported for compulsory discharge and client profiles. Some organizations adapted a guideline to the local situation before implementing it, sometimes because the guideline was not satisfactorily specified for the target group (see for instance § 11.3.3). Other organizations decided not to implement the guideline. However, the general conclusion was
that the products from Scoring Results have become better known in the field and also better implemented compared to the earlier evaluations (Spits et al. 2009b).

It should be noted that these evaluations were based on self-reports via interviews by telephone. Besides, these interviews were often conducted with only one and in some cases only a few professionals in each institute for addiction care. Furthermore, the outcomes (the degree of application of a product) are prone to interviewer and interviewee bias. The validity of these evaluation results is therefore limited. It should also be noted that for each separate guideline, available for not longer than three years, the answers were categorized in pre-defined stadia of implementation: orientation, insight, acceptance, change (or adaptation), and maintenance (Grol et al. 2006). In several organizations the guidelines were changed before implementation, and in some other organizations the guidelines were not implemented at all. Finally, recommendations were presented for updating several guidelines and other products, because they are either outdated or not implemented (Spits et al. 2009b).

The researchers also studied opinions about the factors that influence the implementation of guidelines. These factors were divided into: 1) individual factors (cognitive, motivational and behavioural) that refer to the patient, the professional, the manager and others who use the guideline; 2) social factors like professional training, teams and networks; 3) organizational factors like structures and processes and means; and 4) societal factors such as funding and legal measures (Grol et al. 2006). The individual factors that were mentioned most frequently were the attitude of professionals in addiction care, characteristics of the guideline, and the way of introducing the guideline. A social factor of importance appeared to be the degree of cooperation within teams of professionals. Clear division of responsibilities and working pressure were often mentioned as organisational factors. The societal factors that were mentioned were mainly financial factors like funding and facilities. Successful implementation of guidelines was also reported to be enhanced by guidelines being brief and clear for professionals and management. Implementation also needs a planned strategy and increased information sharing (Spits et al. 2009a; Spits et al. 2009b).

Besides these more general studies on the implementation of guidelines in mental health care and addiction care, separate reports have been published on the implementation of the guideline for detoxification and the guideline for methadone maintenance treatment. These reports will be reviewed below in § 11.3.3 (detoxification) and § 11.3.4 (methadone maintenance treatment).

11.3.3 Modification of the guideline for detoxification to promote implementation

The guideline for detoxification (see § 11.2.3) is used by eight of the eleven approached regular institutes for addiction care, covering about 90% of all regular addiction care in the Netherlands (Spits et al. 2009a). Another publication (Van Oosteren et al. 2009) showed that one regional institute for addiction care added some more specific modules to the four-week outpatient module of this guideline. These modules were based on experiences in this outpatient setting indicating that drug dependent people are often not motivated for treatment, are frequently in need of more structure in their life, and often have serious physical health deficiencies.
Therefore, mandatory modules were added paying attention to the following: 1) daily contacts on working days; 2) group meetings, both twice a week, and both for increasing structure and enhancing motivation; 3) physical revalidation exercises twice a week; 4) active involvement of 'significant others' (partners, family); and 5) active outreach work when relapse is probable.

The amended guideline was tested among fifteen clients, showing satisfactory results. This pilot was considered a success. Fourteen clients were abstinent directly after the end of the program. Six weeks later, thirteen were still abstinent and client satisfaction measures were high. Although some clients had difficulties with the mandatory character of the program, most felt satisfied about the intensified control measures. The satisfaction working with the guideline of the professionals involved was also high, because they initially did not expect the clients to be able to complete this demanding detoxification program (Van Oosteren et al. 2009).

11.3.4 Small-scale pilot-implementation of the guideline on methadone maintenance treatment (RIOB)

The Dutch guideline on methadone maintenance treatment resulted from a critical discussion about the gradual deterioration of the methadone treatment (see § 11.2.4). It took several years before the conditions were met for implementation of the guideline in four institutes of addiction care (Rutten et al. 2009). The two most important and straightforward conditions for implementation were: 1) the willingness to participate and to cooperate; 2) the possibilities offered to do so, that is time, money, active management support, sufficient physical facilities, and commonly shared treatment targets; 3) the readiness to critically reflect on daily practice; 4) multidisciplinary cooperation; 5) an active working group within each organization; and 6) training of professionals (Loth et al. 2006).

The construction of the guideline was not following a predetermined procedure, but two phases were discerned: a development phase, and a pilot-implementation phase. Realization took place via action research. The basic assumptions of this design for research and development was the interdependence of three factors: 1) the development of the guideline content; 2) the limits set by the prevailing policy of the organization of addiction care; and 3) the adjustment of the guideline content based on process evaluation results. Due to this design, the two phases of the guideline construction were interconnected.

The question has remained how to implement the RIOB in all institutes for addiction care. The recommendations of the implementation report suggest that the guideline should be translated to organization-specific handbooks that enable more consensus on targets, target groups, methods, and implementation of methadone maintenance treatment (Loth et al. 2006). A final recommendation points at the necessity of a national structure for the routine monitoring of the clinical effects of methadone treatment (Verbrugge et al. 2005;Walburg 1997). The implicit assumption seems to be that routine outcome monitoring will increase the use of these guidelines.

In the near future, a new guideline for methadone treatment will be built upon the current one (see § 11.2.4). The new guideline will be more strictly evidence based by following a specific procedure coinciding with current procedures in medical science.

11.3.5 Future developments
Two seemingly inconsistent developments can be seen in the guidelines movement in the Netherlands, though perhaps less in addiction care than in mental health care: standardization and diversification.

The initial idea and goal of evidence-based medicine was and is to diminish ineffective variation in care for equal or comparable health problems. A certain degree of standardization should guide clinical practice towards a higher comparability of clinical practice for similar problem areas. The assumption is that this will also lead towards a higher quality of cure and care for the patients. Standardization can be considered a congruent by-product of evidence-based medicine. Guidelines are a step on the path of changing health care in the direction of evidence-based medicine.

Nevertheless, standardization in this sense has its limits. National guidelines can partly be a specification of international guidelines, because international guidelines are often directed at governmental organizations and institutions for public health. These general guidelines should be translated and adapted towards recommendations that fit national or regional daily-practice situations (Burgers et al. 2009; Burgers et al. 2004; WHO 2009). The current guidelines in the Dutch addiction care are still rather generally formulated. Therefore, some perspectives on guideline construction stress the importance of diversification of guidelines by improving the clinical value of guidelines. This could be done by adapting the content of these guidelines to specific subgroups and circumstances, based on the results of guideline implementation found in naturalistic, practice-based studies among these subgroups. In this sense, adaptation may be recommended to improve clinical outcomes, quality of life and client satisfaction. Specification or diversification may also increase the user-friendliness and consequently the use of these guidelines.

Diversification may also be the product of the commitment of managers, professionals and patients in the construction of guidelines. It has been shown that the implementation can be improved by involving these stakeholders from the start in the construction of guidelines. One of the dangers that remains however, is that the adaptation of the guidelines may result in a decrease of the effectiveness of interventions, when compared to the original interventions based on well-controlled studies. Thus, treatment integrity may be violated.

The products of the AGREE Collaboration and the products of the Guidelines International Network (GIN) are well known in the Netherlands, and many professional organizations are member of one or both organizations. In the Netherlands a separate organization has been initiated, namely the Platform Evidence-Based Guideline development (EBRO). About 30 Dutch professional organizations are member of the EBRO Platform. The targets of EBRO largely overlap with those of GIN (Theuvenet et al. 2004).

In conclusion
Evidence-based guidelines, protocols, manuals, assistance documents, performance indicators, bench marking, total quality management, project management, performance management, change management, innovation management, implementation management, break-through management, time management, case management, meta-management of management development, Diagnosis Treatment Combinations, categories of intensity of

---

care, and routine outcome monitoring: the target of all these management tools was to improve the quality of the mental health care and the addiction care.

However, the evaluations reviewed above already showed that, apart from the positive effects, the abundance of ‘management’ has also had its drawbacks. In its manifesto “Power & Counter Power, Enough is Enough”, the Steering Group “Enough is Enough” has summarized the management drawbacks as follows: pressure on the real quality of care, quantity being more important than quality, systems for care being dominated by systems for production and accountability, production being more important than the client, more and more regulations and more and more amendments on the regulations, professionals not being taken seriously and professionals not being trusted, bureaucracy, and, last but not least, professionals wasting a lot of their precious time to more and more registration obligations to provide more and more information (Graafmans 2006).

11.4 Comparison with the WHO guidelines on pharmacological treatment of opiate dependence

In this paragraph, a comparison will be made between Dutch guidelines and the WHO recommendations on 1) choice of treatment, 2) opioid agonist maintenance treatment, 3) management of opioid withdrawal and 4) pregnancy. Data are used from the existing two Dutch guidelines on opiate treatment, that is the guideline on pharmacological maintenance treatment of opiate dependence and the guideline on out- and inpatient detoxification.

For each recommendation below, it is stated whether the guidelines in the Netherlands include this recommendation, even if not with exactly the same wording. According to the EMCDDA guidelines for drafting this paragraph, only one answer has been selected for each recommendation.
<table>
<thead>
<tr>
<th>Name of Assessors: André van Gageldonk, Trimbos Institute, Netherlands Institute of Mental Health and Addiction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Choice of treatment</strong>&lt;sup&gt;84&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>1.2</strong> For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td><strong>1.3</strong> For opioid-dependent patients not commencing opioid agonist maintenance treatment, consider antagonist pharmacotherapy using naltrexone following the completion of opioid withdrawal. Do the present guidelines include this recommendation?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>2 Opioid agonist maintenance treatment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.1</strong> For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td><strong>2.2</strong> During methadone induction, the initial daily dose should depend on the level of neuroadaptation; it should generally not be more than 20 mg, and certainly not more than 30 mg. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td><strong>2.3</strong> On average, methadone maintenance doses should be in the range of 60–120 mg per day. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td><strong>2.4</strong> Average buprenorphine maintenance doses should be at least 8 mg per day. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td><strong>2.5</strong> Methadone and buprenorphine doses should be directly supervised in the early phase of treatment. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td><strong>2.6</strong> Take-away doses may be provided for patients when the</td>
</tr>
</tbody>
</table>

---

<sup>84</sup> Both 1.2 and 1.3 are not explicitly recommended, but the standard detoxification (withdrawal) treatment in the Netherlands is with methadone. Naltrexone was used temporarily in an experiment with rapid detoxification.

<sup>85</sup> Not recommended, but this is a reality in the Netherlands where buprenorphine is not (yet) as regularly used as methadone. Buprenorphine was only recently registered as a medicine and is paid on medical request by the health insurance company.

<sup>86</sup> The recommended starting dosis methadone is 20 mg for patients who do not use often heroin, and 40 mg when frequent heroin use is suspected.

<sup>87</sup> This is not explicitly recommended but implicitly assumed to be present, to be done.
benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review. Do the present guidelines include this recommendation?

2.7 Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence. Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>2.7</th>
<th>Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence. Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>□ □ □ □</td>
</tr>
</tbody>
</table>

3 Management of opioid withdrawal

3.1 For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used. Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>3.1</th>
<th>For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used. Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>□ □ □ □</td>
</tr>
</tbody>
</table>

3.2 Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>3.2</th>
<th>Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>X □ □ □</td>
</tr>
</tbody>
</table>

3.3 Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>3.3</th>
<th>Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>X □ □ □</td>
</tr>
</tbody>
</table>

3.4 Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal. Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>3.4</th>
<th>Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal. Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>□ □ □ □</td>
</tr>
</tbody>
</table>

4 Pregnancy

4.1 Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy. Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>4.1</th>
<th>Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy. Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□ □ X □</td>
</tr>
</tbody>
</table>

4.2 Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered. Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>4.2</th>
<th>Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered. Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□ X □</td>
</tr>
</tbody>
</table>

WHO guidelines coherence: only to be applied to guidelines applied for guidelines on closed settings

88 Being pregnant is considered a contraindication for prescription of buprenorphine.
In case your guidelines are about closed settings (“closed settings” refers to prisons, work camps, compulsory drug treatment centres and any other institution in which people are detained), state whether they agrees with the “Clinical guidelines for withdrawal management and treatment of drug dependence in closed settings” freely downloadable at: (http://www.who.int/hiv/pub/idu/wpro_withdrawl/en/index.html).

For each recommendation, please state whether your guidelines include them (even if not with exactly the same wording). Please select only one answer.

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
<th>Specify</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do the present guidelines agree with the “Clinical guidelines for withdrawal management and treatment of drug dependence in closed settings”?</td>
<td>☐</td>
<td>☐</td>
<td>X&lt;sup&gt;89&lt;/sup&gt;</td>
<td>☐</td>
</tr>
</tbody>
</table>

---

<sup>89</sup> There are no recommendations for closed settings in our guidelines.
One of the priority areas of the EU Drug Action Plan 2009–12 is to get a better overview of guidelines for addiction treatment in Europe, their development and implementation as well as their roles with regard to assuring the quality of addiction treatment services. To contribute to this goal, this report includes a discussion of national guidelines for addiction treatment. In the course of a research project (Zurhold und Degkwitz 2009) studying the corresponding guidelines in Europe and also of a Reitox Academy on this theme organised by the EMCDDA in February 2010, it has shown, however, that Austria has no national guidelines that correspond to the definition by the EMCDDA or what is understood to correspond to this definition at international level. National guidelines should be developed by independent experts in a standardised process in which all stakeholders, professions and clients have been integrated, and should be based on systematically collected research evidence. As a rule, review by third parties and public consultation are also part of the process of producing guidelines. The guidelines and standards that are available in Austria do not meet these criteria. Nevertheless they are relevant as a basis for the delivery of addiction treatment in Austria, therefore selected examples of such guidelines as well as their development and translation into action are described in the following chapter.

**11.1 History and overall framework**

The federal structure of Austria’s administration is one of the reasons why no national guidelines for addiction treatment exist: many public health tasks and competence areas are provincial matters. Moreover, in Austria the discussion of the matter of national quality standards for medical treatment has started later than in other countries. The Federal Act on the Quality of Health-care Services (GQG; BGBl I 2004/179) effective as of 1 January 2005 provides the legal framework for the advancement of systematic quality research. The Act provides that quality standards for the delivery of health-care services be developed, in cooperation with the relevant stakeholders, in particular the health-care professionals involved as well as patients. Then the Federal Minister for Health may either issue Federal Quality Guidelines (BQLL) which recommend the use of the resulting quality standards or adopt a binding Decree stipulating their use as Federal Quality Directives (BQRL). The standards must permit nationwide implementation across sectors and professions, and must be in line with the general principles of health promotion and transparency as well as the state of the art of medicine and experience with regard to effectiveness and efficiency. In order to perform this task, in 2007 BIQG was established, an institute specialising in healthcare quality, as a business unit of GÖG, a national research and planning institute for health care in Austria. Since September 2007, BIQG has focused on providing a basis for producing quality standards. International experience and recommendations were used as input for preparing a metaguideline (GÖG under preparation), which defines the process of drawing up guidelines. According to the Metaguideline for Methods of Developing and Implementing Quality Guidelines, organisations may propose themes for Federal Quality Guidelines or Directives. These themes are weighted and ranked in a defined
prioritisation process and eventually guidelines are drawn up on behalf of the Federal Ministry of Health or the Federal Health Agency (BGA). In addition, it is possible to file applications for recognition of papers as Federal Quality Directives (e.g., if a medical society or association has already produced a quality standard): in this case, it is verified in an accreditation procedure whether the formal criteria for Federal Quality Directives are met. At present, six themes are being reviewed. In order to draw up a Federal Quality Guideline or Directive on addiction treatment, it would be necessary to propose this theme for further examination.

Both BQLL and BQRL quality standards specify a certain path of action and decisionmaking with regard to treatment and care services and recommend proven, effective instruments and procedures, departure from which is admissible or may even be required in well-founded cases. Any deviations should adequately be documented, however. Either type of standard (BQLL and BQRL) is produced by multidisciplinary teams in a systematic procedure, with decisions based on consensus. Different to other member states of the EU, in Austria the focus is not solely placed on medical treatment, but other services are also included. Any existing medical, care or treatment standards are taken into consideration as source standards if their quality meets the defined criteria.

Apart from the process of guideline production, which still is in its early stages, also other actions have been undertaken in Austria to enhance or ensure the quality of medical treatment. In the specific case of substitution treatment for patients addicted to opioids, a regulation has existed for many years already, adopted for reasons of quality assurance and as a response to safety and health policy concerns. The first ordinance (an internal decree with instructions by the Minister for Health to the health authorities and public health officers responsible for the supervision of oral opioid substitution treatment) was issued in 1987. In accordance with the principle of last resort provided under the then Narcotic Drugs Act, it was not permitted to prescribe oral substitution medications for the sole reason of severe, treatment-resistant addiction to opioids: it had to be established in every individual case that any other form of treatment was extremely unlikely to bring about the desired results. Only after the adoption in 1998 of the Narcotic Substances Act was substitution treatment explicitly recognised by law as one of several possible forms of treatment. In 2007 the aforementioned ordinance was replaced by a decree which also lays down a binding framework for attending doctors (GÖG/ÖBIG 2007b as well as Chapters 1.1 and 5.1). A further decree was issued according to which the delivery of substitution treatment services requires the attending doctors’ completion of further training in OST (GÖG/ÖBIG 2006 as well as Chapter 1.1 and 5.1).

In Austria, consensus papers drawn up in cooperation with, and initiated by, experts or professional associations have frequently been drawn up in order to promote uniform standards of treatment. These consensus papers are typically based on practical experience, while scientific evidence tends to be taken into account only indirectly and not in a systematic way. If scientific publications (e.g., Fischer/Kayer 2006, Busch et al. 2007) or guidelines (e.g., from Germany) are available when consensus papers are prepared, they will be considered for the paper, however. On the other hand, Austrian experts in turn have also been asked to contribute to guidelines drawn up in other countries or by international organisations (see Chapter 7.2). Many experts argue that it is reasonable to draw on practical experience as an essential source of knowhow for preparing consensus papers, as years of daily work indeed provide an invaluable basis of evidence which, in a complex process of careful decision-making, also take into account the individual situation of addicted patients (ÖGABS 2009). According to these experts, the drawback of relying on a scientific evidence base is that it primarily considers the results of clinical trials published in high ranking journals, and the conditions under which such studies are carried out often differ from actual practice.
Moreover, in this context one has to bear in mind that the results or recommendations from other countries are influenced by the drug policies and also possible restrictions in those countries and caution has to be exercised when translating such findings to other countries. This particularly applies to substitution treatment delivered to people addicted to opioids, because in Austria a wider range of medications may be prescribed than in other countries. Also, both at federal and provincial levels, organisational guidelines exist for providers of drug support and treatment services, which also aim at contributing to quality assurance in addiction treatment.

11.2 Existing guidelines: Narrative description of existing guidelines

Table 11.1 provides a list of the standards and guidelines that are relevant for addiction treatment in Austria. Our reports of past years (see GÖG/ÖBIG 2007b and 2008c) as well as Chapters 1.1 and 5.1 of this report provide additional details on the regulations concerning substitution treatment and the further training requirements as laid down in the Substitution Decree and the amendments of 2007 and 2009, respectively. Regarding the selection of consensus papers, please note that the list does not claim to be exhaustive. While taking care to include the most important and most recent papers, it has also been attempted to cover different themes and settings. The consensus statement by the Austrian Society of Neuropsychopharmacology and Biological Psychiatry (ÖGPB 007) deals with several aspects of addiction treatment. It discusses epidemiology, genesis and clinical manifestations as well as substance-related secondary damage, i.e., health problems caused by alcohol, opioids, benzodiazepines or other psychoactive substances. This is followed by a description of the chain of treatment and forms of treatment, as well as — rather general — recommendations for approaches to specific target groups (e.g., children and young people). Carinthia's guidelines for diagnosing and treating opioid addiction (Amt der Kärntner Landesregierung 2007a), which were initiated by the Drug Forum of Carinthia and drawn up by a working group on behalf of the Drug Forum, also discuss various aspects of addiction treatment. The guidelines aim at promoting an objective discussion of best practices in addiction treatment in Carinthia, improving the quality of treatment and establishing uniform treatment standards while taking into account public safety interests as well as individual needs of patients. They include detailed recommendations for diagnosing, indication, drug-free treatment as well as pharmacologically assisted treatment and also services provided by persons other than physicians (psychosocial counselling, psychotherapy, housing support, etc.) as well as specific advice regarding safety in substitution treatment.
The manual for drug patients in Vienna published by the Medical Association of Vienna (Ärztekammer für Wien 2004) primarily focuses on substitution treatment but also discusses other forms of intervention. It provides recommendations for the treatment of addicted patients and describes different approaches to and philosophies of treatment. Furthermore, the themes of indication and the practical delivery of OST are treated. It also points out the importance of individualised treatment regimes within a wide range of available options as well as the need for multidisciplinary orientation. The consensus paper by the Austrian Society of Pharmacologically Assisted Treatment
of Addiction (ÖGABS 2009) exclusively deals with substitution treatment. It defines objectives and the development as well as the political and social framework of opioid substitution treatment in Austria. Its main part consists of specific, detailed recommendations for integrating OST in the system of addiction treatment as well as practical implementation. It also stresses the need for approaches that take into account individual needs and demands of the patients.

One consensus paper specifically addresses the theme of treating addiction patients with chronic hepatitis C (Haltmayer et al. 2001). It is based on a multidimensional fiveaxis model and defines detailed criteria for advice, diagnosis and indication. It was drawn up by experts on the basis of literature sources as well as practical experience. With regard to prison settings, the guidelines for doctors treating prisoners (Pont und Wool 2006) and the substitution guidelines for prisons (BMJ 2005) deserve mention. The former discuss approaches to drug abuse and addiction in prisons and underline the importance of opioid substitution as well as early diagnosing of addiction diseases as a contribution to harm reduction. However, they hardly provide concrete recommendations or instructions for translation into practice. By contrast, the substitution guidelines for prisons, apart from discussing objectives and different strategies, also include specific details of implementation.

Organisational guidelines aimed at quality assurance of addiction services have been adopted at both federal and provincial levels. The guidelines for application for announcement in the Federal Collection of Statutes, according to Section 15 of the Narcotic Substances Act, of institutions and centres providing services with regard to abuse of narcotic drugs (BMGF 2004) also contribute to assuring the quality of services in the respective addiction advice and treatment centres. For instance, the centres must have treatment or intervention strategies that define both the theoretical background and the goals and target groups of the services delivered. A profile of services has to be drawn up, and certain minimum services have to be provided. In addition, the centres have to meet defined structural and staff requirements, and annual reports have to be submitted. The funding guidelines issued by the Vienna Addiction and Drug Coordination Office stipulate similar conditions (SDW 2008).

Plans for new guidelines and standards, or guidelines and standards under preparation, primarily focus on describing services in the form of catalogues on the one hand and the related quality and continuity standards on the other, in particular regarding links between inpatient and outpatient services and across different service providers (see Chapter 5.2).

11.3 Implementation process

Implementation of the aforementioned standards by the attending doctors and addiction treatment and support services is voluntary because, with the exception of decrees and organisational guidelines, they are mere recommendations. Therefore the authorities in charge (i.e., public health officers, Ministry of Health, Vienna Addiction and Drug Coordination Office) only supervise adherence to the provisions of the obligatory organisational guidelines and decrees. In Carinthia, a guide has been published to assist public health officers, which lists competences regarding individual provisions of the Narcotic Drugs Decree as well as ways of ensuring whether doctors delivering OST meet the corresponding regulations (Amt der Kärntner Landesregierung 2007b). The activities undertaken to safeguard consistency in the execution of the Decree primarily focus on information and communication of knowhow by means of further training schemes. For this purpose, quality circles have been established, among other further training events.

The Act on Doctors (BGBl I 1998/169, latest amendment published in BGBl I 2009/144) obliges doctors to treat diligently and without distinction any person, either healthy or ill, who turns to them for medical advice or treatment. In addition, doctors shall
regularly take part in recognised further training programmes organised by the Provincial or Austrian Medical Associations or in recognised further training programmes of other countries and, according to the state of the art of medicine and practical experience, while meeting any applicable regulations and professional quality standards, restore the wellbeing of the sick and protect the healthy (Act on Doctors, Section 49, Para. 1). The detailed regulations for substitution treatment, as provided by the Decree of 2007 issued on the basis of Section 10, Para. 1 No. 5 of the Narcotic Substances Act, were regarded as too restrictive by the doctors, arguing that this limited their competences defined by the Act on Doctors. The modifications laid down in the amendment to the Decree on Narcotic Drugs adopted late in 2009 as a result of experience with the existing Decree (see GÖG/ÖBIG 2008c and 2009b as well as Chapter 5.1) have increased the doctors' acceptance. What continues to be controversial is the fact that treatment-related decisions which are not in line with the Decree may still have legal consequences for the attending doctor in question. The issue of criminal law aspects of substitution treatment thus was a focal theme at this year's Substitution Forum at Mondsee organised by the Austrian Society of Pharmacologically Assisted Treatment of Addiction (ÖGABS). At the Forum the view was expressed that the current situation was quite intricate indeed: substitution treatment is closely linked to criminal and civil law, but appropriate analysis and deliberation of OST are lacking (no studies, expert articles or supreme court decisions)\textsuperscript{47}. Several strategies have been pursued in order to advance the implementation of standards that are not obligatory but provide orientation. For instance, the recommendations by ÖGABS have been communicated on the occasion of professional events such as the Substitution Forum or further training programmes such as the quality circles organised by the Medical Associations. In addition they were sent to all Provincial Addiction and Drug Coordinators, public health officers and other experts and bodies, and they have been published on several websites (e.g., of ÖGABS and the Medical Association of Lower Austria). The other standards mentioned in this chapter are distributed in a similar way. In order to achieve practical application to the greatest possible extent it is important to cooperate with experts from several professions when standards are drawn up, as this is essential for finding a consensus that is backed and eventually communicated by the experts themselves.

BACK TO TOP
In Poland, the system of specialist substance dependence treatment is part of the health care system for individuals with mental disorders. Running programmes for individuals dependent on psychoactive substances is not ruled by guidelines or readymade standards of therapeutic conduct. Substance treatment in Poland is based on the model of learning through practice and a number of strategies developed by non-governmental organizations are successfully implemented in treatment units.

The system of drug treatment is based on a wide range of services and therapeutic methods that fit the patient's needs. Health care services are provided through inpatient and outpatient clinics, which hold the status of public or non-public health care units. Assistance methods for drug dependent individuals fall within two main areas: psychosocial methods and pharmacological treatment. Psychosocial methods include a therapeutic community, cognitive-behavioural psychotherapy, 12 steps therapy, case management and self-help groups. In practice, treatment units combine these approaches. Pharmacological treatment is mainly provided through substitution treatment programmes and detoxification. Specific requirements regarding the conduct of substitution treatment are defined in the regulation of the minister competent for health matters.

Despite the lack of clear guidelines concerning the medical conducts in Poland, efforts are made to maintain the high quality of services provided. Consequently, standards in drug treatment, rehabilitation and harm reduction programmes as well as the accreditation system of treatment units have been developed. The accreditation in health care covers the examination of a health care unit in terms of meeting the requirement set out by the accreditation standards and, if successful, awarding accreditation to the unit. Standards in drug treatment, rehabilitation and harm reduction programmes have been developed by the expert team of the Minister of Health. Standards of countries which enjoy a long tradition of quality assurance, especially the United Kingdom and the United States, were used in the process. The standards refer to the issues of patient's rights, ensuring the continuity of treatment, improving quality of services, controlling infections and meeting standards on medical drugs.

In Poland, the system of training professionals in drug therapy and rehabilitation has been put in place. It is based on the requirement of completing a specialist training course approved and certified by the minister competent for health matters. An additional element is the introduction of the Drug Therapist's Code of Ethics. It was developed in response to the needs of the community of drug therapists regarding increasing the control of ethical matters among staff of the drug treatment system. The Code does not constitute universal law; however, the consent of a therapist to be listed as a member of the Code obliges him or her to follow principles and standards defined therein.
PORTUGAL

11. History, methods and implementation of national treatment guidelines

11.1. History and overall framework

Until 1987 there was no inter-departmental drug abuse prevention plan in Portugal. In 1976 the Cabinet for Coordinating the Fight Against Drugs (GCCD) was created, under the Presidency Council of Ministers. This Cabinet coordinated and gathered information from other two Centres for the Study and Profilaxy of Drugs (CEPD). These three structures were responsible for demand reduction issues and the Centre for Drug Research and Control (CICD) was responsible for supply reduction. By that time, some hospitals, as for instance Santa Maria in Lisbon, also provided drug treatment services.

The National Program Projecto VIDA was created in 1987, under the name Integrated Drugs Fight Plan. Aware of the complexity of the drug problem, the government proposed 30 measures, including prevention, treatment, reintegration and supply reduction, to be implemented by 6 different Ministries. At the same time, Portugal was facing an important drug problem of heroin and cannabis and the Taipas Centre was created in Lisbon by the Ministry of Health. It was conceived as an integrated unit, comprising an outpatient clinic, an inpatient detoxification unit, a 24 hour emergency unit (to handle psychological emergencies rather than life-threatening intoxications) and a day care unit with a strong reintegration purpose. The team was young and very motivated and included psychiatrists, psychologists, nurses and social workers. During the first year, there were 3000 new patients in treatment.

In 1989 two other specialised centres were opened in Oporto and Faro and, in 1990, the Ministry of Health created the Service for the Prevention and Treatment of Drug Abuse (SPTT), a department to which was given the responsibility of implementing and managing the specialised treatment centres, including the CEPDs, which were integrated in this Service.

In 1990, some of Projecto VIDA's 30 measures were restructured and the Interministerial Commission and the National Council were created to increase the political commitment in the fight against drugs, as well as to mobilise the civil society awareness to the problem.

The main Drug Law was issued in 1993, as well as directives related to money laundering, certification of NGO's working in the field of drug treatment and Projecto VIDA's access to lottery revenues for funding demand reduction projects.

The problem of drug abuse was always recognised in its medical aspects. Even before the treatment centres were integrated in the Ministry of Health, the psycho-social and prevention aspects always played a significant part in the approach of the problem. At that time, however, there was some concern about the close institutional relationship between the treatment and the legal systems. By giving the Ministry of Health the responsibility of drug treatment in 1987, the Government recognises the need to formally separate supply and demand issues and to face the drug user as a person with a health problem independent from the legal/criminal consequences of the act. The same philosophy is reflected in the Drug Law which states that offenders who committed drug related crimes and have a drug problem may, in certain circumstances, be given a suspended sentence if they entry in a drug treatment program.
Separation of supply reduction and demand reduction areas is also reflected in Projecto VIDA’s philosophy. The relevant legislation started by including into the national program measures related to both supply and demand issues and lead to the redefinition of Projecto VIDA as the National Drug Abuse Prevention Program, which maintains a close contact with the public authorities in the area of supply reduction, but has only legal competencies in prevention issues.

During the nineties, many outpatient clinics were created, one in each city and several in the suburban areas of Lisbon and Oporto, comprising 45 teams working in 78 outpatient clinics. Often, through a process of meiosis, each pioneer team would divide itself into two or three new autonomous centres.

During this fast growing period, a large number of professionals with different background, including several general practitioners, felt motivated to work in the Institute, either full or part-time, while there was a shortage of psychiatrists in the country.

Each new team leader always had a training period of up to three months in one of the pioneer comprehensive centres, learning with senior colleagues the daily clinical practice of outpatient and inpatient units. Other members of the new team, psychologists, social workers and nurses, also received their own training. When someone had a difficult clinical situation there was always a senior colleague, or the national clinical director, one could contact and ask for advice. The professionals of the different teams had regular clinical supervision, a practice which has given consistency to the professional intervention.

After the general elections in March 2002, the new government’s program in this area stated “drug abuse as a health problem and the need for the government to act in order to minimise this social problem”.

The same document maintains the Portuguese Institute for Drugs and Drug Addiction (IPDT) as the coordinating agency in the field but relocates it from the Presidency of the Council of Ministers to the Ministry of Health, now responsible for drug issues coordination. General national priorities include: for prevention - the promotion of healthy life styles; for treatment - further coordination and quality control, as well as more support to drug users in prison; and, for rehabilitation - redefinition of the rehabilitation programs after their current evaluation. Special emphasis is placed upon the setting up of outreach work programs, and of all initiatives, which may prevent drug, related infectious diseases, namely AIDS/HIV.

In November 2002 the Institute on Drugs and Drug Addiction (IDT) was set up, resulting from the merger between the Service for the Prevention and Treatment of Drug Abuse (Serviço de Prevenção e Tratamento da Toxicodependência – SPTT) and the Portuguese Institute for Drugs and Drug Addiction (IPDT).

Between 1997 and 2002, the Institute promoted eight comprehensive courses of post-graduate level to professionals working or intending to work in drug addiction, summing 200 participants. Each course was composed of a theoretical part of 80 hours and a practical instruction of 200 hours.

Since 1988, and for more than 20 consecutive years, the ‘Taipas’ Centre has promoted an annual 2-day national scientific meeting. Everybody attended the meeting which contributed to the maintenance of a social network. Invited foreign scientists and clinical doctors, mainly from France, Spain and the USA, bring new scientific discoveries and new methodologies. In the last 8 years, likewise, the Institute has also promoted an annual national congress.

As a rule, each team organizes regular events (conferences or workshops), way of sharing knowledge and clinical practice and discussing with other professionals their latest experiences and results.
11.2. Existing guidelines: narrative description of existing guidelines

11.3. Implementation process

In Portugal, the role of guidelines in assisting practitioners about the most adequate intervention in a specific situation was always recognised. Several guidelines were developed with a view to ensure treatment appropriateness and homogeneity of interventions. Below, some of those guidelines are described.

1. Manual of concepts and procedures of the Multidisciplinary Information System

Since the creation in Portugal of a national body coordinating the drug-related treatment that the gathering and data analysis of the population treated has become a priority.

In this context, we tried to build (between 1990 and 1995) a chart of data collection allowing to define users profile and evolution. At that moment, it wasn’t possible to go further than the number of new patients and the number of consultations. Also, each year was promoted an analysis based on the different socio-demographic and clinical data collected in a representative sample of the users.

In 1995-2002 period, a new impulse was giving to the National Information System, with the identification of the information needed, the creation of tools for gathering and recording data and implementation of the System in the local units. In 2003, due to a reorganisation of services, the System was stopped, jeopardizing its national coverage.

In 2005, the strategy concerning the National Information System was revised and the key elements for the Multidisciplinary Information System defined, using part of the previous requirements and therefore developing an online clinical file.

This substantial evolution facilitated access of different experts to their colleague’s registrations, promoting the cohesion and the articulation of the multiple somatic, psychological and social interventions. Also, the dissemination of information was increased, allowing for the patient to be followed in his therapeutic way by the clinical file.

The Multidisciplinary Information System created standardized registers for each professional domain (Medicine, Psychology, Nursing, Social intervention, Occupational Therapy, Physiotherapy and Nutrition (ICD 10\textsuperscript{90}, ICPC\textsuperscript{91}, ICNP\textsuperscript{92}, etc.).

This achievement was reached by developing an informatic application centralized, accessible via browser from any IDT, I.P. network spot, which gathers more then 70 local databases and promotes a strict control of the repeating users and the data analysis and information production.

In conjunction with the importance of developing record data tools, it was defined that, due to the number and diversity of professionals responsible for collecting and recording data, as well as the size of the records, guidelines to promote more reliable information based on the Multidisciplinary Information System should be drafted.

A Manual of Procedures and Concepts was developed, integrating EMCDDA’s and other international and national sources, which aims to harmonize the interpretation of concepts and the data collection procedures and defines the various tasks with specific instructions to

\textsuperscript{90} International Classification of Diseases
\textsuperscript{91} International Classification of Primary Care
\textsuperscript{92} International Classification of Nursing Practice
perform them. Thus it attempts to answer the question: “Who collects? Which data? When? How?”

This Manual was built as a dynamic tool that, will evolve with the contributions, questions and requests for clarification of the local IDT, I.P. units. At the same time, procedures for periodical monitoring of data reliability are being implemented near the points of gathering and recording information.

In terms of data processing, an application called “Business Intelligence” is being created, which, allowing for standardized reporting, will answer to most of the information needs for supporting clinical or management decisions or to respond to EMCDDA and WHO requests.

The implementation of this System started in 2009 and is close to conclusion. It involved approximately 1 200 professionals (who will use daily this tool), the migration of 70 databases of 3 different systems and the setting up of an helpdesk particularly active in this initial period.

Naturally, such a project involved an adjustment period of several tools, from tuning of IT infrastructure (network communications equipment, servers, tuning the database, etc...), to functional evolution of the application (by improving their integration into the daily work of different professionals and correcting errors identified), through organizational adaptation to a model that is intended to be more demanding and rigorous on the information production.

2. Regulations for inpatient treatment in private institutions and their governmental financial support

Health care for drug users is organised in Portugal mainly through the public network services of treatment for illicit substance dependence, under the Institute on Drugs and Drug Addiction and the Ministry of Health. In addition to public services, certification and protocols between NGOs and other public or private treatment services ensure a wide access to quality-controlled services encompassing several treatment modalities.

Portugal considered necessary to regulate the functioning of these private units, with profit or not, and adopted in 1999 the legal framework to support the families of drug users in the area of treatment (Decree Law n° 72/99, of March 15th).

This Decree defined the reimbursement to be granted by the state, the costs incurred by patients in treatment in private health units and the requirements, procedures, mechanisms and criteria for funding of services. Their functioning is regulated in different aspects such as: overall capacity of the unit (number of beds in therapeutic communities and detoxification clinics, number of users for day care centers), duration of specific treatments and amount to be paid by State for each user, etc.

With the new competences of IDT, I.P. in alcohol issues, the Government extended to alcoholics the treatment instruments available for drug users (Order n° 18683 of July 14th). The fact that these rules are inscribed in a legal text allowed for a better implementation, as they are mandatory for private health units, being IDP, I.P. responsible for their supervision.

3. Manual of Standards Guiding Therapeutic Program with Opioid Agonist

The therapeutic programs with opioid agonist aimed at replacing the illicit use of an opioid by the administration of an opioid drug prescription, full or partial agonist (Methadone or Buprenorphine), procedure which should facilitate stopping or reducing the illicit use and to
reduce the risks and arms related to a risky behavior. This is a substitution treatment, usually temporary, in a user already addicted to opioids.

Opioid agonists are important resources in providing health care for some patients dependent on opioids. The use of these substances allow:

- To be integrated in a therapeutic program and to facilitate the treatment of other diseases, psychic or somatic, that may coexist in the drug users.
- To reduce the use of illicit substances and limit the use of injection, source of viral transmission and infections;
- To counter exclusion and improve the social and professional insertion;
- To improve interpersonal and family relationships;
- To promote the ability to live without using any psychoactive substances, including methadone or other opioids.

In Portugal the use of methadone was initiated in Oporto in 1978 and currently remains the drug most used in opioid substitution treatment.

The Levoalfacetilmetadol - LAAM - was introduced in Portugal in 1995, but suspended in 2000 after a recommendation of the European Medicines Agency (EMEA), following reports of serious cardiac disorders in patients undergoing therapy with LAAM.

Buprenorphine, marketed in Portugal as Subutex and used for the first time in 1999, is currently the 2nd most commonly used in therapeutic programs with opioid agonist.

Substitution treatment is widely available in Portugal, through public services such as specialised treatment centres, health centres, hospitals and pharmacies as well as NGOs and non-profit organizations.

In the beginning, each treatment team prepared their own set of guidelines and afterwards, in 2006, the IDP, I.P. developed an instrument for clarifying and guiding the intervention: a Manual of Standards Guiding Therapeutic Program with Opioid Agonist, with the purpose of standardizing procedures, methodologies and terminology and thus promoting greater consistency in the intervention. This manual is waiting formal approval, but is already used in daily work practices of the professionals involved in substitution treatment processes.

4. National guidelines for the social intervention in reintegration

In 2009, the Guidelines for Social Intervention - An Intervention Model in Reintegration (MIR) were adopted, constituting a set of principles and assumptions which configure strategic pillars of intervention with drug users.

The guidelines, developed by a working group with experts on illicit substances and alcohol coming from different regions, was a process widely participated with debates on reintegration, concepts and of deepening knowledge on the practices and services provided, gathering and systematizing several years of experience of IDT, I.P.experts.

Based on the models of integrated intervention and case management preconised by IDT, I.P., the objective of these guidelines for social intervention are: 1) to promote the sistematization and harmonization of interventions in reintegration; 2) to promote the efficiency and effectiveness of social intervention trough a common methodology for planning, assessment, intervention, monitoring and evaluation used by all professionals and available to all users; 3) to ensure the quality of the intervention, considering the assessment and the comparability in the sense of continuous improvement and full quality.
This model of intervention, underlying a set of assumptions that frame the professional and ethics practices of the reintegration teams, should be adapted to the specific characteristics of intervention contexts and to users.

The following elements should be emphasized:

a) Putting users at the center of the action, guaranteeing and ensuring full accomplishment of their citizenship rights and duties, in the respect of the dignity and freedom of choice of users as an ethic pattern to guide all activity.

b) Assess the multidimensional needs of users, through the development of a social diagnosis and inventory of the multidimensional needs and different implications for the integration path.

c) Create a meaningful relationship with the patient, based on mutual trust. The involvement and commitment of the expert in users acquisitions, contributing to the establishment of a relationship of trust and complicity, encouraging users to continue their reintegration process with determination and trust.

d) Negotiate and contractualize an Insertion Individual Plan, reflected in the drafting of the whole integration path, defining objectives, strategies to be taken, responsibilities and goals, priority actions at medium and long term, which meet the personal and social needs of the patient, as they are defined at each step of the evaluation process.

e) Intervene in a logic of integrated response, at team level and on interinstitutional and intrainsitutional articulation. The connexion of the different IDT, I.P. areas involved in the process of users rehabilitation, as well as the close collaboration with external partners, appears to be an inalienable factor in integrated interventions, only way of satisfying needs for individual development, maximizing available resources and adapting them to the the interventions needed.

f) Ensure the continuous and systematic monitoring of users in the process of empowerment and integration in a case management logic. The continuous and systematic monitoring starts when the social diagnosis and the Insertion Individual Plan are concluded and should continue until the user needs are fulfilled and the Insertion Individual Plan accomplished and evaluated. Tracking the insertion path is also accompanied by the support to the acquisition and development of tools of personal, social and professionals competences, which can reduce the insecurity feeling and promote a behaviour and progressive trust in himself and others.

g) Ensure the development of practices of social mediation, aimed at creating conditions for the social systems to guaranty the effectiveness and sustainability of interventions undertaken at individual level, the reorganization of routines and reference frames in the acquisition and/or repurchase of personal, social, professional and citizenship skills.

This Model of Intervention applies to all IDT, I.P. users, which problematic use of psychoactive substances require a specialized social intervention.

The phases of MIR are: 1) the initial assessment of the situation with the drafting of a social diagnosis, which allows negotiation and contractualization; 2) planning and Insertion Individual Plan; 3) an intermediate evaluation of the Insertion Individual Plan for a period set by the expert; 4) final evaluation of the Insertion Individual Plan; 5) social release; 6) follow-up.

Tools for social assessment and for the development and evaluation of the Insertion Individual Plan were created as instruments to support the Model’s implementation.

In October 2009, the guidelines were distributed to the regional and local IDT, I.P. structures as Technical Guidelines with the assumption that their implementation had to be in
in accordance with the specific characteristics of each service and team, context of intervention and target users. They were adopted by 87% of the services and a year later, their implementation is under evaluation, to identify constraints and introduce improvements. The results of this evaluation will be available in 2011.

5. Building an ICNP1.0® Catalogue on Alcohol and Other Drug Addictions

By 2009, the different informatic documentation systems on heath care in the IDT, I. P. did not cover nursing interventions. In the absence of previous standardization, the record of these interventions were in paper format, with important discrepancies (as there are 56 care units in the country) and various denominations for similar interventions or the same denomination with different meanings. This situation made impossible to count nursing interventions in addictions and impossible to ensure the continuity of this kind of care for addicts, a typology of clients with important geographical mobility.

The National Multidisciplinary Information System, implemented in 2009 in all outpatient services, included an initial standard nursing information system, which already establishes the more usual nursing diagnosis and interventions for patients with alcohol and/or drug addiction related problems. This catalogue adopts the terminology of International Classification for the Nursing Practice (ICNP®), supports nurses in the definition of nursing diagnosis and guide their decisions within their respective clinical interventions. The catalogue is not standardized, but has been used at national level (only mainland) by all nurses in outpatient services.

The International Classification for Nursing Practice (ICNP®) Program of International Council of Nurses (ICN) was contacted in an attempt to develop and improve the registration system and to obtain information on other ongoing projects in the field of nursing addiction. As ICN was not aware of this or any other catalogue or project in this area, IDT, I.P. decided to give continuity to our project.

So, since June 2009, a team of eight nurses working with addicts in the five regional delegations of IDT, I.P. (five of them working in outpatient units and the others three working in inpatients units), is developing the first ICNP® Nursing Minimum Data Set (NMDS) in the addiction area known around the world. This Catalogue on Addictions Nursing will include diagnosis, interventions and outcomes sensitive to nursing care and their intensity. The project includes the participation of a nurse from the Portuguese Nursing Order and can be found at http://www.icn.ch/ID182.htm

In a near future, the group also intends to ask for the cooperation of Members of the National Association of Users of Psychoactive Substances (CASO - Association), which is being created and will contribute to the validation of the contents of the ICNP® Catalogue.

The ICNP1.0® catalogue used in the inpatient services of IDT, I.P., should be concluded by December 2010, followed by the preparation of the future ICNP1.0® catalogue for the outpatient services. The produced catalogues will be sent to the Nursing Order.


The Support Guide on Intervention in Harm and Risk Reduction (the “Support Guide”) was developed in a context where the National Network for Harm and risk reduction expanded in number and diversity of specialized agencies implemented and when the existing guidelines were exclusively focused on a specific type of agency, the street teams. By that time, other
structures more expressive than the street teams, were implemented, of low threshold, such as the Support Units for drug users without social/familiar integration, the Substitution Treatment in low-threshold and Contact Points (structures defined by the Decree-Law No 183/2001 of 21 June).

Two other factors, added to this scenario, contributed to the need of establishing intervention guidelines in Harm and Risk Reduction (RRMD): the fact that this being a relative new area of intervention meant that few publications existed in Portugal and that the main model of implementation for specialized agencies in RRMD was the private/public paternship, which requires a greater effort to promote quality standards.

Thus, the definition of the Support Guide was based on the definition of a scientific and technical framework for RRMD intervention, as developed by several non-governmental agencies.

The Support Guide was therefore targeted to non-governmental agencies that implement RRMD projects, but also to IDT, I.P. experts in charge of monitoring these projects. In the drafting of this Guide, were involved several experts and governmental agencies working in this field, in a way to reflect the state of play of the scientific literature and debate and the Portuguese experience. The Support Guide covers also several aspects as the integration of RRMD in the strategy against addictions, the concept definition, the RRMD paradigm, the scope of this type of behaviour, its guiding principles and objectives. On the other hand, it also seeks to define the essential elements of each type of specialized structures inscribed in the legislation, finally addressing the issue of expert’s teams.

Once published, the Support Guide was launched at the IDT, I.P. National Conference in May 2010 and distributed to the Institute decentralized bodies, especially among those responsible for the coordination of the RRMD mission at regional and local level and to all specialized agencies partners of IDT, I.P., being used as background material for training programs in RRMD.

Currently, it is foreseen to make an assessment by the second semester of 2011 on the knowledge and appreciation of the Guide among the target audiences.

7. Technical Guidelines for the Implementation of Programs of Opioid Substitution of Low Threshold

The relevance of the definition of the Technical Guidelines for the Implementation of Programs of Opioid Substitution of Low Threshold (the “Technical Guidelines for the PSO-BLE) is determined by the nature of this type of program, which involves the handling of a medicinal product. By their nature, complexity and level of adjustment to a specific population, the implementation of these programs requires clear guidelines that constitute a support for the professionals who execute them locally, while ensuring that users have access to a program with high level of quality.

Based on the principles of pragmatism and humanism, the programs and measures of harm and risk reduction were inscribed in the National Strategy on the Fight Against Drugs (1999-2004), adopted by the Council of Ministers - Resolution No. 46/99 of April 22th (Presidency of the Council of Ministers, 1999).

Following the Strategy and the subsequent recognition of the legitimacy of these measures by international agencies, a first diploma defining the structures of harm reduction was adopted. This legislation (Decree-Law No. 183/2001, 21st June) defines the legal framework
of the Prevention, Harm and Risk Reduction Policies. As stated in Article No. 42 of the Decree-Law the PSO-BLE pursue the following objectives:

A) The decrease of heroin use, its replacement by methadone to be distributed through programs of high accessibility, without requiring immediate withdrawal and in adequate facilities;

B) The increase and the regularity of contacts drug users/ health team, which can contribute, particularly to future withdrawal. ”

Also, in the National Plan Against Drugs and Drug Addiction 2005-2012, the need to provide, in comprehensive and coordinated programs, opioid substitution of low-threshold is reinforced. The implementation of these responses is guided by the logic of proximity and focus on the individual, emphasizing values such as citizenship, participation and accessibility.

However this measure was only regulated on 2007, June 25th, by the Administrative Rule No. 748 and 749 of 25 June 2007 (Annex II), which set the requirements and procedure for the establishment and functioning of programs and structures of Harm and Risk Reduction and the rules for allocating public funding.

For developing the "Technical Guidelines for the PSO-BLE", IDT, I.P. conducted a study which characterized the PSO-BLE implemented in the treatment facilities, noting that there was a wide variety of rules, procedures and objectives. Moreover, the fact that the IDP, I.P. also finances non-governmental organizations, which implement this type of program would also carry greater diversity of practices. Thus, notwithstanding the necessary adjustments to local and individual realities, it was considered important to set guidelines.

Thus, the "Technical Guidelines for the PSO-BLE" target all professionals in public and private organizations that intervene in these programs. Its definition involved the analysis of existing guidelines at international level and practices in various treatment facilities. The first draft was done by IDT, I.P. involving also the Clinical Management and on a second phase, it was sent to the decentralized IDT, I.P. units for discussion.

This document is still under discussion, but its approval is expected shortly. Despite this, in 2009 IDT, I.P. organized, at regional level, several training sessions and meetings to explain the guidelines.

11.4. Comparison with WHO guidelines

| Name of Assessors: Dr. José Pádua – Director of Treatment and Rehabilitation Department, IDT, I.P. |
|---------------------------------------------------------------|---|---|---|
| 1. Choice of treatment | Yes | No | Not applicable | No answer |
| 1.2 For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment. Do the present guidelines include this recommendation? | X | ☐ | ☐ | ☐ |
| 1.3 For opioid-dependent patients not commencing opioid agonist maintenance treatment, consider antagonist | X | ☐ | ☐ | ☐ |
pharmacotherapy using naltrexone following the completion of opioid withdrawal. Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>2</th>
<th>Opioid agonist maintenance treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td></td>
<td>X</td>
</tr>
<tr>
<td>2.2</td>
<td>During methadone induction, the initial daily dose should depend on the level of neuroadaptation; it should generally not be more than 20 mg, and certainly not more than 30 mg. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td></td>
<td>□ X □</td>
</tr>
<tr>
<td>2.3</td>
<td>On average, methadone maintenance doses should be in the range of 60–120 mg per day. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td></td>
<td>X □ □</td>
</tr>
<tr>
<td>2.4</td>
<td>Average buprenorphine maintenance doses should be at least 8 mg per day. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td></td>
<td>□ X □</td>
</tr>
<tr>
<td>2.5</td>
<td>Methadone and buprenorphine doses should be directly supervised in the early phase of treatment. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td></td>
<td>X □ □</td>
</tr>
<tr>
<td>2.6</td>
<td>Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td></td>
<td>X □ □</td>
</tr>
<tr>
<td>2.7</td>
<td>Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td></td>
<td>X □ □</td>
</tr>
</tbody>
</table>

3 | Management of opioid withdrawal |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td></td>
<td>□ X □</td>
</tr>
<tr>
<td>3.2</td>
<td>Clinicians should not routinely use the combination of</td>
</tr>
<tr>
<td></td>
<td>□ X □</td>
</tr>
<tr>
<td></td>
<td>opioid antagonists and minimal sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>3.3</td>
<td>Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</td>
</tr>
<tr>
<td>3.4</td>
<td>Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal. Do the present guidelines include this recommendation?</td>
</tr>
</tbody>
</table>

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□</td>
<td>X</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1</td>
<td>Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy. Do the present guidelines include this recommendation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2</td>
<td>Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered. Do the present guidelines include this recommendation?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>X</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BACK TO TOP
Chapter 11. History, methods and implementation of national treatment guidelines

The existing Romanian regulations define the institutional framework and procedures of a comprehensive and integrated care system destined for drug users, which is based on case management.

The standardisation of the care system occurred in 2005\textsuperscript{93} with the establishment of the rules of operation of the integrated service system for drug users:

- the stages of the provision of medical, psychological and social care services, the situation in which care is provided (upon the request of the user or of the legal representative; upon the decision of the prosecutor or of another judicial body, as appropriate; in cases of emergency);
- the fields for which evaluation is made (personal and drug use history, bio-medical conditions and current complications, psychological and/or psychiatric conditions and complications, social and family conditions, legal status);
- orienting criteria for the selection of a programme adjusted to the profile of each user;
- types of integrated care programmes designed for drug users.

The regulation also lays down the institutional framework in which assistance is provided\textsuperscript{94}:

- drug prevention, evaluation and counselling centre (DPECC) (out-patient) – provides medical, psychological and social care and case management,
- day centre (out-patient, over a 12-hour interval) – provides assistance,
- therapeutic community-type centre, protected housing, social residence or others (hotel-type) – assistance services,
- integrated addiction care services (IACC) (out-patient) - provides medical, psychological and social care,
- in-patient detoxification centres, units and departments (hospitalisation) – medical detoxification services,
- harm reduction services (out-patient and mobile units) – harm reduction,

\textsuperscript{93} Governmental Decision no. 860/2005 approving the Enforcement regulation of the provisions of the Law no. 143/2000

\textsuperscript{94} The provision of care services for drug users, without an authorisation as provided by the legal regulations, is considered misdemeanour and is punishable by a fine ranging from 10,000 RON to 15,000 RON; in order to strengthen the integrated medical, psychological and social care system designed for drug users, a series of regulations were issued to ensure the activities carried out by service providers are standardised: Decision no.16 of October 2, 2006 approving the Minimum compulsory standards on case management in the field of assistance for drug users (NAA, OG no. 899/06.11.2006) and Decision no. 17 of October 2, 2006 approving the Methodology for the formulation, amendment and implementation of the customised care plan for the drug users (NAA, OG no. 899/06.11.2006). Thus, the provision of services in the field of drug assistance should be done through a series of integrated services: medical, psychological and social care, and all services should be coordinated through case management. Case management is a service applied continuously throughout the care process by the case manager, a specialist in the DPECC structure. This method helps coordinate the services provided to drug users: evaluation of the user, setting up an integrated care programme, formulating the customised care plan and implementing measures according to the plan, monitoring and evaluating the measures of the customised care plan, re-evaluation, resumption of the programme by changing the plan or the integrated care programme, if necessary, and collaboration between suppliers, advocacy.
• mental health laboratory\textsuperscript{95} cu day stationary – out-patient substitution (methadone maintenance programme).

11.1 HISTORY AND OVERALL FRAMEWORK

The supply of assistance services for drug users had an oscillating tendency from 1990 to 1996 and was not regulated by law. In the context of higher treatment demands the Pilot centre for the treatment of drug-addicted people was created in 1997 within Gheorghe Marinescu Hospital in Bucharest and the Treatment unit for drug-addicted people became operational as part of the Psychiatric Hospital Socola in Iasi. The Pilot centre for the treatment of drug-addicted people (31 beds) was the only facility in Romania providing substitution medication (methadone). At that time, out-patient\textsuperscript{96} treatment did not exist (methadone could not be used outside the hospital) and there were no treatment programmes for non-hospitalised patients\textsuperscript{97} or rehabilitation services. At the end of 1998, this pilot centre was closed down out of various reasons and drug users continued to be treated only in the psychiatric units of the hospitals in Bucharest. Two detoxification\textsuperscript{98} centres were working in 1999 (in Bucharest and Iasi), a single counselling centre \textit{Crisis Centre for Children and Adolescents} within the Mental Health Laboratories (MHL) in the 4\textsuperscript{th} District\textsuperscript{99} and a single after-care centre in Bălăceanca (county of Iffov, close to Bucharest). Pursuant to the Order no. 963/1998\textsuperscript{100}, methadone treatment could be initiated only after the determination of the psychoactive substance the user was consuming, but the psychiatric and intensive care units across the country did not possess the adequate equipment (urine and blood-based drug and metabolites testing devices)\textsuperscript{101}. As a result, there were numerous relapses among drug-addicted people until 1999 because of the missing links in the therapeutic chain (e.g. social-vocational centres and therapeutic communities) that might improve the efficiency of the

\textsuperscript{95} The Ministry of Public Health (MPH) issued the Order no. 372/2006 which lays down measures for the promotion and protection of mental health and for the prevention of psychiatric diseases. The order lays down rules on how to evaluate mental health and initiates the territorial organisation of mental health services in geographical areas, referred to as psychiatric units that provide the following services: out-patient services, mobile assistance, rehabilitation, inpatient treatment and residential services. The re-organisation of the mental health services aims at increasing the quality and accessibility of this type of services and at ensuring community-based psychiatric assistance, for adults, teenagers and children, as separate categories.

\textsuperscript{96} Other medical institutions have also been contacted by addicted people, especially those including emergency and toxicology services, even though they provided only diagnosis and immediate care.


\textsuperscript{98} “In 1999, methadone tablets were used in the substitution treatment, under the brand of SINTALGON. Clonidine, classic and atypical neuroleptics, tranquillisers and carbamazepine were other types of medicines used in detoxification treatment. Because in Romania there is not a guide, unanimously accepted at national level, referring to the specific drug addiction treatment, the choice of substances to be used in substitution treatment (detoxification) was random according to the experience and criteria of the psychiatrists. […]Several re-admissions were recorded for detoxification purposes”. - National Report on the Drug Problem in România in 1999, pg 51

\textsuperscript{99} Does not exclusively target drug issues, but includes drug counselling for those who seek information and for those who have already started to use drugs or have been admitted in treatment for drug addiction problems.

\textsuperscript{100} Although the MH Order 963/1998 includes provisions for the completion of the methadone-based therapeutic programme by specific psycho-therapeutic practices, occupation therapy and recovery treatment, the provisions was not observed because of the lack of specialised staff in the psychological-social treatment of drug addicted people.

\textsuperscript{101} The equipment could be found only in the Detoxification centre in Bucharest, the After-care centre in Bălăceanca hospital, the Toxicology unit of the Emergency hospital Floresca in Bucharest and the Toxicology Department in the Clinical Central Hospital for Children “Grigore Alexandrescu” – Bucharest.
treatment and because, after screening, drug users were not entitled to charge-free medical assistance\(^{102}\).

The first response came from the responsible ministry in 2000 and was meant to adjust to the assistance needs in the field. It translated in the Public Health National Programme of the Ministry of Health (Programme 8) and enabled the setup of pilot treatment units in several psychiatric hospitals\(^{103}\), and of the first Methadone maintenance centre. The enforcement regulation of the Law no. 143/2000 on countering the illicit drug trafficking and use was the legal framework of the setup of services for the care of drug-addicted people, as provided by MH structures:

- drug intoxications (overdoses) are treated in intensive care and emergency units across the country;
- substitution-free in-patient detoxification: Prof. Dr. Al. Obregia Psychiatric Hospital in Bucharest – 2 units; St. Stelian Medical Centre in Bucharest; Socola Psychiatric Hospital Iaşi; Psychiatric Hospital Jebel – county of Timiş; in other psychiatric hospital (e.g. Central Military Hospital, Emergency Clinical Hospital Floreasca etc.) without possessing specialised units;
- methadone maintenance centres: Mental Health Laboratory 4th district, Mental Health Laboratory 3rd district and St. Stelian Medical Centre – Bucharest;
- out-patient evaluation and treatment centre: Constanţa (Palazu);
- after-care: Bălăceanca Hospital – county of Ilfov and Socola Hospital – county of Iaşi.

In time the treatment supply has remained unchanged and some services declined: some units were closed down or worked only formally\(^{104}\), while the rest\(^{105}\) operated in a precarious material and professional state\(^{106}\). Additionally, the services and structures designed for drug-addicted users were funded by the MH in a very intricate manner also very difficult to assess\(^{107}\), and the methodologies related to methadone maintenance programmes and,

\(^{102}\) “the cost of a 10-day detoxification a patient has to pay is 70 US dollars, an amount which is extremely high considering the average income per capita” – Brigade for Countering Organised Crime and Corruption, Focal Point – National Report on the Drug Problem, 1998, p.26

\(^{103}\) 16th unit of the Psychiatric Clinical Hospital Al. Obregia in Bucharest

\(^{104}\) “the same was the case of the detoxification specialised units in Tg. Mureş, after-care in Jebel and Gătaia, both in the county of Timiş, and the units in Palazu Mare – county of Constanţa and the municipality of Tărgu-Mureş did not join the service suppliers` chain” – NAA (2003) Evaluation report of the drug phenomenon in Romania – 2002, p. 39-41;

\(^{105}\) In line with the Order of the Minister of health and family no. 187/2002 the following units were recognised as treatment facilities: Psychiatry hospital „Al. Oregia“ (Bucureşti) – 2 detox units; Mintal health laboratory no. 4 Berceni (Bucureşti) – methadone maintenance; Psychiatry hospital „Socola“ (Iaşi), after-care and detox; Psychiatry hospital Bălăceanca – after care; Diagnosis and treatment centre St. Stelian (Bucureşti) – detox and methadone substitution treatment; Psychiatry and emergency hospital Jebel – treatment unit; Toxicology units of all county hospitals where acute drug related intoxications are treated.

\(^{106}\) The staff that worked in the units did not benefit from specific training in the field of drug users’ assistance, and it was made up if specialists who used to work in psychiatry units. Methadone substitution treatment and alternative therapy were done at random and dictated by the personal treatment experience and criteria of the psychiatrists, as, at that time, the specialised staff in the field was missing (only three specialised staff in the entire country).

\(^{107}\) “Specialised diagnosis and treatment units are funded by the Secondary programme 1.5 – Promotion of health and education – 2nd objective. Diagnosis and treatment of drug-addicted people and Secondary programme 2.13 – Drug addiction therapy and are not strictly differentiated. Thus, the Public Health Directorate General and the Sanitary State Inspection report 12 such units, the Office of the State Secretary for European Integration – 7, and the National Health Insurance House -9. Moreover, a joint order of the Minister of Health and the National Health Insurance House stipulates the medical units to be funded by the National Programme, without mentioning the units referring strictly to the diagnosis and treatment of drug users, and, implicitly, one
subsequently, the provision of this substitute in the available centres was inadequate, generating even cases of methadone trade on the “black market”. Additionally, the inexistence of a comprehensive therapeutic chain lead to an increasing number of relapses, which made recovery quite an impossible task, in most of the cases\textsuperscript{108}.

Drug addiction treatment was provided in medical units\textsuperscript{109} of the MH from 2003 to 2004: three methadone substitution treatment centres\textsuperscript{110} (only in Bucharest), a few non-substitutive treatment centres (in Bucharest, Iasi and Timis), two after-care units (Bălăceanca -near Bucharest and Socola - near Iaşi)\textsuperscript{111} and two community centres in Vurpăr and Şura Mare (county of Sibiu), coordinated by religious communities\textsuperscript{112}.

The following year, pursuant to the GD no. 1093/2004, the 47 Drug Prevention, Evaluation and Counselling Centre (6 in Bucharest and one in each county) became territorial structures of the NAA\textsuperscript{113} and, in line with the standards of the National System for the Medical, Psychological and Social Care of drug users\textsuperscript{114}, the coordination of the care of drug users and the overall management of each case along different services have been structured since 2005 in the following assistance levels:

- \textit{1\textsuperscript{st} level} – identification and referral of drug users to specialised services providing assistance for basic medical and social needs (emergency services, primary medical care, general social services, harm reduction services);
- \textit{2\textsuperscript{nd} level} – made up of specialised public health units and the drug prevention, evaluation and counselling centre, provides specialised care (multi-disciplinary review, drug evaluation and counselling, specialised care, simultaneous and continuous), monitoring and referral to the 3\textsuperscript{rd} level;
- \textit{3\textsuperscript{rd} level} – provides specific care and a high level of specialisation (detox, therapeutic communities, day centres etc) and reinsertion\textsuperscript{115}.

In the context of the Medical, Psychological and Social Care National Programme (MPSCNCP) for drug users, 15 Integrated Addiction Care Centres (IACC)\textsuperscript{116} were starting to

\textsuperscript{108} The evaluation system of the treatment results was not put in place by the end of 1998. Later on, the evaluation indicators or these programmes were broken down in two categories: physical indicators (average no. of patients/medical unit, total no. of units providing treatment to drug-addicted people) and efficiency indicators (average cost/treated patient, average cost/unit providing treatment to drug-addicted people). The reports of the Public Health Directorate show the average cost/patient in the first 6 months of 2003 amounted to 2,959,188.2 lei, and the average cost/unit was 112,192,887.5 lei. – NAA (2003) Evaluation report of the drug phenomenon in Romania – 2002, p. 40.

\textsuperscript{109} Treatment for acute intoxications and withdrawal syndrome, detoxification, in-patient and after-care and/or alternative therapies

\textsuperscript{110} Total capacity of 400 people

\textsuperscript{111} Limited capacity centres (cca. 8 places) and not known by the drug users' community or the medical community – NAA (2004) Situation in the field of drugs – 2003, pg. 31

\textsuperscript{112} The centres became operational in September 2006 and started providing the following type of services: prevention, patient review, psychological care, social care and case management

\textsuperscript{113} no reference to: alcohol, medically prescribed psychoactive substances, people under 18, assistance in detention settings

\textsuperscript{114} 1\textsuperscript{st} and 3\textsuperscript{rd} level services are provided in the public, private, mixed or non-governmental system, 2\textsuperscript{nd} level in the public system

\textsuperscript{115} Decision of the NAA president no. 1563395/2005; Decision of the NAA president no. 4/2007 approving the operation of CAIA Pantelimon, Decision no. 9/2007 approving the operation of CAIA Pericle, Decision no.
be put in place to provide assistance services for the 2nd and 3rd level (out-patient detox and methadone, suboxone and naltrexone substitution treatment). The first IACC (named CAIA Pantelimon) was opened in Bucharest, June 26, 2007. Later on four more centres were opened from 2007 to 2008: CAIA Pericle (for beneficiaries residing in Bucharest – 5th and 6th districts), CAIA Obregia (for beneficiaries residing in Bucharest – 3rd and 4th district), CAIA Bihor and CAIA Iași. Additionally, NAA created two day centres for drug users in 2007, one of which had a social-vocational purpose (currently not operational), and the Romanian Association against AIDS (ARAS) created a methadone substitution treatment centre with the support of Matei Baș Infectious diseases institute. It's worth mentioning that even though in that year there were several centres providing maintenance treatment with agonist medication as compared to previous years, it was necessary to create the legal framework for the setup and management of the waiting list to be used in the NAA’s integrated addiction care services, which might lead to the conclusion that the services are still insufficiently developed.

Several legal projects were initiated/formulated in 2008 to support the development of the prevention and integrated care services for drug users.

11/2007 approving the operation of CAIA Obregia; in 2007 also was set up a closed-circuit pharmacy authorised by the MHI, which ensures the provision of medication for all CAIA services
16 medical, psychological and social care, evaluation services for the drug user, case management, customised care plan, which are also provided by the DPECC
18 Substitution treatment with buprenorphine, naloxone and naltrexone was introduced at the end of 2007 in CAIA
19 provides medical, psychological and social services for the beneficiaries living in Bucharest – 1st and 2nd district and in Ilfov
20 County in the North-West region of Romania
21 County in the North-East region of Romania
22 within the UNODC-funded project “HIV/AIDS prevention and treatment among injecting drug users in community and penitentiaries”
23 NAA President’s decision no. 13/2007
24 Health national programmes 2008 (GD no. 357/ 26 March 2008) which provide for the following efficiency indicators, in the evaluation unit: average cost/ urine drug test – 20 lei; average cost/client in outpatient treatment – 320 lei; average cost/patient in substitution – 120 lei, and in the 2.2. secondary programme 2.2 (HIV infection and supervision subprogramme): access to HIV counselling and testing for populations at risk (comerical sex workers, injecting drug users, homeless people, prison inmates, MSM)
25 e.g National programme for the medical, psychological and social care of drug users – 2009-2012, approved by GD no. 1.102/18.09.2008, proposing concrete intervention measures for the completion of the national system of prevention and care services for drug users, services that are designed to provide an integrated approach adequately adjusted to the needs of the clients and the local community (outreach services, participation of the families and communities in the therapeutic chain and public funding of NGO-run specialised services) and the ORDER no. 1.389/4.08.2008 – approving the Authorisation criteria and methodology for the centers that provide services for drug users and the Compulsory minimum standards of the organisation and operation of the centres that provide services for drug users.
Chart of the assistance services for drug users in Romania

Source: National Anti-drug Agency – Standards of the National System for the Medical, Psychological and Social Care of Drug Users

The provision of medical, psychological and social care of drug users is performed in the following stages: 1. evaluation (identification of the personal features of the user)\textsuperscript{126}; 2. inclusion in a customised care programme (PIT)\textsuperscript{127}; 3. formulation of the therapeutic, psychological and social care plan (PIA)\textsuperscript{128}; 4. implementation and monitoring of the

\textsuperscript{126} performed on several fields: 1. personal medical record and drug use history, signs of intoxication and/or abstinence syndrome based on the medical record and drug use history and the specific symptoms; 2. biological-medical conditions and current complications which, although not linked to abstinence syndrome or intoxication, call for treatment because they can generate risks or can complicate care and recuperation; 3. psychological and/or psychiatric conditions and complications and other conditions that can generate risks or can complicate care and recuperation, such as: retention/resistance to treatment, relapse potential, resumed use etc; 4. social and family conditions that can be sources of individual, family or community support or can prevent/hinder care; 5. legal status, previous and current.

\textsuperscript{127} a) 0 drug low intensity programme – PIT 1 which provides: basic and specialised medical services; abstinence support with antagonist opiate medication; psychological and/or psychotherapeutic counselling; drug testing; social care; legal advice; information, education and training to reach an education, cultural and relationship level that would allow for social participation and the access to community-support services; b) 0 drug programme – PIT 2 which, in addition to PIT 1, provides: substitution or non-substitution detoxification, outpatient or inpatient; c) 0 drug stabilisation programme – PIT 3 which provides the medical/psychological or psychiatric/social and legal services specialised for drug related diseases and/or diseases caused by drug use, which call for immediate intervention; d) harm reduction programme – PIT 4, with the following options: substitution programme with opiate agonist medication (methadone prescription and administration), syringe exchange and/or other harm reduction measures, providing counselling services for a risk-free drug use, information provision on current assistance services; coverage of basic needs: food, hygiene, clothing, rest.

\textsuperscript{128} The customised care plan for drug users consists of: general information on the beneficiary, the aim of the programme, main issues and priority issues, strengths/weaknesses, objectives and expected deadlines, intervention schedule, responsible staff and treatment grid. The customised care plan clarifies four objectives: the means to provide care, the types of services, the assistance measures, and the choice of adequate and
measures provided for in the customised plan; 5. evaluation of the implementation of measures provided for in the customised plan and their results.

The provision of social care services for drug-addicted users was regulated in 2008, once NAA in cooperation with the Ministry of Labour, Social Solidarity and Family and the Ministry of Public Health formulated the compulsory minimum standards of the organisation and operation of the centres that provide services for drug users and the authorisation methodology for these centres. The services provided by the DPECC, public and private medical units, along after-care and psychosocial rehabilitation are: individual, family and group psychotherapy; occupational therapy and psychiatric disease treatment. The integrated chain of medical, psychological and social care of drug users was partially created as links were still missing such as the social services and therapeutic community-type services, assistance care services for the children of drug users, services in the prison system and dual diagnosis care centres.

11.2 Existing guidelines: narrative description of existing guidelines

11.2.1 Framework, types of interventions, groups addresses

A. Detoxification treatment:
In line with the legislation in effect in 2000, detoxification was possible only based on the legal-medical expertise (confirmation of addiction diagnosis) and once the beneficiary accepted to undergo regularly and randomly checks of drug metabolites. Other methods were also provided for in the law: psychotherapy and substitution treatment (only after the detection of drug metabolites in the body):

- complete hospitalisation in closed-circuit detoxification units which could be left once the person was released with an obligation to undergo after-care – psycho-social rehabilitation until the end of the detoxification period;
- out-patient substitution based on methadone or other specific substances (levo-alpha-acetyl-metadol, buprenorphine): a person should meet one or several criteria to available procedures. Assistance procedures differ by the intensity of the intervention, according to the degree to which it corresponds to the needs of the drug users, and can be: emergency, low or high intensity outpatient treatment, residential or inpatient treatment. Characteristics are settled for each type of assistance and clear indications are provided to support the choice of a certain type of care. The provided services and interventions can be medical, psychological and social, while the structure, adequate and available to drug users, is directly connected to the care providing centres.

Social care services are stipulated in the Framework regulation for the organisation and operation of social care institutions (G.D. no. 1434/2004 laying down the tasks and the Framework regulation for the organisation and operation of Directorate General of the Child’s Social Care and Protection, issued by the Government, OG no. 869/23.09.2004) and in the methodological enforcement rules of the legal provisions on social services (GD no. 68/2003 on social services, issued by the Government of Romania, OG no. 619/30.08.2003)

The Ministry of labour, social solidarity and family authorised the 41 DPECC as social services suppliers in 2006

Detoxification length is determined according to the condition and evolution of the patient, but should not exceed 30 days, and admission can be done once or twice a year, upon request

legal framework for substitution: Law no. 73/1969 on the status of narcotic products and substances with narcotic content, and the Minister of Health’s Instructions no. 103/1979 which comprise the enforcement rules of the mentioned law, regulate the legal chain of narcotic products which include SINTALGON tablets (methadone) and the M.H. Order no. 963/1998 approving the general methodological rules for the organisation and provision of medical care, treatment, and residential care to psychoactive substance (narcotics) abusers
enter the programme\textsuperscript{133}. Could be discontinued by the progressive reduction of doses when: the person had three consecutive positive results on regular checks; the person would disclose inadequate behaviour and attitude towards the staff or other patients; in case of medical contraindication and upon request. Readmission would be an option three months after exclusion;

- in the institutions subordinated to the Ministry of Interior and Ministry of Justice, in case the person included in this type of programme is in the prosecution stage or in other hospital units in case the person is admitted to another ward for somatic disorders.

Methadone had become available in outpatient substitution treatment since 2002, and the prescription of take away dosage over a period of 10 to 14 days has also become possible. Prescription is given by the physician through the mental health laboratory where drug-addicted users undergo treatment, based on marked prescriptions and on the authorisation issued by the public health directorates (valid 3 months from issuance).

The Order no. 1389/513/282 of August 4, 2008 approving the Criteria and methodology for the authorisation of centres that provide services for drug users and the Compulsory minimum standards of the organisation and operation of the centres that provide services for drug users\textsuperscript{134} lays down the Specific criteria for the organisation and operation of the detoxification centre\textsuperscript{135}: admission/hospitalisation\textsuperscript{136} awaiting detoxification is decided by the doctor of the detox centre based on the recommendation of the drug prevention, evaluation and counselling centre\textsuperscript{137}, family doctor or other drug service providers. The physician

\textsuperscript{133} the inclusion criteria in an outpatient substitution treatment (methadone substitution) are: positive diagnosis of psychoactive substance addiction syndrome (mental and behaviour disorders caused by psychoactive substance use); age over 18 (the parents’/legal representative’s consent is needed for users under 18); biological evidence of addiction (positive urine test); addiction history of minimum two years, based on medical evidence; 3 failed non-substitution detoxification attempts; addiction related diseases (HIV/AIDS infection, tuberculosis, cardiac failure, B and C chronic hepatitis, major psychiatric disorders); opiate-addicted pregnant women; poly-drug use; addicted people with underage dependants. The specialist responsible for the programme can interpret these criteria and formulate a final decision of programme inclusion or exclusion – 2\textsuperscript{nd} annex of the Enforcement regulation of the provisions of the Law no. 143/2000 on countering the illicit drug trafficking and use (approved by GD no. 860/2005)

\textsuperscript{134} Issued by: MPH (No. 1.389 of August 4, 2008), Ministry of labour, social solidarity and family (no. 513 of August 15, 2008) and Ministry of Interior and Administrative Reform (No. 282 of August 24, 2007), published in the OG no. 830 of December 10, 2008

\textsuperscript{135} Detoxification centre – Minimum criteria on staff structure and professional skills: the Centre has the following full-time staff: a psychiatrist, a psychologist, a social worker, nurses and medical aid. a) the physician has graduated a higher education institution and is licensed in medicine, psychiatry specialisation and a member of the Medical Board in Romania. b) the psychologist has graduated a higher education institution and is licensed in psychology or equivalent, has an individual practice certification for one of the professional specialisations: psychology, psychological and psychotherapy counselling, in line with current regulations. One psychologist is ensured for 6 to 8 beneficiaries. c) the social worker has completed a higher education institution and is licensed in social work, is a member of the Social Work National Board in Romania. There should be one social worker for 10 to 12 beneficiaries. d) the medical assistant is a member of the Nurses Board and has an individual practice certification. There should be one nurse for 6 beneficiaries. Medical assistants should be continuously present, and continuance should be ensured in shifts, according to the law. e) medium education medical aid; there should be one medical aid for 20 beneficiaries.

\textsuperscript{136} Hospitalisation procedure is provided for in the organisation and operation rules of the centre

\textsuperscript{137} The beneficiary must comply with the internal regulations of the centre, during hospitalisation. The regulation is notified upon admission. To this aim, the beneficiary testifies by signature that he/she has been informed and that he/she will observe the regulation
informs the beneficiary on the methods used during detoxification and on the prescribed treatment. In case demands outnumber available beds in the detox centre, a waiting list is made up by the centre’s physician. During hospitalisation, the beneficiary receives treatment adjusted to his/her personal needs and the needs related to substance addiction, in line with good practices guides. The treatment can be changed at any time according to the clinical condition and the evolution of the beneficiary, with a pre-notification. During hospitalisation, the physician can decide that analyses be conducted to detect the presence of drugs. If results turn out positive, the services can be re-evaluated or the beneficiary released, as appropriate. Detoxification can begin only after the conformation of the addiction diagnosis, according to the Diagnose and statistical manual for mental disorders IV/International code of diseases no. 10, further referred to as DSM IV/ICD 10, and by detection of drugs in the beneficiary’s body fluids. Detoxification period is established based on the condition and evolution of the beneficiary, but no more than 30 days. During hospitalisation, case management is ensured by the drug prevention, evaluation and counselling centre in cooperation with the centre’s staff.

In case of refusal of prescribed medication by the beneficiary throughout hospitalisation, the treatment will be re-evaluated together with a physician, and if the beneficiary continues to refuse the proposed therapeutic plan, he/she will be released. The case in which the beneficiary undergoes treatment under court order is an exception. In this case, the beneficiary is informed of the treatment, without asking for his/her consent.

B. After-care and psychosocial rehabilitation services include a range of measures addressing psychic addiction and regaining the social and professional abilities that have been lost because of drug use:

- **2000** – *specialised psychiatric services, psychological counselling and psychotherapy services* (minimum 180 days) and measures to *prevent blood borne diseases*\(^{138}\). Medical supervision is ensured in a *medical unit*, public or private, together with a *family, person or community*, that presents the necessary skills to perform this type of supervision, and the prevention of blood transmission of pathogen micro-organisms among injecting drug users is provided by *non-governmental organisations*;

- **2003** – *social services*\(^{139}\) provided within social care services that, with the help of multi-disciplinary teams, performs a comprehensive evaluation and draws a customised assistance and care plan. The novelty of the service consists in the orientation towards former drug users, those who continue using drugs and their families.

Prompted by the need to provided accessible working instruments adjusted to the needs of the specialists in the field, experts in different fields of opiate addiction, working in treatment centres, elaborated a good practices guide in 2010 during a UNODC-funded project: *Clinical guide on substitution treatment for opiate addiction*\(^{140}\). The guide is approved by the Ministry during hospitalisation. In the case of detoxification treatment, the beneficiary signs an agreement regarding medical care, which is implemented throughout hospitalisation; a breach of the regulation shall cause the patient to be released on disciplinary charges or shall lead to a re-evaluation of the therapeutic measures. The legal representative shall sign the agreement in the case of underage beneficiaries.

\(^{138}\) in which inclusion is done upon request and consist of specific counselling and enabling access to the use of single use syringes

\(^{139}\) Comprehensive range of measures and actions oriented towards the social, personal and family or group needs in order to overcome difficult situations, prevent social marginalisation and exclusion and promote social inclusion (e.g. housing homeless people over a limited period of time; provision of support measures for labour integration)

\(^{140}\) prof. dr. Dan Prelipceanu, dr. Gabriel Cicu. – Bucharest : Publication of the Romanian Psychiatric Association, 2010
The topics approached in the guide refer to:

- Evaluation awaiting substitution treatment inclusion;
- Substitute detoxification (on long and short term);
- Buprenorphine-naloxone substitution treatment. Maintenance programme (induction, stabilisation, discontinuance/detoxification, transfer from one substitute to another);
- Methadone substitution treatment. Maintenance programme (induction, stabilisation, discontinuance/detoxification, transfer from one substitute to another);
- Drug related psychiatric pathology and substitution treatment – dual diagnosis;
- Methodology for maintenance programme based on substitution medication;
- Complementary psycho-social interventions in the substitution treatment for opiate addiction.

Thus, the guide contains:

- instruments for the clinical evaluation of drug addiction in view of inclusion in substitution treatment, and for the case supervision: screening instruments, diagnosis instruments, instruments for the evaluation of drug related problems, instruments for diagnosing psychiatric co-morbidity (dual disease or pathology) and instruments for the evaluation of aspects related to motivation and mood;
- contraindications of a certain type of detoxification or treatment (based on buprenorphine-naloxone and methadone), treatment initiation rules, induction, stabilisation, discontinuance/detoxification, initiation treatment, dosage change, transfer from one substitute to another and end of treatment.

11.2.2 Target groups

The Order no. 1389/513/282 of August 4, 2008 lays down the specific organisation and operation criteria for the detoxification centre and the specific organisation and operation criteria in the case of substitution treatment with opiate agonist medication:

1. Substitution treatment inclusion criteria:
   a) age over 18 or 16 years, when the benefits of treatment exceed the secondary effects and only upon the written consent of the legal representative;
   b) DSM IV/ICD 10 diagnosis of opiate addiction;
   c) positive result of opiate tests in body fluids.

2. Guidance criteria for inclusion in substitution treatment:
   a) repeated attempts to cease drug use;
   b) drug use risk behavior;
   c) HIV/AIDS;

141 Detoxification centre – Minimum criteria on staff structure and professional skills: the Centre has the following full-time staff: a psychiatrist, a psychologist, a social worker, nurses and medical aids. a) the physician has graduated a higher education institution and is licensed in medicine, psychiatry specialisation and a member of the Medical Board in Romania. b) the psychologist has graduated a higher education institution and is licensed in psychology or equivalent, has an individual practice certification for one of the professional specialisations: psychology, psychological and psychotherapy counselling, in line with current regulations. One psychologist is ensured for 6 to 8 beneficiaries. c) the social worker has graduated a higher education institution and is licensed in social work, is a member of the Social Work National Board in Romania. There should be one social worker for 10 to 12 beneficiaries. d) the nurse is a member of the Nurses’ Board and has an individual practice certification. There should be one nurse for 6 beneficiaries. Nurses should be continuously present, and continuity should be ensured in shifts, according to the law. e) medium education medical aid; there should be one medical aid for each group of 20 beneficiaries.
d) pregnant women;
e) serious organic or psychiatric pathology;
f) poly-addiction.

The Clinical guide for substitution treatment for opiate addiction, mentioned before, refers to the following target groups: heroin users, patients infected with HIV/HBV/HCV, underage patients, pregnant women, patients with a dual diagnosis and poly-addiction. The guide specifies that launching a substitution treatment for patients with indication should not be delayed, but if the delay is unavoidable, the following categories have priority in accessing substitution treatment programmes: pregnant women, HIV infected people and their partners who are opiates users; HBV infected people (positive for anti-HBs and anti-Hbe) and their partners who are opiate users.

11.3 implementation processes

There are not factors that might complicate the application of the guide considering that:

- it is based on good practices models, guides formulated or promoted in other more experienced countries and promising results in the treatment of drug users, such as USA, Great Britain or Ireland\textsuperscript{142} or by international bodies: EMCDDA, NIDA, NIAAA, WHO, UNAIDS, UNODC;
- although not a compulsory condition, the guide is approved by the Ministry of Health, the Medical Board in Romania, Romanian Psychiatry and Psychotherapy Association and certified by the National Administration of Penitentiaries;
- It has been formulated by specialists working in opiate addiction treatment centres, with proven experience in the treatment of different aspects of opiate addiction;
- Addresses specialised staff without particular experience in the field: doctors (psychiatrists working with adults or children, infection specialist, family doctors or general practitioners), clinical psychologists, social workers, nurses, sociologists and psychotherapists working in any type of unit working on the treatment of opiate addiction.

11.4 comparison with the who guidelines

By comparison to the recommendation in the WHO guide, in Romania, the substitution treatment for opiate addiction provides:

1. Choice of treatment:
   - for the pharmaceutical treatment of opiate addiction, clinicians provide opiate substitution treatment with opiate agonist and on opiate antagonist medication (naltrexone);
   - generally, patients are not advised to use an opiate agonist as maintenance treatment; recommendations are made based on the results of patient care review;

• the antagonist pharmacotherapy, which provides for the use of naltrexone after an opiate detoxification treatment, is considered in the decision not to start a maintenance treatment with opiate agonist medication.

2. Maintenance treatment with opiate agonist medication:
• Buprenorphine-naloxone or methadone substitution treatment can be an option in the maintenance treatment with opiate agonist medication;
• In the methadone treatment, the daily dosage depends on the neuro adjustment level, does not generally exceed 20 mg and should never exceed 30 mg;
• The average dose of substitution methadone ranges from 60-120 mg/day (the average dose is 100 mg/day in most of the cases); in Romania methadone is being sold as pills of 2.5 mg, 5 mg or 20 mg.
• The average buprenorphine-naloxone maintenance dose reaches 20 mg/day;
• Methadone and buprenorphine-naloxone doses are directly supervised in the initial treatment stage;
• Awards granted during substitution treatment are settled considering the medical, psychological and social criteria (not just medical) in the frame of the customised care plan monitoring (PIA)\textsuperscript{143};
• Psychological-social support is routinely provided in correspondence with pharmacological treatment for opiate use.

3. Opiate withdrawal management:
• The guide recommends the opiate withdrawal management, the use of descending doses of opiate agonists, although alpha-2 adrenergic agonists can also be used;

\textsuperscript{143} Pursuant to the Order no. 1389/513/282 of August 4, 2008 approving the Criteria and methodology for the authorisation of centres that provide services for drug users and the Compulsory minimum standards of the organisation and operation of the centres that provide services for drug users, the Substitution programme is done according to the following methodology (privilege method): a) month 1 - 3 included - induction. Treatment induction is performed and the maintenance dose is settled by hospitalisation or daily presence in the centre; b) month 4-6 – one privilege. At the end of the first three months of substitution treatment, the physician, social worker and psychologist make an evaluation. If urine tests have turned out negative during the three months and the beneficiary complies with the care and individualised plan, the doctor can make a proposal for the beneficiary to self-administer a daily dose on one particular day/week during the next three months...Lost or destroyed doses are not replaced and the beneficiary takes sole responsibility for the product. If there has been at least one positive test in those three months, daily administration follows, similarly to the first three months of treatment and the beneficiary is re-evaluated after 3 months; c) month 7-9 – two privileges (with the observation of the conditions imposed for the first privilege); d) month 10-12 – three privileges (with the observation of the same conditions); f) after the 19th month – treatment every other week (with the observation of the same conditions); 5. Special situations: Moving to another place of residence. In case the beneficiary must leave his/her place of residence to go to another city in which substitution treatment can be continued, the doctor issues a recommendation, which includes the daily treatment dose, administration route and the unit which has an evidence of the beneficiary. If substitution treatment is not available in that place, the beneficiary receives the amount corresponding to three-day treatment. Leaving the country. In case the beneficiary is leaving the country, he/she will contact the care system available in the destination country in order to continue treatment. To this aim, the doctor will issue a medical letter in which the beneficiary’s data, the time the beneficiary spent in the centres, the daily treatment dose and administration route are mentioned. In exceptional cases, the beneficiary can carry the amount correspondent to the substitution treatment throughout the travel, within a 30-day limit, according to the law. In case the beneficiary is a prison inmate, the substitution treatment is ensured by the legal body that holds the beneficiary in custody, in line with the legal provisions. The judicial body will request data referring to the daily dose and treatment method from the doctor working in the centre which keeps records related to the beneficiary.
• Doctors should not currently use opiate antagonists in combinations with sedatives in managing opiate withdrawal;
• Psychological-social support is routinely provided in correspondence with pharmacological treatment for opiate withdrawal.

4. Assistance of opiate using pregnant women:
• substitution treatment with opiate agonist medication is used in treating opiate addiction during pregnancy;
• The buprenorphine-naloxone combination is used for opiate addiction treatment similarly to other users.

Assistance in detention areas (penitentiaries, arrest): no special guide exists, but the treatment of people in detention or on remand is similar to the one used for people at large.
SLOVENIA

11. History, methods and implementation of national treatment guidelines prepared by Milan Krek

11.1 History and overall framework

In 1988, when Slovenia was still a part of Yugoslavia, the National Expert Committee for Alcoholism and other Toxicomania, operating within the National Health Committee, adopted the opinion that methadone programmes for treatment of drug addicts would not be implemented in Slovenia. At the time, the committee emphasised that doctors refusing to comply with the ban and implementing methadone programmes for drug addicts would be subject to strict sanctions. In addition, all prisons in Slovenia were sent instructions not to implement any methadone programmes nor keep methadone in prison clinics (Šoltes 1995). In 1989, the first methadone maintenance programme in Slovenia was started by psychiatrist Vesna Novak at the Vojnik psychiatric hospital. However, she was forced to cancel the programme a year later due to profession pressure (Nolimal 1995). As the number of opioid users was increasing uncontrollably, the need for an appropriate form of treating illicit drug dependence also grew. Psychiatric dependence treatment based on outpatient and inpatient treatment was the only form of treatment available to drug users at the time. In 1991, outpatient clinics for methadone prescription were established almost simultaneously in Koper and Ljubljana without a legal basis in existing national legislation. In Koper, Milan Krek implemented a dispensary treatment method combined with methadone prescription, referral of addicts to psychiatric treatment and therapeutic communities as well as social assistance for addicts, such as employment and field work with users. Moreover, he also began carrying out drug-related harm reduction programmes. The outpatient clinic for drug addicts in Ljubljana was organised within general medical practice and managed by Branka Čelan Lucu. This clinic also maintained contact with non-governmental organisations. No uniform rules on methadone prescription were imposed at national level; consequently, cases of methadone abuse were not uncommon in practice. As methadone was only available in two centres, many drug users who were not provided with suitable treatment would drive to these centres from distant locations and burden the clinics established primarily for local purposes. There was a great need for the establishment of appropriate guidelines, which would define conditions for admission to programme, programme development and programme funding.

The first guidelines for methadone treatment were drawn up in 1992 by various authors. While they were never adopted at national level, they did provide a good starting point for developing new guidelines. The group of doctors who prescribed methadone applied these guidelines in their work. In 1993, doctor Andrej Kastelic and his co-workers prepared new Recommendations for Doctors for Treatment of Illicit Drug Dependence. In 1994, a cross-sector meeting brought about the adoption of harmonised guidelines for methadone programme implementation, which were then adopted by the Health Council and confirmed by the Minister for Health in the same year (Nolimal 1995). Thus, the guidelines became the official guidelines for the treatment of illicit drug dependence in Slovenia (Zdravstveno varstvo 2005).
The legal basis for implementing the programme had not been defined precisely before the Act Regulating the Prevention of the Use of Illicit Drugs and the Treatment of Drug Users, which was adopted by the national assembly in 1999. The Act specifies that treatment under this act includes methadone maintenance and other substitution treatments approved by the Health Council, the supreme professional coordination and advisory body of the Minister for Health in the field of health service, health care and health insurance. Furthermore, the Act defined the establishment of a network of centres for the prevention and treatment of illicit drug use in Slovenia, where substitution therapy for illicit drug dependence was also introduced. The Minister for Health was given the responsibility to designate the coordinating body for centres for the prevention and treatment of illicit drug use, which proposes the dependence treatment doctrine and verifies the implementation of the doctrine (recommendations) as well as coordinating professional cooperation between centres for the prevention and treatment of illicit drug use. The Act also specified that the structure and method of work related to the coordination of centres for the prevention and treatment of illicit drug use should be prescribed in more detail by the minister responsible for health. Moreover, the Ministry of Health is held responsible for supervising the work activity of centres for the prevention and treatment of illicit drug use and the treatment of illicit drug addicts in accordance with this Act (Official Gazette of RS, No. 98/1999). In 2002, the Ministry of Health adopted the Rules on supervising the work activity of centres for the prevention and treatment of illicit drug use, specifying in more detail the method of appointing the commission for the supervision of the work of centres as well as defining its operating rules (Official Gazette of RS, No. 43/2000). The Ministry also adopted the Rules on the structure and method of the work of services coordinating the centres for the prevention and treatment of illicit drug use in the same year. Under these rules, the members of the coordinating body are heads of centres for the prevention and treatment of illicit drug use, two representatives of the Ministry of Health of the Republic of Slovenia and two representatives of the Centre for Treatment of Illicit Drug Use. The centre coordinating body plans and submits the doctrine to the Health Council, verifies the implementation of the doctrine of illicit drug dependence treatment, and coordinates professional cooperation between centres for the prevention and treatment of illicit drug use in the Republic of Slovenia. The coordinating body can also propose the organisation of professional training to the Ministry of Health as well as suggest criteria for the work of experts in programmes for the treatment of illicit drug use to relevant professional organisations. Moreover, the centre coordinating body participates in preparing scholarly journals and other training materials and controls research projects conducted in centres for the prevention and treatment of illicit drug use in the Republic of Slovenia. The centre coordinating body cooperates with the Commission for Supervision of the Work of Centres for the Prevention and Treatment of Illicit Drug Use and may suggest regular or irregular supervision (Official Gazette of RS, No. 43/2000). The centre coordinating body was thus established as an expert body monitoring the implementation of recommendations in practice and suggesting recommendation updates. While exercising control, the Commission for Supervision of the Work of Centres for the Prevention and Treatment of Illicit Drug Use used guidelines first adopted within sectors and later by the Health Council. In its work, the commission also observed additional guidelines established by the coordinating body for centres for the prevention and treatment of illicit drug use. During the first years of operation, initial guidelines, which had been adopted by the Health Council, were constantly updated with additional decisions of the centre coordinating body, the process continues until this day. These guidelines considerably
improved the performance of centres for the prevention and treatment of illicit drug use, facilitated the development of the network of centres for the prevention and treatment of illicit drug use, harmonised the approach to dependency treatment and enabled greater accessibility of treatment for drug users.

In 2001, the coordinating body for centres for the prevention and treatment of illicit drug use of the Ministry of Health of the Republic of Slovenia issued new methadone guidelines (Kastelic et al. 2001). The guidelines were translated from the original document published by Annette Verster in Ernest Buning in 2000 within the Euro-Methwork programme. These guidelines are, of course, regularly updated at regular meetings of the coordinating body for centres for the prevention and treatment of illicit drug use in accordance with its mandate.

In individual prisons prescribing methadone as a medicinal product for the treatment of dependence was already a common practice before 1994. Later the trend slowly spread to all Slovenian prisons, which began following guidelines adopted by the Health Council in 1994. 2001 saw the introduction of the principle of new methadone guidelines issued in the same year (Kastelic et al. 2001). In 2009, Centres for the Prevention and Treatment of Illicit Drug Use took over the treatment of dependence in prisons and have since provided treatment in line with the 1994 guidelines and the 2001 Methadone Guidelines (Uprava za izvrševanje kazenskih sankcij, 2009).

*Figure 11.1: Number of prisoners involved in methadone maintenance treatment in Slovenia prisons by year from 2000 to 2009*

Source: Prison Administration of the Republic of Slovenia
11.2 Existing guidelines for the treatment of illicit drug dependence

Recommendations for doctors for the treatment of illicit drug users.

They were confirmed by the Health Council of the Ministry of Health of the Republic of Slovenia in 1994. The guidelines were targeted at:
- doctors treating illicit drug addicts;
- general practitioners, gynaecologists and obstetricians;
- psychiatrists;
- hospital emergency departments;
- prison doctors.

The recommendations specified general principles in the use of medicinal products for the treatment of illicit drug addicts, conditions for admission to treatment programmes and conditions for methadone prescription.

The guidelines defined procedures for introducing methadone treatment, stabilisation of opioid addicts in methadone treatment and principles of hospital detoxification, including principles of outpatient detoxification. Moreover, the guidelines also dealt with necessary medicinal products and procedures in the treatment of illicit drug dependence, while the second part specified conditions for implementing the methadone maintenance programme according to regions.

The Centre Coordinating Body guidelines from 2001

The guidelines were formed on the basis provided by the Euro-Methwork international network. Slovenian experts participating in the centre coordinating body then updated the guidelines with experience gained in Slovenia. At the beginning, the guidelines include an overview of doctrines of methadone use for medical purposes in the EU. The second chapter provides evidence of effective methadone use for medical purposes with significant emphasis on effective control of the spread of HIV among drug users involved in methadone maintenance treatment. The use of methadone for medical purposes reduces drug injection and the danger of HIV infection and hepatitis C spreading among drug users. Appropriate methadone treatment also causes a significant decrease in the overdose death rate among drug users. Another important side effect of methadone treatment is increased employment and education opportunities and a considerably lower rate of criminal offences committed by the individuals involved. In addition, such programmes are highly efficient in terms of public health and, given their efficiency, also cost effective. The guidelines further present good clinical practice based on good clinical diagnostics and assessment of the dependence level for individual persons. This is followed by treatment planning, which aims at reaching certain goals. In relation to goals and opportunities, planning defines various forms of treatment, such as short-term detoxification, long-term detoxification, short-term maintenance programmes and long-term maintenance programmes. Special attention is placed on introducing methadone treatment, with all necessary procedures related to introducing methadone therapy precisely defined. The guidelines also include recommended detoxification regimes and suggestions for the maintenance programme, highlighting the importance of the daily methadone dose. Additional emphasis is placed on especially vulnerable groups, such as: pregnant women, new-borns, adolescents, persons infected with HIV or hepatitis, persons suffering from mental disorders, polytoxicomaniacs, members of
minority and ethnic groups, persons serving a prison sentence and travelling drug addicts. Another important part of the guidelines defines the use of other substitute products and the method for the distribution of methadone. A special chapter deals with programme organisation and includes human resources needs, human resources training and team work organisation. Finally, the guidelines provide crucial information on how programme users can become involved in programme development and implementation, while the fifth chapter defines programme evaluation (Kastelic et al. 2001).

11.3 Guideline implementation

In Slovenia, the guidelines for the prescription of substitute medication and treatment of illicit drug dependence are always introduced through the network of centres for the prevention and treatment of illicit drug use. Based on decisions made by the coordinating body for centres for the prevention and treatment of illicit drug use, heads of centres must ensure the implementation of guidelines in everyday practice. Other fields, for instance, surgery, obstetrics, etc., are familiarised with guidelines through the centre coordinating body. The latter they forward guidelines to professional organisations, which then pass them on to doctors. Centres for the prevention and treatment of illicit drug use cooperate with regional health care institutions and doctors, providing them with guidelines when necessary. Doctors employed in centres for the prevention and treatment of illicit drug use also work as external professional counsellors in the field of the treatment of illicit drug use at health care institutions and prisons. Generally, maintenance therapy is always introduced within the network of centres for the prevention and treatment of illicit drug use. As the discipline of addictology is developing rapidly, all novelties in the field are considered by the coordinating body for centres for the prevention and treatment of illicit drug use and regularly integrated in the guidelines system. Thus, the guidelines presented serve as a basis which is constantly updated to include new approaches in line with the modern development of science and clinical practice in the field.

11.4 Comparison with WHO guidelines

Choice of treatment

In Slovenia, illicit drug addicts can freely decide in favour of a form of treatment of illicit drug dependence that they find most suitable. They can enter a therapeutic process at Centres for the Treatment of Illicit Drug Dependence, which have no waiting period and implement various forms of dependence treatment. In Slovenia, doctors conduct the following forms of substitution treatment for treating opioid dependence:

1. methadone;
2. combination of buprenorphine and naloxon in a 4:1 ratio;
3. slowly releasing morphine;
4. buprenorphine.

Illicit drug users can also attend the following programmes without a waiting period:

1. low-threshold programmes, where activities are aimed primarily at reducing the harm caused by illicit drug use;
2. therapeutic communities;
3. rehabilitation programmes.
Associated mental disorders are also treated in outpatient psychiatric clinics and psychiatric hospitals. It must be pointed out that cooperation between all programmes is at a high level, thus enabling programme users to move between programmes in a smooth and timely manner.

Management of withdrawal
In Slovenia, withdrawal as a result of opioid discontinuation is first treated with psychosocial therapy; if the latter proves unsuccessful, medical therapy with non-opioid medication is introduced (analgesics, sedatives and soporifics). In case of failure and after consultation with a psychiatrist, the doctor and the patient may decide in favour of substitution treatment for dependence. Counselling, family therapy and behavioural therapy are also organised in the process.

The following forms of outpatient treatment of withdrawal are available in Slovenia:
1. detoxification and establishment of abstinence without medical therapy and with the help of psychotherapy;
2. detoxification with the help of non-opioid medication;
3. detoxification with the help of opioid medication;
   a) short-term detoxification with opioid medication;
   b) long-term substitution treatment with opioid medication, lasting more than 6 months.

Most outpatient forms of detoxification can also be carried out in prisons, whereas slowly releasing morphine may not be used there.

Hospital detoxification
This is carried out in the Ljubljana centre for treating drug addicts as hospitalisation. Detoxification is carried out at the inpatient unit, using medical therapy as well as psychosocial treatment and interventions.

Dependence treatment in pregnancy
When pregnancy is confirmed, the user of illicit drugs is advised to immediately begin substitution maintenance treatment of opioid dependence. Maintenance therapy is provided until the end of pregnancy, using methadone or buprenorphine. In this case, doctors from centres for the prevention and treatment of dependence work together with gynaecologists who monitor the pregnancy, social services and non-governmental organisations which administer pregnancy programmes.

WHO guidelines coherence

<table>
<thead>
<tr>
<th>Name of Assessors: Milan Krek IVZ</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Choice of treatment</td>
</tr>
<tr>
<td>1.2 For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>☑</td>
</tr>
<tr>
<td>Section</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>1.3</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>2.1</td>
</tr>
<tr>
<td>2.2</td>
</tr>
<tr>
<td>2.3</td>
</tr>
<tr>
<td>2.4</td>
</tr>
<tr>
<td>2.5</td>
</tr>
<tr>
<td>2.6</td>
</tr>
<tr>
<td>2.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>Management of opioid withdrawal</strong></th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used. Do the present guidelines include this recommendation?</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td>Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3</td>
<td>Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4</td>
<td>Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal.</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Do the present guidelines include this recommendation?
<table>
<thead>
<tr>
<th></th>
<th>Pregnancy</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td><strong>4.1</strong> Opioid agonist maintenance treatment should be used for the</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>treatment of opioid dependence in pregnancy. Do the present guidelines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>include this recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td><strong>4.2</strong> Methadone maintenance should be used during pregnancy in</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>preference to buprenorphine maintenance for the treatment of opioid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>dependence; although there is less evidence about the safety of</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>buprenorphine, it might also be offered. Do the present guidelines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>include this recommendation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**WHO guidelines coherence:**

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>1.</td>
<td>Do the present guidelines agree with the “Clinical guidelines for</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>withdrawal management and treatment of drug dependence in closed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>settings” in hospitals</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SLOVAKIA

Review of relevant legal norms
A/ Essential legal frameworks applicable in the present territory of the Slovak Republic were and are:

Constitution Act No. 23/1991, by which there is Declaration of Basic Right and Privileges stated as Constitution Act of Federal Assembly of the Czech and Slovak Federative Republic.


B/ Treatment, of patients with drug dependence in the Slovak Republic, adjusted by general as well as special legal regulations; the essential regulation is:


Further on, there are areas of health care:

Act No. 577/2004 Coll. on The Scope of Health Care Cleared based on public health insurance and on payments for services related to health care provision, amended by Act No. 661/200;


Act No. 580 Coll. on Health Insurance amended by Act No. 594/2007;


Act No. 126/2006 Coll. on Public Health;


Act No. 140/1998 Coll. on Medicines and Medical Aids amended by Act No. 270/2007;

Act No. 219/1996 Coll. on Protection from The Abuse of Alcohol Beverages and on the Establishment and Operation the Sobering-up Stations amended by Act No. 214/2009 Coll...

These key Acts are in gestion of the Slovak Republic Ministry of health.

C/ Important related legal norms in other sectors, in which there are:

Act No. 305/2005 Coll. on Social Legal Child Protection and Social Guardianship and on change and amendments of some Acts, which is in gestion of the Slovak Republic Ministry of Labour, Social Affairs and Family;

D/ In gestion of the Slovak Republic Ministry of Justice:


**E/** Specific legal norms – guidelines for treatment elaborated in gestion of the Slovak Republic Ministry of health:

**Concept of the section Drug Dependences.** Official Publication of ministry of health 1995, part 8 – 9;

Professional direction on standards for diagnostics and treatment in the section Drug Dependences Official Publication of ministry of health 2003, part 12 – 15;

Methodical instruction on provision of methadone maintenance treatment for patients with dependence on opiates and with chronic course of the disease Official Publication of ministry of health 2004, part 21 – 27;

Concept of health care in the section Medicine of Drug Dependences Official Publication of ministry of health 2006

**F/** Further related ordinances and regulations issued by the Slovak Republic Ministry of health:

Regulation of the Slovak Republic Ministry of health No.428/2006 Coll., that determines minimum requirements for personal provision of material-technical equipment of individual types of medical facilities;

Regulation of the Slovak Republic Ministry of health No. 540/2001 Coll. that constitutes binding standards for Health Statistics;

Decree of the Slovak Republic Government No. 322/2006 Coll. on the method of further education of medical workers, constitution of specialised departments and constitution of certified work activities;


Decree of the Slovak Republic Government No. 751/2004 Coll. on Public Minimum Network of Health Care Providers;

Decree of the Slovak Republic Government No. 776/2004 Coll., by which the medical performances catalogue is issued;

Decree of the Slovak Republic Government No.777/2004 Coll., by which the health insurance list is issued;
Official Publication of the Slovak Republic Ministry of health part 4 – 9 the year 2005: 9 Professional regulation Of the Slovak Republic Ministry of health on provision management of nursing care in institutional healthcare facility;

Official Publication of the Slovak Republic Ministry of health part 35 – 46 year 2005: 68. Professional regulation Of the Slovak Republic Ministry of health on administration of nursing care documentation;


Regulation of the Slovak Republic Ministry of health No.306/2005 Coll., by which the list of subsidiary/similar diagnoses is constituted;

Regulation of the Slovak Republic Ministry of health No.363/2005 Coll., by which the scope of nursing care practice is determined, provided by a nurse individually and in cooperation with a doctor;


Charta of patients’ rights

Annexes:
Methodical instruction for provision of methadone maintenance treatment (MUP) for patients with dependence on opiates and with chronic course of disease

Professional regulation on standards for diagnostics in the section Drug Dependences

Act No. 214/2009 that changes and amends Act of the NR SR No. 219/1996 Coll. Coll. on Protection from the Abuse of Alcoholic Beverages and on the Establishment and Operation the Sobering-up Stations and on changes and amendments to some Acts

Concept of Health Care in the section Medicine of Drug Dependences

Concept of the section “Drug Dependences”

BACK TO TOP
FINLAND

11. Drug use treatment recommendations

Background

In the early 2000s, there were two recommendations valid in Finland concerning substance abuse treatment: the general substance abuse service quality recommendations published by the Ministry of Social Affairs and Health and the Association of Finnish Local and Regional Authorities (Päihdepalvelujen laatusuositukset, 2002) and the Current Care guidelines for drug abuser care published by the Finnish Medical Society Duodecim (2006). The Current Care recommendations are evidence-based clinical practice guidelines which the Finnish Medical Society Duodecim has been publishing since 1997; there are now 97 recommendation documents covering a variety of areas of medicine.

The preparation and application of general quality recommendations represents a type of control by information that was typical of the early 2000s. The various quality recommendations for substance abuse services are considered to have helped substance abuse service units, local authorities and regional licensing and control authorities in implementing the Act on Welfare for Substance Abusers and to have specified in more detail what exactly is meant by high quality in substance abuse services. These recommendations have been the most useful in helping substance abuse care units to self-evaluate the quality of their operations. The structured quality assessment forms drawn up for substance abuse care units on the basis of the quality recommendations have been a good tool for developing the general circumstances of the units (personnel, facilities, treatment processes) and for comparing units. However, the quality recommendations for substance abuse services have not contained any specific recommendations for treatment for substance abusers.

The drug use treatment recommendation in the Current Care series published by Duodecim is the only Finnish recommendation that specifically addresses drug use treatment. Entitled Treatment of Substance Abusers, it was published online and in print on 23 January 2006. This guideline was drawn up by a working group appointed by the Finnish Medical Society Duodecim and the Finnish Society of Addiction Medicine, consisting of physicians and other top experts in the field. The document is an evidence-based clinical guideline whose recommendations fall into four categories according to the strength of the evidence backing them up.

Treatment of Substance Abusers, Current Care Guideline

The Current Care Guidelines are summaries of the diagnostics of and effectiveness of treatment for individual disorders, drawn up by the best experts in the field. They are not a substitute for the personal judgement of a physician or other health care professional in diagnosing any individual patient or in deciding on his/her care.

The purpose of the Guideline is to provide information to clarify treatment of drug problems, to improve cross-discipline co-operation, to promote networking and to influence attitudes. The Guideline is intended for personnel in both basic and technical fields.
specialist medical care, for private physicians, for special substance abuse services, for social services, and for substance abuse NGOs.

In the Current Care Guidelines, the scientific value of evidence is rated by a four-tier ranking. The Guideline is grouped into evidence reviews separated by sub-headings, the statements in these reviews being explained with a brief description of the original research or system survey behind them. The scientific validity of each of these is given as a letter (A to D) immediately after the description, and the bibliography references are given as endnotes.

The key message of the Treatment of Substance Abusers Current Care Guideline is about the problems of drug use and the importance of a diversity of treatment. Drug addiction involves significant threats to personal health. Drug use is often linked with mental health problems, and psychiatric expertise is needed in coping with these. An open, neutral and non-judging approach is needed for treating drug problems and preventing their adverse impacts. The Guideline emphasises the importance of a relationship of trust in treatment and psychosocial methods as the basis for care. Substitution treatment for opioid addiction is noted to be effective. Providing treatment for a drug abuser is ultimately less expensive for society than not providing treatment.

The Guideline covers health problems caused by intoxicating substances and the mixed use of drugs and benzodiazepines, how to identify them, what treatments are given for the various substances, and the care system. Other addictive substances (such as nicotine) and abuse of pharmaceuticals are not discussed. There is a separate Guideline for Treatment of Alcohol Abuse. Legal problems are only addressed as regards drug testing and working life. The Guideline does not discuss primary or secondary prevention of drug problems. The problems of children and young people are only addressed as child welfare issues.


Implementation

The Guideline is available in the online databases most commonly used by Finnish physicians, such as www.terveysportti.fi. A printable version of the Guideline (http://www.terveysportti.fi/xmedia/hoi/hoi50041.pdf, PDF) in Finnish, summaries in Finnish and in English, as well as versions for patients in Finnish and in Swedish are available at www.kaypahoito.fi.

Also, the Finnish Society of Addiction Medicine has held several training sessions for presenting the contents of the Guidelines to health care professionals.

When the Current Care Guidelines are updated in the future, a suitable indicator will be determined for each Guideline. The aim is to evaluate the introduction of a recommended procedure or treatment and changes in treatment practices in individual organisations or nationwide. The proposed indicators mainly reflect changes in processes. This project was launched in spring 2009.
**History and overall frameworks**

**Description of the national situation**

National guidelines are drafted by the Swedish National Board of Health and Welfare (NBHW), which is an independent authority. Guidelines are prepared in areas of healthcare that concern many people and cost society a great deal of money. There should also be a need for guidance. Publications include both a support for management and governance, which is probably of more interest to decision makers, and the scientific documentation on the internet, which is more for those who work in healthcare. Today, work is mainly conducted in a special unit at this authority, which describes the objective of the work on guidelines as follows: “We want to contribute to patients and users receiving equal healthcare throughout the country. We do so by recommending the most effective treatments and methods. However, we also do so by pointing out which treatments and methods should not be included in healthcare because they are ineffective and perhaps even harmful.”

Internationally, the NBHW’s national guidelines are unique in many ways. However, the most prominent characteristic is the work on systematic and open priorities.

Most European guidelines are just like the Swedish, evidence-based and strive to remove measures with insufficient effects or applicability. However, the work on systematic and open prioritisations is unique to the Swedish guidelines.

**Method for systematic and open prioritisations**

Based on a common platform and established model, NBHW obtain help from independent experts that systematically seek, review, evaluate and rank methods based on fundamental ethics and the best available science and tried experience.

The prioritisation group consists of people with a base in healthcare or the social services. The group ranks condition-treatment pairs based on a collective evaluation of how serious the condition is, what effect the treatment has and the treatment’s cost-effectiveness. The strength of the existing scientific evidence for the treatment’s effect and cost-effectiveness is also significant to the ranking. Ethical considerations also influence the prioritisation group’s ranking.

What is also unique is that the documentation on the prioritisation decisions, the grounds and the reasoning are openly presented for all who want to study them.

**Most like British NICE**

The guidelines that are otherwise most similar to the Swedish guidelines are those prepared by the National Institute for Clinical Excellence (NICE) for healthcare in the United Kingdom. Like the NBHW’s national guidelines, the British guidelines are drafted by independent authorities with help from experts. One difference is that NICE does not rank its recommendations.

**Not tied to commercial interests**

Compared with various European guidelines that are prepared in cooperation between the specialist associations of many different countries, the Swedish
guideline work is financed by the state and is thereby not tied to commercial interests.

In addition, the guidelines address the entire healthcare chain and have multi-professional participation. Health economy assessments are another important part of the National Board of Health and Welfare’s National Guidelines. The open process and broad basis among decision-makers in the healthcare system are also strengths.

**Published guidelines**
- Depression and anxiety
- Diabetes
- Stroke
- Cardiology
- Addiction
- Breast, colorectal and prostate cancer
- Blood clots/VTE
- Asthma and COPD
- Hip fractures

**Guidelines under production**
- Lung cancer
- Motor organ diseases
- Disease prevention methods
- Dental care

**Preliminary guidelines**
- Schizophrenia
- Dementia

**Towards “evidence-based” addiction treatment**
The strive for a more research-based focus in the care and treatment of individuals with abuse and dependence problems concerning alcohol and other drugs first became noticeable at the end of the 1980s. As Blomqvist (Abrahamson et al., 2009) writes: “The development of Swedish addiction treatment has, in the opinion of many people, been controlled more by healthcare-ideology convictions, shifting therapeutic fashions and political and economic fluctuations than by research-based knowledge regarding the scope and nature of addiction problems, the patient’s needs and the consequences of various interventions (...). Another way of describing the development is to say that addiction treatment time and again instilled hopes for future success in the form of new and promising ideas or models, which it later had difficulty in fulfilling (Lindström, 1986, Lindström, 1992). Major expectations have been tied to new pharmacological preparations, new psychosocial treatment methods and new coordinating strategies, such as “matching”, which was the (now deceased) mantra of the 1990s.”

**Research surveys**
A dissertation by Lindström (Lindström, 1986, Lindström, 1992): “Val av behandling för alkoholism - en studie av missbrukarvårdens förutsättningar, organisation och resultat” [Choice of treatment for alcoholism – a study of the conditions, organisation and results of addiction care] from 1986 (also published in English in 1992 as a revised version entitled: “Managing alcoholism – matching clients to treatment”) can be said to constitute a pioneering work in Sweden with regard to systematic reviews of international research in the area of addiction treatment. It received considerable
attention in the profession, in part because it showed that the improvements that could be observed directly after completed treatment subsided relatively quickly. A more consistent matching – “right patient to right treatment” – was seen as the most important change in order to achieve more long-term stable treatment results.

The “evidence based” concept began to be used more frequently at the end of the 1990s, also with regard to the social services. Within the framework of the NBHW, a special centre was established (later reorganised into the “Institute for the development of methods in social work – IMS”), which had the task of promoting a more research-based approach in various ways, including in the addiction treatment provided by the social services. An anthology entitled “Treatment of alcohol problems” was published by the centre in 2000 and included contributions from some of the most prominent Swedish researchers in the field.

In 1996, a researcher at Lund University (Fridell, 1996) published a research survey on “Institutional forms of treatment of addiction – organisation, ideology and results”, which was particularly focused on the treatment of drug abusers. This is the first time that the treatment of drug abuse was the subject of a Swedish knowledge compilation.

In 2001, the Swedish Council on Technology Assessment in Health Care (SBU) published an “evidence-based knowledge compilation” on the “Treatment of alcohol and drug problems” (Statens beredning för medicinsk utvärdering [SBU], 2001a, Statens beredning för medicinsk utvärdering [SBU], 2001b), comprising two volumes, of which the second specifically discusses “psychosocial treatment of drug dependence” and “pharmacological treatment of opioid and cocaine dependence”. SBU’s compilation is based solely on randomised controlled trial (RCT) studies, where a randomly selected group received a certain “specific” treatment and another, likewise randomly selected group, received a “standard treatment”. Meta analyses of the values for outcomes were conducted on studies where possible.

Substitution treatment
A national programme for maintenance treatment with methadone was introduced in Sweden in 1966 on a trial basis at Ulleråker Hospital in Uppsala. This type of treatment was long controversial, however, both from drug-policy and healthcare-ideology perspectives. It was first approved in 1983 as a treatment in agreement with “science and tried experience”, but was surrounded by multiple restrictions and special regulations. The number of patients that could be undergoing methadone treatment was limited – from 150 at the beginning and gradually increased to 800 in 1999.

Various evaluations, both of the Swedish programme and internationally (presented in SBU’s report, among others), have indicated the effectiveness of well-managed methadone treatment. This, together with the introduction of buprenorphine in 1999, which was more freely prescribed and where a major leakage to the illegal market occurred, led to the NBHW approving changed regulations for substitute treatment in 2004. This change meant that the ceiling for the maximum number of treated clients was removed. The objective was to strengthen the patient’s position, to make the treatment available to all who needed it, to apply more stringent requirements on close cooperation between healthcare and the social services, and to reduce the leakage.

A knowledge survey prepared by an expert group (“Pharmaceutically assisted treatment of heroin abusers”) and a handbook that developed the provisions of the
regulations were published in 2004 (Socialstyrelsen, 2004) and supplemented the authoritative regulation. Somewhat revised regulations entered into effect as of 1 March 2010.

**National guidelines**

The NBHW’s national guidelines for addiction treatment were issued in 2007 (Socialstyrelsen, 2007c, Socialstyrelsen, 2007d). This is the first time that the NBHW prepared guidelines addressed to both the social services and healthcare.

The objective of the guidelines is to make addiction treatment more uniform. The guidelines are based on underlying evidence prepared by a large number of experts which was refined and ultimately formulated by a workgroup within the NBHW. A reference group contributed opinions on both the work process and the texts included in the guideline document.

The document includes some 50 recommendations and concerns prevention and early discovery, treatment methods and follow-up.145 The guidelines present what methods are the most effective and have scientific support. There is also a list of what measures and efforts have weak or non-existent support.

The guideline document also contains a special section on implementation that primarily concerns the organisation and skills development in addiction treatment.

**Existing guidelines: narrative description of existing guidelines**

**Description of existing guidelines**

*Guidelines for pharmaceutically assisted treatment of opiate dependence*

**Authoritative regulation**

The NBHW’s regulations and general guidelines regarding treatment with methadone or buprenorphine in opiate dependence (SOSFS 2009:27) stipulates that substitution treatment may only be given at a medical facility that professionally provides healthcare in accordance with the Health and Medical Services Act (SFS 1982:763). The operations must be reported to the NBHW directly after they commence, as well as if they are discontinued. In addition, it is also stipulated that only a physician with specialist expertise in psychiatry who is active at such a medical facility may prescribe substitution treatment – to a patient who must be a minimum of 20 years of age and has had documented opiate dependence for at least one year (if “exceptional grounds” exist, individuals under the age of 20 may be treated, however).

Substitution treatment may not be administered if the patient is dependent on alcohol or other drugs, has been excluded from addiction treatment in the past three months, or is subject to compulsory institutional care. Exceptions from these provisions may, however, be made if a person has HIV or some other serious infection or disease.

A detailed treatment plan must be established for each patient – in consultation with the social services if necessary – and the responsible physician is charged with an obligation to continuously monitor the treatment plan, and review the plan at least once a year. The regulation also contains rules on the circumstances under which treatment should be discontinued: insufficient participation, repeated relapses into

---

145 Treatment of opiate abuse is not discussed in the guideline document, since a regulation and knowledge compilation for this area was published previously.
drug abuse, extensive alcohol abuse, manipulation of urine samples, or narcotics crimes.

When treatment begins, the pharmaceuticals should be administered under the supervision of healthcare personnel at regular return visits to the medical facility, but may also be administered at another medical facility if special grounds exist. However, if specific requirements are met, the physician may let the patient handle his or her medication on his or her own.

Knowledge survey
In the summary section of the document, it is noted that “several psychosocial treatment methods are documented to be effective in heroine dependence. All are characterised by a high degree of structure, and focus on the actual abuse behaviour. In scientific studies, positive effects of such treatment have only been able to be shown if the patient received active pharmaceutical treatment at the same time.” It is also confirmed that the best results are achieved when psychosocial methods and pharmaceutical treatment are combined in what is called “pharmaceutically assisted treatment” (SOSFS 2009:27).

With regard to the medications on hand, it is said that “the documentation is most extensive for methadone. Good effects are achieved with this substance in terms of retention in treatment, decreased abuse and improved social function. The substance also has a documented effect in terms of reducing mortality. For buprenorphine, there is documentation that is more limited in scope, but agrees with the same measurements of effect. The substance offers an attractive pharmacological profile, since its partial agonist characteristics limit the risk of overdose and the risk of developing dependence. The documentation for naltrexon is divided, and although positive effects have been described on the short term, few appear to complete the treatment. The substance can probably be of significance to patients in an early phase of dependence, or for socially stable patients where there is considerable social pressure to remain in treatment” (SOSFS 2009:27).

Attention is paid to the risk of leakage to other substance abusers in treatment with agonists, but it is emphasized that “with well-prepared use in high-quality operations, these risks can be minimised at the same time that the positive treatment effects can benefit the patients” (SOSFS 2009:27).

The document recommends “a graduated treatment strategy that seeks to achieve the best possible effect at the lowest possible level of risk in each individual case”. In concrete terms, this strategy means that “patients that are in the early stages of dependence development and/or have a high degree of social stability can (...) be experimentally treated on the lowest level, which entails a focus on psychosocial methodology, with a possible addition of naltrexon. In structured, regular follow-up of the kind recommended here, it quickly becomes clear if this treatment is sufficient for the patient, as well as which patients should continue to the next level. This level includes psychosocial treatment supported by medication with buprenorphine. Sufficiently long, consistently implemented treatment, followed by structured evaluation at this level will also indicate if the strategy is appropriate. If this is not the case, methadone-maintenance treatment currently represents the best documented and probably most effective treatment for reducing the risks of morbidity and mortality” (SOSFS 2009:27).

By way of conclusion, it is emphasized that “the treatment process should be characterised by flexible adjustment over time. The supporting and supervisory
structure should, for most patients, be pronounced in the initial phases of the treatment. As the patient gradually stabilised in terms of social function and being free from drugs and his or her ability to take personal responsibility for the treatment increases, focus should shift to promoting his or her acceptance of personal responsibility” (SOSFS 2009:27).

Comparison with WHO’s guidelines

The Swedish guidelines differ on a few points from the WHO recommendations. WHO recommends methadone as the primary choice for “most patients”, while the Swedish guidelines “graduated treatment strategy” described above recommends that treatment can begin with naltrexon or buprenorphine after an assessment of the patient’s social situation and/or degree of dependence problems. The Swedish guidelines also differ somewhat from the WHO guidelines with regard to the recommended size of the doses (see table 11.1).

---

Table 11.1 WHO guidelines coherence

<table>
<thead>
<tr>
<th>Name of Assessor:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peter Valverius, M.D.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. **Choice of treatment**

1.2 For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment.

<table>
<thead>
<tr>
<th>Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

1.3 For opioid-dependent patients not commencing opioid agonist maintenance treatment, consider antagonist pharmacotherapy using naltrexone following the completion of opioid withdrawal.

<table>
<thead>
<tr>
<th>Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

2. **Opioid agonist maintenance treatment**

2.1 For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine.

<table>
<thead>
<tr>
<th>Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

2.2 During methadone induction, the initial daily dose should depend on the level of neuroadaptation; it should generally not be more than 20 mg, and certainly not more than 30 mg.

<table>
<thead>
<tr>
<th>Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

2.3 On average, methadone maintenance doses should be in the range of 60–120 mg per day.

<table>
<thead>
<tr>
<th>Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

2.4 Average buprenorphine maintenance doses should be at least 8 mg per day.

<table>
<thead>
<tr>
<th>Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

2.5 Methadone and buprenorphine doses should be directly supervised in the early phase of treatment.

<table>
<thead>
<tr>
<th>Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

2.6 Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review.

<table>
<thead>
<tr>
<th>Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>

2.7 Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence.

<table>
<thead>
<tr>
<th>Do the present guidelines include this recommendation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
</tr>
</tbody>
</table>
### 3 Management of opioid withdrawal

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used. Do the present guidelines include this recommendation?</td>
<td>□</td>
</tr>
<tr>
<td>3.2</td>
<td>Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</td>
<td>□</td>
</tr>
<tr>
<td>3.3</td>
<td>Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal. Do the present guidelines include this recommendation?</td>
<td>□</td>
</tr>
<tr>
<td>3.4</td>
<td>Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal. Do the present guidelines include this recommendation?</td>
<td>□</td>
</tr>
</tbody>
</table>

### 4 Pregnancy

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy. Do the present guidelines include this recommendation?</td>
<td>□</td>
</tr>
<tr>
<td>4.2</td>
<td>Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered. Do the present guidelines include this recommendation?</td>
<td>□</td>
</tr>
</tbody>
</table>

---

**National guidelines for addiction treatment**

The document “National guidelines for addiction treatment” was published by the NBHW in 2007 (Socialstyrelsen, 2007c, Socialstyrelsen, 2007d), and is based on the work in five expert groups that resulted in “underlying evidence” comprising 500 pages. The aforementioned knowledge surveys from SBU and CUS constituted the basis for this work, and were supplemented by reviews of treatment studies up to and including mid-year 2004.

The work of the expert group is summarised in five chapters:
- Discovery and prevention work
- Assessment instruments and documentation
- Narcotics – psychosocial treatment and pharmaceutical treatment
- Alcohol – psychosocial treatment and pharmaceutical treatment
- Pregnant women

One more chapter discusses the subject of “addiction and simultaneous psychiatric and/or somatic disorders”.

As a guide for addiction treatment in both healthcare and the social services, 53 different recommendations are presented with regard to specific interventions and measures. The recommendations, which are not ranked, are based mainly on a total appraisal of the degree of scientific evidence (graduated to four levels according to the evidentiary value and uniformity of the results) and an economic assessment. Sometimes, organisational possibilities and obstacles have played in for which measures are recommended.
Recommendations for treatment of individuals with drug abuse or dependence

Five psychosocial treatment methods are recommended:

- Cognitive behavioural therapy with a focus on addiction
- Brief intervention/Motivational Interviewing (MI)
- Community Reinforcement Approach (CRA) treatment
- Dynamic therapy
- Family therapy with a focus on addiction.

In a comment, it is noted that “a factor common to the methods that exhibit an effect is that the treatment is characterised by a clear structure, focus on the addiction, well-defined measures and detailed guidelines (manual)”.

Furthermore, for this client/patient category, it is recommended to:

- Identify and provide support to the individuals in their networks that can support treatment and rehabilitation.

Specifically for individuals with cannabis abuse or dependence, it is recommended that:

- Treatment should be focused in part on immediate abstinence with supervised urine testing and in part on disruptions in cognitive functions.

Specifically for individuals with opiate abuse or dependence, it is recommended that:

- The medications Methadon or Subutex be administered in combination with psychosocial treatment in accordance with the National Board of Health and Welfare’s regulations.

Specifically for individuals with cocaine abuse or dependence, the following are recommended:

- The medication disulfiram (Antabus)
- Cognitive behavioural therapy.

The chapter “Narcotics – psychosocial treatment and pharmaceutical treatment” in the guideline document describes the scientific, organisational and economic grounds and motivations for these recommendations in more detail.

Expert group’s factual documentation

For in-depth studies of that presented in the guidelines and a more in-depth description of the background of the recommendations, the expert groups’ “underlying evidence” – a document of slightly more than 500 pages – is available on the website of the NBHW.

Implementation process

Guideline implementation process

Guidelines for maintenance treatment of opiate dependence

County councils and municipalities were informed of the regulations and recommendations for pharmaceutically assisted treatment of opiate abusers through a newsletter from the NBHW. A nationally coordinated operations audit of maintenance treatment was conducted by the NBHW in spring 2007. The results are summarised in the report (Socialstyrelsen, 2007b) as follows:

“According to estimates, there are approximately 28,000 people in Sweden today with serious drug abuse. One of the sub-objectives of the Swedish narcotics policy is to get people with addiction problems to end their abuse. One way of achieving the sub-objective is to offer opiate..."
abusers pharmaceutical treatment in the healthcare system under
controlled conditions.

On 1 January 2005, the National Board of Health and Welfare’s
regulations and general guidelines regarding pharmaceutically assisted
maintenance treatment of opiate dependence (SOSFS 2004:8) entered
into effect. Under these regulations, all medical facilities that are
specially established for dependence care and have registered with the
National Board of Health and Welfare have the opportunity of offering
such treatment. The provisions include strict and formal requirements
on caregivers, clinic managers and treating physicians.

With the aim of mapping what places in Sweden and the extent to which
pharmaceutically assisted maintenance treatment of opiate dependence
is conducted and then follow up and examine the application of the new
regulations, the National Board of Health and Welfare’s regional
supervisory units conducted a nationally coordinated operations audit in
spring 2007. The audit comprised all county councils and regions and
all 53 medical facilities where these activities are conducted. In
connection with the audit, the National Board of Health and Welfare
also gathered opinions from a number of social service administrations,
patients concerned and the Swedish Prison and Probation Service.

This survey indicated that 2,440 patients were under treatment on 31
December 2006. Of these patients, 1,894 were treated in public
healthcare (39 institutions) and 546 in private healthcare (14
institutions). Operations were conducted in all county councils and
regions except two (Blekinge and Jämtland).

After the audit, the National Board of Health and Welfare drew the
following conclusions:

- There are unacceptable deficiencies in terms of the county
councils’ statutory obligations to plan their healthcare based on
prevailing needs. Only eight of the surveyed county councils and
regions provided information on the estimated need for
pharmaceutically assisted maintenance treatment of opiate
dependence. In addition, planning activities take place with
private caregivers in only three county councils.

- In the majority of county councils, there are no such guidelines
for the operations that the caregivers, under the regulations, are
obliged to establish. In addition, there are no written directives
and procedures for maintenance treatment in around half of the
county councils.

- Half of the county councils are unable to meet the demands of
the care guarantee for the patient group concerned. This
conclusion is based on the study commissioned by Mobilisation
against Narcotics (MOB).

- In the operations (the clinics), there were more deficiencies in
formal respects. There were varying degrees of a lack of
established, documented targets and procedures pursuant to
the provisions of the regulations. In some operations, there was
a lack of treatment plans as well as procedures for cooperation
with the social services in the medical assessment of whether to
provide maintenance treatment. Furthermore, in approximately
one fourth of the clinics, there were no local instructions for the handling of pharmaceuticals and procedures for the physician disclosure obligation under the Firearms Act.

The audit did not encompass purely medical and psychosocial patient treatment. However, from the roughly 400 questionnaire responses received from patients under treatment, it is unambiguously clear that they are very satisfied with the treatment and that they have been accepted for treatment.

In the opinion of the National Board of Health and Welfare, it appears as if some county councils – for various reasons – do not prioritise the care of this patient group, although this type of care meets the requirements of science and well-tried experience. The questionnaire responses from county councils indicate a lack of commitment in the issues in several cases. The audit also noted that there is a clear risk that patients, depending on where in the country they reside, have differing chances of receiving adequate care and treatment. However, like all other patients, these patients are also covered by the caregivers’ responsibilities under the Health and Medical Care Act.

The audit shows that significant improvements are required in terms of supply and availability to pharmaceutically assisted maintenance treatment of opiate dependence. Formal guidelines, directives and procedures are also required. The National Board of Health and Welfare will follow up on the measures on the part of the caregivers and the clinical managers within the scope of its on-going supervisory activities.”

At present (autumn 2010), there are a total of 64 units that provide pharmaceutically assisted maintenance treatment in Sweden.

Implementation and educational support for national guidelines
In 2007, the NBHW published a text that aimed to constitute an “implementation and educational support” for the national guidelines published in the same year (Socialstyrelsen, 2007a). It emphasizes the significance of achieving cooperation and collaboration between the activities of healthcare and the social services for the care and treatment of individuals with addiction problems. The text also discusses the importance of specialisation within the primary municipal social services, which for small municipalities may presuppose that multiple municipalities jointly build up specialised units. In addition, the contact between addiction care and self-help organisations and other supportive networks is emphasized as an important complement.

“Knowledge for practice”
In April 2008, the Government adopted a strategy for the development addiction care up to and including 2010. Within the scope of this strategy, the state and the Swedish Association of Local Authorities and Regions (SKL) signed annual agreements regarding the implementation of national guidelines in the area under the name “Knowledge for practice”. In the initial agreement, it was established that the work should be long term.

A fundamental premise is that municipalities (social services) and county councils/regions (healthcare) must take joint responsibility for development. In
September 2009, all county councils/regions and 150 (of 290) municipalities were involved in the development work.

The development work will continue during 2010 on the sub-objectives that the parties:

• have developed the healthcare chain so that necessary efforts are available and can be offered at a local level
• have clarified the division of responsibility between the social services and healthcare, and developed the structures for collaboration
• have personnel with adequate and up-to-date expertise to perform their duties in accordance with the national guidelines, which are based on current research, experiences of practitioners and choices of the patients.

For the work in 2010, the Government allocates SEK 29,550,000 (3.2 million Euro) in the scope of the agreement. For the three-year period, the Government has allocated approximately SEK 85 million (9.2 million Euro) in total to the implementation work.

SKL offers those who work with addiction treatment in the participating counties and municipalities training in a number of areas, e.g.

• implementation methods
• process management
• management training for sustainable development
• training of instructors in assessment instruments such as AUDIT, DUDIT and ASI
• training of instructors in Motivational Interviewing (MI).

Evaluation and research concerning the introduction of the guidelines
The implementation of “Knowledge for practice” shall be evaluated by researchers at Lund University on behalf of the NBHW and reported to the Government no later than 31 December 2011. However, in some parts of the country, evaluation projects of various types have already been conducted.

In 2009, the Jönköping County Administrative Board conducted a questionnaire study of the county’s 13 municipalities, which is presented in the report “How are the National Board of Health and Welfare’s national guidelines for addiction treatment used?” One municipality did not respond to the survey, but the other 12 said that they were aware of the guidelines. Five municipalities had reached formal agreements regarding implementation, but the others had begun to introduce them “in some manner”. However, seven municipalities said that they had not been allocated resources for the implementation.

In connection with the publication of the NBHW national guidelines for addiction treatment, development funding was granted for Göteborgs Implementering av Riktlinjer [Gothenburg’s Implementation of Guidelines – GIR] and Riktlinjer i Samverkan [Guidelines In Collaboration – RIS] in Region Västra Götaland. The objective of RIS and GIR is for the collaboration between the three principals – municipality, region and correctional care – to achieve a level of quality at the local level that benefits the individual. RIS is county-wide while GIR is limited to Gothenburg.

The objective of the projects has been for personnel in correctional care (non-institutional), healthcare (psychiatry, dependence care and primary care) and social services who meet and care for people at risk of or with established addiction to
obtain greater understanding of the guidelines, better opportunities to implement the guidelines and a stronger desire to use the guidelines.

RIS’ assignment primarily comprised four different parts: arranging knowledge conferences, establishing and supporting five sub-regional workgroups, recruiting and training competence supporters and constructing a website for knowledge distribution. The work within Gir has largely been coordinated with RIS.

The consulting firm engaged to evaluate both of the connected projects confirms in its report (Ramböll Management Consulting, 2010) that “… the knowledge conferences were the most important contribution to increasing the personnel’s understanding of the guidelines. The municipality’s personnel, who appeared to have been well represented at the conferences, are assessed to have good knowledge of the guidelines and the conferences are judged to be important to distributing information about the guidelines and their implementation. Material from the conferences was found to be available on the projects’ website, but the website’s inherent value for increasing understanding of the guidelines is judged to be limited. The competence supporters are judged to only have contributed to an increased understanding of the guidelines to some extent. However, a small proportion of the competence supporters said that they contributed to the distribution of knowledge of the guidelines to a large extent.”

In Stockholm County’s north-western region, some 100 addiction treatment workers from the county council’s dependence care and the social services worked together on the national guidelines for addiction treatment (Socialstyrelsen, 2007d) in a study circle format. This work is part of a longer development endeavour with the objective of care and treatment offered to people with addiction problems in north-western Stockholm being based on well-tried experience, the best possible knowledge and the individual user’s/client’s/patient’s experiences and wishes – in other words an evidence-based practice. The Research and Development (R&D) unit in the region studied the process and summarises the conclusions as follows147:

- “In the north-western municipalities, there is collaboration between primary municipal addiction care and county council municipal dependence care that functions well more or less.
- The principals’ differing requirements and regulations have some impact on the collaboration.
- The participants report that discussing the work and its problems in a study circle format has been meaningful. There is a continued need to develop local and regional forums to discuss the work.
- The most common source of knowledge is clinical experience, so-called “everyday knowledge”.
- By discussing and analysing problems with seemingly everyday methods and approaches, conditions are created for formulating and documenting the practical work, which is an important part of evidence-based practice. The fact that this is missing is a dilemma in addiction care.
- If addiction care is to develop an “Evidence-based practice – for the benefit of the patient” (SOU 2008:18), structures are needed in the organisations in order to manage and take care of knowledge and experiences that already exist and are acquired.”

In an earlier study in the region, the R&D unit found that “approximately 70 percent of the personnel in the north-western municipalities’ addiction care are trained in the evidence-based methods that are recommended in the guidelines. However, one result from observations conducted in all study circles is that the methods are not stringently applied, in accordance with manuals and training, where the importance of method compliance is emphasized. In the circles, it is clear that parts or elements of the methods are used in the daily patient work instead. The obstacles to applying the methods are said to be a lack of time, case load and organisational conditions.”

In 2010, the Centre for Social Research on Alcohol and Drugs (SoRAD) at Stockholm University published a report entitled “Towards better addiction care?”(Abrahamson et al., 2009) about the possibilities of basing the addiction treatment work in four organisations on evidence. The study is based on two questionnaire surveys of treatment personnel and one interview survey of clinic managers. The study targeted a representative selection of care and treatment units in four different organisations with the task of providing care and treatment to people with addiction problems: the municipal social services, the county council-based dependence care, the state care under the Care of Abusers (Special Provisions) Act and non-institutional correctional care also under state direction. For practical and financial reasons, the study was limited to operations in central Sweden.

The study’s results indicate that the major problem of addiction care is not primarily a lack of knowledge of effective treatment methods. Rather, it is a matter of the financial and organisational conditions being such that many patients are not offered the help they desire and need. Another deficiency brought up in the report is that addiction care staff “…largely appear to lack possibilities of ‘learning by experience’ in any substantial sense through continuous documentation, follow-up and critical examination of one’s own work,” to thereby be able to build up locally rooted ‘well-tried experience’. According to the researchers behind the study, addiction care needs to become a “learning organisation” to a greater extent.

In the concluding discussion and the conclusions themselves, the researchers emphasize the need to apply a broader approach to the problems rather than only focusing on greater method knowledge:

“One way of summarising what the presented results have to say about the conditions of the four organisations studied in order to develop evidence-based addiction care is to relate them to the programme for evidence-based medicine developed by Sacket et al (1997) and which is repeatedly referred to in this report. In this programme, as in many of the discussions conducted regarding evidence-based Swedish addiction care, it is established that such a practice must be based on (i) external, scientific knowledge of the effects of various treatment methods, (ii) the practitioners’ well-tried clinical experience and (iii) the client’s or patient’s own perception of what needs to be done.

The emphasis in both the National Board of Health and Welfare’s guideline document and the strategy for implementing these guidelines prepared by the Swedish Association of Local Authorities and Regions (SKL) clearly lies on the first of these points. The implicit assumption appears to be that the Swedish addiction treatment’s greatest problem is the lack of knowledge of and competence to use adequate and effective specific treatment methods, and that the solution is primarily to
provide training in such methods. Significantly less attention is directed at both of the other points, and the potential organisational and resource problems of addiction care and their role in a broader societal perspective are discussed to a very limited extent.

The results presented in this report can, however, be said to indicate that the responsible parties in this endeavour are at risk of missing the mark, at least if this is to develop and improve Swedish addiction treatment for the benefit of the opportunities of the patients concerned to find a sustainable solution to their problems. While many of the operations studied, particularly in the social services, accordingly appear to be somewhat well equipped with regard to expertise in and the use of several of the methods recommended by the National Board of Health and Welfare, the conditions for developing work with patients and improving the results appear less beneficial in other respects.

Looking at the possibilities of learning from personal experience according to the second point Sacket et al brings up; the practitioners indeed appear to not lack occasions to discuss their own work with their colleagues in an organised format. At the same time, the results provide a picture that these discussions are only rarely based on empirical data on the outcomes of their own efforts, which probably means that most units have hardly established procedures to continuously build up a locally rooted, well-tried experience of a type that could constitute a correction of and supplement to the generalisation and in some sense abstract knowledge that effect research offers.

In terms of the patients’ opportunities to influence the choice of measures and the course of their own treatment process in accordance with the third point proposed by Sacket et al, the results indicate that a large majority of the practitioners indeed view it as principally important to take into account the patient’s own opinion, but that there in reality is a lack of established procedures to do so and that factors such as ‘intuition’, the opinions of colleagues and managers and – not least – financial and political realities play a significant role in the help that the individual patient is offered. In this context, the facts that there is not any particularly high degree of consensus among addiction care staff as to what type of problems substance abuse and dependence actually are and that alcohol problems and drug problems largely appear to be viewed in different ways are seen as a problem. These differences can reasonably be assumed to have some relevance to what treatment different employees concretely offer their patients and to the possibility of developing a coordinated ‘evidence-based practice’ at different units.

Lastly, there is reason to emphasize that practitioners in addiction treatment clearly extensively attribute the difficulties they encounter in their work to such conditions as insufficient financial resources, cooperation difficulties between the care system’s various parts, a lack of interest in and of knowledge of addiction issues among both decision-makers and the public, and to a surrounding society that does not offer the patients the material and social opportunities after completed care and treatment that would be needed to earnestly improve the long-term outcome of the efforts.
Consequently, a reasonable summary conclusion – or perhaps rather a summary hypothesis based on the results presented – is that the prospect of the on-going effort to develop addiction treatment on the long term providing positive effects in the form of an offering more attractive to the patients and a better overall outcome would be significantly brightener if the responsible parties could adopt a broader and more flexible perspective of what evidence-basing means – with greater emphasis on making the care system a ‘learning organisation’ and on finding ways of guaranteeing the patients’ own influence – than what appears to have been the case to-date” (Abrahamson et al., 2009).
UNITED KINGDOM

11. History, methods and implementation of national treatment guidelines

11.1 Introduction
The United Kingdom has a long tradition of providing guidance for professionals involved in the provision of drug treatment. There are a large number of guidelines covering a wide range of topics, settings and client groups. This chapter provides an overview of the development of treatment guidelines in the UK, the framework within which they operate, their content, the groups they address and the methods of implementation. Finally, a selection of UK guidelines will be compared with relevant WHO guidelines.

The definition of treatment guidelines used by the EMCDDA is as follows:

“Guidelines are systematically developed statements to assist practitioners and patient decisions about appropriate interventions for specific circumstances. Commonly guidelines include a set of recommendations or steps that can be followed when implementing an intervention. For example, quality guidelines for treatment may refer to treatment processes e.g. guidance for binding levels of assessment, individual treatment planning, informed consent, pathways of care, referrals. They may also include the evaluation processes that refer e.g. to binding documentation (entry/discharge), retention, supervision, evaluation of client satisfaction, outcomes. The content of guidelines is commonly based on the available research evidence.”

11.2 Historical, cultural and institutional context

The Pharmacy Act 1868 was the first instance of drug control in the UK, stipulating a list of drugs including opium that were only to be sold by pharmaceutical chemists. The combined use of alcohol and drugs was incorporated into the Inebriates Act 1898, which covered drug taking as well as alcohol, if the substance was ingested through drinking. In this era, treatment was provided through institutionalisation involving physical, mental and moral reform.

In the 1920s, the disease model of addiction had been widely accepted (Berridge, 1984). In 1921, the Home Office regulation had tightened the controls over dangerous drugs but still allowed doctors to use them in the practice of their profession. However, there was not a clear consensus as to what was appropriate medical practice in this area. Hence, the Rolleston Committee on morphine and heroin addiction was established in 1924 by the Home Office, constituted of nine doctors, which reported to the Minister of Health. The Rolleston report was published in 1926 (Ministry of Health 1926). It provided recommendations for the secure provision of medication using dangerous drugs and for the gradual withdrawal from drugs of dependence. But it also established the medical consensus that maintenance prescribing for opiate addiction was a legitimate approach in some cases; alongside addressing other issues such as the use of psychotherapeutic approaches, re-education of the will and improvements in social conditions of the patient.
In February 1956, the Home Office issued a publication entitled *The Duties of Doctors and Dentists under the Dangerous Drugs Act and Regulations 1956* (Home Office 1956) giving guidance to doctors and dentists about the possession and supply of dangerous drugs and warning that there had been cases in which doctors and dentists had been convicted of offences related to diversion of prescribed dangerous drugs “to the gratification of their own addiction”.

In the late 1950s, new synthetic opiates were being manufactured and doctors started to use them for therapeutic purposes and found that they had addictive properties.

In the 1958, the Department of Health and Social Security (DHSS) set up an Interdepartmental Committee, known as the Brain Committee, to review, ‘in the light of more recent developments’, the advice given by the earlier Rolleston Committee. The first Brain Report was published in 1961 (HM Government 1961) and effectively endorsed the main conclusions of the earlier Rolleston Report. However, the report was publicly criticised for failing to recognise the extent of the problems of addiction in Great Britain. In the early 1960's, heroin addiction had started to increase – mainly in London. Hence, the Brain Committee was re-convened in July 1964, and the second Brain Report was published in 1965 (HM Government 1965). The second report recognised that there was a major problem with addiction to cocaine and heroin and that the main source of supply was over-prescribing by a small number of doctors. It recommended that further measures were required to deal with the problems and that only doctors on the staff at specialist drug dependency treatment centres be licensed to prescribe these particular substances for the management of addicts; and that it should be a statutory offence for other doctors to prescribe these drugs to an addict for the treatment of addiction. The Committee recommended increased prescription-writing requirements for dangerous drugs and the establishment of a register of all addicts. The latter action was mainly to avoid the prescribing by more than one doctor to the same patient at the same time; it had only limited effect in this regard and was discontinued in 1997. An advisory committee was also recommended to keep under review the whole developing problem of drug addiction.

*The Drugs (Prevention of Misuse) Act 1964* controlled amphetamines in the United Kingdom and was later used to control LSD. In response to increasing drug problems and with the emergence also of a ‘Black Market’ in drugs from illicit sources, the law was subsequently changed. *The Misuse of Drugs Act 1971* (and the Regulations of 1973), repealed the majority of previous legislations and made it unlawful for individuals to possess or supply a controlled drug unless an exception or exemption applied. This Act forms the basis of current UK drug laws.

The first UK guidelines for the clinical management of drug misuse, *Guidelines of good clinical practice in the treatment of drug misuse* were issued in 1984 by the DHSS in the context of a growing drug problem. The committee consisted of experts from the medical profession, who based their assessment of good practice largely on their experience rather than from a substantial body of research evidence, which was not available at the time. It was hoped that the guidelines would help reduce the cases where prescribing practice might be seen as irresponsible. The guidelines have since been revised in 1991 (DH et al. 1991), 1999 (DH et al. 1999) and 2007 (DH and the devolved administrations 2007). The revisions show a change in approach to drug treatment in the UK over the years, with a greater balance developing between abstinence-oriented, maintenance-oriented and other harm reduction approaches. In the latter editions, the opinion of experts still remains a key
element but the guidelines are able to draw on a much wider and more in-depth, peer-reviewed evidence base.

The historical development of treatment for drug misuse in the UK has occurred in the context of a uniquely long experience in the use of prescribed opiate substitution therapy, the development of specialist addiction teams to manage the emerging increasing demands for treatment; and, derived from both of these sources of experience, the development of authoritative and increasingly detailed treatment guidelines. Within this framework, there is still the flexibility for both the practitioner and service user to exercise choice, with an emphasis on person-centred treatment. Whilst the UK clinical guidelines do not create any statutory obligations on doctors, and do continue to allow clinical freedom, they are seen, for example, as important evidence of professional consensus when relevant regulatory bodies are reviewing cases of possible poor professional conduct in the management of addicts.

11.3 Framework and institutional context

Health is a devolved responsibility in the UK. Consequently, guidance has been developed at both a UK and at a national level (with deferring guidance bodies involved). For instance, England, Scotland, Wales and Northern Ireland, all have their own guidance on drug treatment service frameworks. However, there are some guidelines that have been developed to apply across the UK, requiring collaborative work between professional bodies from all four countries. The most relevant example of this type of collaborative work is Drug misuse and dependence – UK guidelines on clinical management (DH and the devolved administrations 2007). In the development of these treatment guidelines, officials of the Government and the devolved administrations were given observer status. It is usual practice to allow such officials only stakeholder or observer status in the development of such authoritative guidelines, to ensure the independence of, and credibility for, the final published documents.

In England, there are 149 local drugs partnerships, commonly named Drug Action Teams (DATs). They are responsible for developing effective partnership working between all local agencies involved with the misuse of drugs. The local partnerships lead on the commissioning of drug services, monitor and report on performance and communicate plans, activities and performance to stakeholders.

In 2001, the National Treatment Agency for Substance Misuse (NTA) was established in England as a special health authority within the National Health Service (NHS) to "...improve the availability, capacity and effectiveness of treatment for drug misuse in England". The NTA has nine regional teams that are involved in the providing support and quality assurance for DATs on their commissioning. One of the key functions of the NTA is the promotion of best practice by providing drug workers with information and guidance on effective drug treatments. Consequently, in England, the NTA are one of the key publishers of drug treatment guidance documents.

In Scotland, a new framework for drugs and alcohol was agreed in 2009 by the Scottish Government, the Convention of Scottish Local Authorities (COSLA) and the NHS. This established 30 Alcohol and Drugs Partnerships (ADPs) operating in specific geographic areas as part of local community planning. ADPs are responsible for developing local outcome-based strategies and co-ordinating

community services to address problem drug and alcohol abuse, based on the needs of an area. ADPs are now more closely aligned within Community Planning Partnerships (CPPs) and this is intended to help ensure effective and integrated planning and commissioning of services to help connect local action to reduce health inequalities with the aims of local drugs and alcohol strategies. ADPs consist of senior officials from statutory and non-statutory bodies and are supported by National Support Co-ordinators seconded to the Scottish Government.

In Northern Ireland, four Drugs and Alcohol Coordination Teams (DACTs), North, South, East and West, cover different district council areas. The DACTs operate as multi-agency partnerships consisting of members within statutory and non-statutory agencies. Currently, DACTs are working on implementing the New Strategic Direction (NSD) for Alcohol and Drugs 2006 – 2011 (DHSSPNI 2006) and so aiming to reduce alcohol and drug-related harm in Northern Ireland. Each team develops a Local Action Plan (LAP), which reflects local need and is essential for implementing the NSD at local level.

Wales has 22 Community Safety Partnerships (CSPs) based in each local authority area. The CSPs consist of local organisations that work collaboratively to reduce crime and substance misuse providing holistic support for substance misusers at a local level. For a comprehensive explanation of funding for drug services in the UK, please refer to Chapter 13.

Clinical governance is a systematic process for monitoring and improving the quality of treatment for all organisations and individuals that provide and that commission drug treatment for drug misusers. The implementation of clinical governance is commonly broken down into a range of domains of activity, and is a statutory requirement for the main organisations that commission treatment for drug misusers, and is either a statutory or a contractual requirement for providers of treatment. One of the key components of clinical governance is the existence of a comprehensive programme of quality improvement activities, including professional and skills development, and use of up-to-date evidence to inform current practice. A central component of quality improvement practice is the use of clinical audit. Local clinical audits are undertaken by services to monitor if they are delivering interventions in line with locally determined standards or guidance and whether they are producing expected outcomes. Findings of such audits will be used to plan improvements. The NTA has produced the document Auditing Drug Treatment (NTA 2008) which facilitates the comparison of audit outcomes, standards or criteria with current clinical guidance.

Apart from Technology Appraisals produced by the National Institute for Health and Clinical Excellence (NICE), which are covered by a legal direction requiring Primary Care Trusts (PCTs) to make funding available for recommended treatments, UK and/or local national-level treatment guidelines have no specific statutory status. The guidelines are not meant to provide a rigid protocol for practitioners, nor do they override the responsibility of the clinician to make appropriate decisions for treatment in consultation with the patient (or guardians/carers where appropriate). However, where guidelines are not followed, practitioners are expected to record the rationale for their decisions and be prepared to defend them should their clinical practice come under scrutiny from their professional bodies.
11.3.1 National Institute for Health and Clinical Excellence (NICE)

NICE is an independent organisation that is responsible for producing national
guidance documents to promote good health and to treat and prevent ill health. All
NICE guidelines are based on an assessment of the available evidence on clinical
and cost-effectiveness and are developed through extensive consultation with
external organisations. NICE develops their guidelines according to certain basic
principles: multidisciplinary involvement in the development of recommendations,
and, where possible, based on systematic reviews and critical appraisals of the
evidence base. The Department of Health commissions NICE to develop health
guidance. Table 11.1 shows the three types of guidance relevant to drug treatment
produced by NICE.

Table 11.1: Types of NICE guidance

<table>
<thead>
<tr>
<th>Type of NICE guidance</th>
<th>Description of the guidance content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology Appraisals</td>
<td>Provides guidance on the use of new and existing treatments, procedures and medicines.</td>
</tr>
<tr>
<td>Clinical Guidelines</td>
<td>Guidance on appropriate treatment for specific illnesses, conditions and diseases.</td>
</tr>
<tr>
<td>Public Health Guidance</td>
<td>Guidance for the NHS and other bodies to promote good health, harm-reduction and avoidance of ill health.</td>
</tr>
</tbody>
</table>

Country status

Whilst NICE was originally established in 1999 to provide guidance to the NHS in
England and Wales, Scotland and Northern Ireland have both implemented NICE
guidance according to their needs. Consequently, the status of NICE guidance differs
throughout the UK as shown in table 11.2.

Table 11.2: Status of NICE guidance across the United Kingdom

<table>
<thead>
<tr>
<th>Country</th>
<th>Which NICE guidance apply</th>
</tr>
</thead>
</table>
| England             | • Clinical Guidelines  
                      | • Technology Appraisals  
                      | • Public Health Guidance                                                                 |
| Wales               | • Clinical Guidelines  
                      | • Technology Appraisals                                                                                     |
| Northern Ireland    | • Clinical Guidelines (with advice on implementing in the context of the health service in Northern Ireland from the Department of Health, Social Services and Public Safety)  
                      | • Technology Appraisals (with advice on implementing in the context of the health service in Northern Ireland from the Department of Health, Social Services and Public Safety)                                                                                  |
| Scotland            | • Multiple Technology Appraisals (with advice on implementing in the context of the health service in Scotland from NHS Quality Improvement Scotland) |

Source: NICE

See: [http://www.nice.org.uk/aboutnice/whatwedo/what_we_do.jsp](http://www.nice.org.uk/aboutnice/whatwedo/what_we_do.jsp)

NICE also produce other types of guidance such as interventional procedures, medical technologies guidance.
Whilst final decisions on referrals are taken by Department of Health Ministers, NICE oversees the process for selecting topics for referral to its work programme and operates an open system whereby anyone can suggest a topic for referral through its website. Suggestions for guidance topics come from a variety of sources:

- members of the general public, patients, carers;
- health professionals (who can all make suggestions online or by post);
- the Department of Health’s national clinical directors and policy teams;
- the National Horizon Scanning Centre (which identifies new and emerging health technologies that may require assessment); and
- within NICE itself.

Topic suggestions are assessed by NICE against a published set of selection criteria and are then reviewed by one of six consideration panels, which are composed of experts of the particular field, generalists who hold good knowledge of the health service, public health and the public sector, and patient and carer representatives. The panel then makes recommendations to the Department of Health where the Health Minister finally selects and refers topics for NICE to produce guidance.

**NICE Technology appraisals**

NICE produces both single technology appraisals (where a single technology is assessed for a single condition) and multiple technology appraisals (which cover more than one technology or one technology for more than one condition). The Centre for Health Technology Evaluation within NICE is responsible for developing technology appraisals.

Technology appraisal recommendations are produced by the independent advisory Technology Appraisal Committee. Members are appointed for a three-year term and are drawn from patient and carer organisations, academia, the NHS and the pharmaceutical and medical devices industry. The committee is organised into four branches and once a member has been allocated to a specific branch, they will remain within that branch for the duration of their term.

Consultee organisations are identified from national groups representing patients and carers, bodies representing health professionals, manufacturer(s) or sponsor(s) of the technology in development, the Department of Health (DH), the Welsh Assembly Government (WAG), specialised commissioning groups, primary care trusts, and local health boards.

NICE invites commentator organisations to take part in the appraisal process and comment on the documents produced during this process. Unlike consultee organisations, they cannot comment on the final recommendations made by the Technology Appraisal Committee. Commentator organisations consist of members from manufacturers of comparator technologies, for instance, National Health Service (NHS) Quality Improvement Scotland, relevant research groups working in the area and other groups such as the NHS Confederation, Social Services and Public Safety for Northern Ireland and professional or patient organisations covering Wales.

In England, the NHS must make funding available for technologies recommended by NICE’s technology appraisal guidance within three months of guidance publication.

---

151 See: [http://www.nice.org.uk/aboutnice/whatwedo/abouttechnologyappraisals/about_technology_appraisals.jsp](http://www.nice.org.uk/aboutnice/whatwedo/abouttechnologyappraisals/about_technology_appraisals.jsp)
In 2009, NICE published the documents *Guide to the Single Technology Appraisal (STA) Process* (NICE 2009a) and *Guide to the Multiple Technology Appraisal Process* (NICE 2009b) to describe the process undertaken in the development of single and multiple technology appraisals. The process for developing single and multiple technology appraisals is shown in Figure 11.1.

**Figure 11.1: Process of NICE Technology Appraisal Development**

1. **Provisional appraisal topics chosen**
   - Provisional list of topics produced by NICE and DH following discussion by consideration panels

2. **Consultees and commentators identified**

3. **Scope prepared**
   - In consultation with DH, the scope defines the disease, patients and technology the appraisal will cover. Consultees and commentators are invited to comment on the draft scope.

4. **Appraisal topics referred**
   - DH refers appraisal topics to NICE

5. **Evidence submitted**
   - Manufacturer/sponsor of the technology invited to provide an evidence submission. All non-manufacturer consultees are invited to submit a statement on the potential cost and clinical effectiveness of treatment.

6. **Multiple Technology Appraisal Process (MTA) – Assessment report prepared**
   - An independent academic centre is commissioned by NICE to review published evidence on the technology and to prepare an assessment report. Consultees and commentators are invited to comment on the report.

7. **STA evaluation report**
   - Will also include evidence from the assessment report

8. **Evaluation report prepared**
   - The report includes all of the evidence looked at by the Appraisal Committee which will include written submissions, patient expert personal statements, clinical specialist personal statements and comments received on the assessment report.

9. **STA evaluation report**
   - Will also include evidence from the ERG

10. **Appraisal consultation document (ACD)**
    - Provisional recommendations from the Appraisal Committee are provided in this document. Consultees and commentators are given four weeks to comment on the document. The document is placed onto the NICE website for comments by health professionals and members of the public. The production of an STA may not produce an ACD. This will only happen if recommendations made by the Appraisal Committee are restrictive, in that the recommendation is one that will be more limited that the instructions for use that accompany the technology.

11. **Appraisal Committee**
    - The committee considers the evaluation report, and hears evidence from nominated patients, carers and clinical experts. The discussions of the committee are held in public.
NICE Clinical guidelines

These guidelines are produced for use by health professionals and NHS organisations and provide best practice guidance across a whole care pathway for a specific disease. Clinical guidelines can help assess the level of individual clinical practice, for training purposes, to ensure patients are in a position where they can make informed decisions and ultimately to improve communication between patients and health professionals. The National Clinical Guideline Centre (NCGC), hosted by the Royal College of Physicians, is commissioned by NICE to develop the scope of the guideline. NICE has four national collaborating centres (NCCs) to help develop the clinical guidelines by harnessing the expertise of the royal medical colleges, professional bodies and patient/carer organisations. Each NCC is a professionally led group. For drug misuse issues, this would be the National Collaborating Centre for Mental Health and it is led jointly at the British Psychological Society and the Royal College of Psychiatrists. The management board of the NCC for mental health comprises all the relevant professional bodies and national organisations as partners.

Once a guideline topic has been announced, stakeholder organisations from England and Wales (which may include national patient and carer organisations and providers and commissioners of services), are encouraged to register their interest. Individuals may also contribute to the guideline development but are required to register online as an appropriate registered stakeholder.

A guideline development group is set up consisting of technical experts, health professionals and representatives of patient and carer groups. This group looks at the available evidence, supported by the independent reviews of evidence produced by the NCC, and will be asked to make comments on draft guidelines before submitting their final recommendations.

There will be a minimum of one public consultation, during which registered stakeholders are able to make comments on the draft guideline. An independent guideline review panel will then review the draft guideline, ensuring that comments made by the stakeholders have been considered.

Once the development group finalises its recommendations, the NCC produces the final guidance. This guidance will be formally approved by NICE and then issued to the NHS.

152 See:
http://www.nice.org.uk/aboutnice/whatwedo/aboutclinicalguidelines/about_clinical_guidelines.jsp
NICE produced the *Guidelines Manual 2009* (NICE 2009c) which provides information about how the clinical guidelines have been developed and advice on the practical aspects of guideline development.

**NICE Public Health Intervention Guidance**\(^{153}\)

Public health topics are prioritised by NICE’s public health consideration panel and referred to NICE by Ministers. As with the clinical guidelines, stakeholders are requested to register their interest soon after the intervention topic is published with a scope on the content of the guideline being produced.

A synopsis of the evidence is prepared, which will also include an economic appraisal of the intervention. This process may be conducted by an independent research body or by NICE itself. Registered stakeholders may be asked to submit additional evidence at any time during the development stage.

A draft intervention guidance document is produced once the Public Health Interventions Advisory Committee (PHIAC) has reviewed the evidence. A consultation period of the draft guidance will be issued to the stakeholders for eight weeks. During this period, stakeholders may also comment on the evidence reviews upon which the draft guidance is based. During this consultation period, the draft intervention guidance is also field tested. A fieldwork report is produced by appropriate professionals, commissioners and practitioners, which is then submitted to the PHIAC.

PHIAC reviews both the comments from the stakeholder consultation and the fieldwork report making appropriate changes to produce the final guidance document. This document is then approved by NICE before it is published.

NICE published the document *Methods for development of NICE public health guidance 2009* (NICE 2009d) which provides information on the methods used for the development of public health guidance.

**NICE: working with the devolved administrations**

In Scotland, the Scottish Intercollegiate Guidelines Network (SIGN)\(^{154}\) is responsible for producing clinical guidelines for NHS Scotland. Both NICE and SIGN are members of the Appraisal of Guidelines, Research and Evaluation (AGREE) collaboration.\(^{155}\) Consequently, NICE and SIGN work with the AGREE collaboration to ensure that their guidelines are as complementary as possible so avoiding duplication of work. This is accomplished by NICE and SIGN developing their guidelines according to the same basic principles: multidisciplinary involvement in the development of recommendations, which are based upon systematic reviews, and critical appraisals of the evidence base.

In Northern Ireland, the NICE Clinical Guidelines and Public Health Guidance documents that have been endorsed act as standards that the Health and Personal Social Services (HPSS) are expected to achieve over time.

---

\(^{153}\) See: [http://www.nice.org.uk/aboutnice/whatwedo/aboutpublichealthguidance/about_public_health_guidance.jsp](http://www.nice.org.uk/aboutnice/whatwedo/aboutpublichealthguidance/about_public_health_guidance.jsp)

\(^{154}\) See: [http://www.sign.ac.uk/](http://www.sign.ac.uk/)

In Wales, the Welsh Assembly Government (WAG) has an agreement in place with NICE covering NICE technology appraisals, clinical guidelines and interventional procedure guidance, which all continue to apply in Wales. Although clinical guidelines issued by NICE are not subject to the Assembly's three months funding Direction, the WAG expects NHS bodies in Wales to take full account of the recommendations made by the Institute when commissioning and delivering services to patients.

The health standards for Wales, set out by the Welsh Assembly Government, ensures that services across the health care setting provide services in line with the clinical guidelines and technology appraisals produced by NICE.

11.3.2 Role of guidelines in the development of treatment quality

Each country in the UK has a minimum standard of health care set by the Government and the devolved administrations. Drug treatment services are required to meet these standards to facilitate a framework for continuous improvement.

11.4 Treatment guidelines: narrative description

Current UK guidelines are based upon a biopsychosocial model of treatment and they recognise that there may be multiple attempts at recovery from drug dependence. The guidelines reinforce the role of clinical staff, in ensuring that individuals with drug misuse difficulties have the same entitlement to NHS and social care services as other patients.

Due to the large number of guidelines that exist in the UK, a select number of guidelines have been chosen for discussion. Drug misuse and dependence: UK guidelines on clinical management (DH et al. 2007) is unique in its applicability across the UK and provides a skeletal framework from which devolved administrations can develop locally appropriate guidance. Models of Care for Treatment of Adult Drug Misusers (NTA 2006) is not a typical clinical guideline per se but is evidence-based guidance on a commissioning framework for drug services. It was developed with the assistance of clinical experts and with reference to the evidence base on effective interventions. It provides guidance on the different types of services needed in a system of care to provide the wide range of interventions required to meet the needs of drug misusers. The guidelines produced by NICE were chosen as they contain key messages from NICE about drug treatment, and because they are also used to inform other guidelines.

The following framework guideline will be reviewed:


Clinical treatment guidelines to be discussed are:

1. Drug misuse and dependence - UK guidelines on clinical management (DH et al. 2007);
2. Drug misuse - Opioid detoxification (NICE 2007c);
3. Methadone and buprenorphine for the management of opioid dependence (NICE 2007a);
4. Naltrexone the management of opioid dependence (NICE 2007b); and
5. Drug misuse - Psychosocial interventions (NICE 2007d).

The socio-medical model of health focuses on the social factors that contribute to health and well-being in society.
The guidelines complement each other and it is recommended that they are used in conjunction with each other.

11.4.1 Models of Care for Treatment of Adult Drug Misusers: Update 2006

This document (NTA 2006), applicable in England, sets out the service framework for commissioning and provision of drug misuse treatment services. This guideline provides managers, joint commissioners, providers and users of drug treatment services with a four-tiered framework for providing drug treatment (Table 11.3). The tiers refer to the level of interventions provided with many agencies providing interventions from a variety of tiers. The degree of individual need and support usually increases with each tier (NTA 2006). Models of Care Update 2006, is due to be updated and the update is likely to reflect a greater focus on the achievement of recovery.

Table 11.3: Tiers of drug treatment provision in England

<table>
<thead>
<tr>
<th>Tier</th>
<th>Interventions</th>
<th>Settings</th>
</tr>
</thead>
</table>
| 1    | • Provision of drug-related information and advice  
• Drug treatment and screening assessment  
• Referral to specialised drug treatment  
• Partnership working with specialised drug treatment teams | • General healthcare  
• Social care  
• Education  
• Criminal justice (those that do not have a main focus on drug treatment) |
| 2    | • Triage assessment and referral for structured drug treatment  
• Brief psychosocial interventions  
• Harm reduction interventions (including needle exchange)  
• Aftercare | • Outreach  
• Primary care  
• Pharmacies  
• Criminal justice  
• Community |
| 3    | • Community-based specialised drug treatment  
• Co-ordinated care planned treatment  
• Drug specialist liaison  
• Harm reduction activities  
• A range of pharmacological interventions  
• Psychosocial interventions  
• Care planned and structured day care programmes  
• Liaison services with mental health, acute medical and social care services | • Specialised drug treatment services in community and/or inpatient settings  
• Primary care  
• Pharmacies |
| 4    | • Inpatient specialist drug and alcohol assessments  
• Stabilisation  
• Inpatient detoxification/assisted withdrawal  
• Residential rehabilitation units  
• Range of drug halfway houses or supportive accommodation  
• Crisis intervention units | • Specialised residential substance misuse units/wards |

Source: NTA 2006
To review the framework for drug treatment, the NTA works in partnership with the Care Quality Commission (CQC), creating detailed criteria for reviewing drug treatment services on an annual basis. Known as Improvement Reviews, these compare the functions of local providers and commissioners of services against specified criteria and those stipulated by the Standards for Better Health.

11.4.2 Drug misuse and dependence – UK guidelines on clinical management

The 2007, Drug misuse and dependence – UK guidelines on clinical management (from here on referred to as the 2007 UK Clinical Guidelines) (DH et al.2007), were developed to update and replace the 1999 guidelines due to advances in the evidence base for drug treatment and clinical practice. The clinical guidelines provide practical guidance for all clinicians but in particular those providing pharmacological interventions (DH et al. 2007).

The clinical guidelines were developed alongside the guidelines produced by NICE in 2007 (NICE 2007a-d). They cover the management and treatment of drug misusers using a broader approach than the NICE guidelines although it is intended that they be used in conjunction with NICE guidelines.

In 2007, DH (England) and the devolved administrations commissioned the NTA to provide a secretariat for the independent working group and separate user and carer advisory groups. The terms of reference were to update the 1999 Clinical Guidelines document, which was the only widely recognised authoritative guideline on drug treatment in the UK up to 2007.

The working group included addiction psychiatrists, general practitioners, nurses, pharmacists, service users and carer representatives and representatives from professional organisations/groups, with Government departments, NICE, the NTA and some named individuals (refer to the guideline for an identified list) granted observer status.

Independent reviewers were commissioned to advise the working group on the current evidence-base for a range of drug-related treatment issues. Recommendations, and the evidence behind these recommendations, were provided to the working group for consideration and rating. The working group also considered information from NICE guidelines and other relevant research and guidance. Through consensus building, the working group reached a conclusion on the best available evidence. The working group chose not to rate their recommendations (and the evidence for these), in order to be in a position where recommendations could be made on important subjects where there was not a substantial research evidence base but where guidance would be of practical use to clinicians.

The NTA managed the consultation process and members of the working group were fully involved. All consultation responses were provided for comment to the working group with their comments taken into consideration for redrafting the guideline document.

For the topics that presented the most consultation comments, a meeting was held by the group to hold further discussions or to reach a consensus. Sections on blood-borne infections and child protection were amended or clarified as a result of this process. For blood-borne infections, there was an increase in detail provided on hepatitis C and information was added on common bacterial infections seen frequently amongst drug misusers. Regarding the child protection amendments, the
The clinical guidelines are applicable across drug treatment services and cover a wide range of components such as clinical governance, health improvement and other essential elements of treatment provision.

For more detailed information about individual guidelines, please refer to the guidance document but as a guide for topics covered refer to Table 11.4.

Table 11.4: Chapter topics from Drug misuse and dependence: UK guidelines on clinical management

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Interventions covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Essential elements of treatment provision, including:</td>
</tr>
<tr>
<td></td>
<td>• Assessment</td>
</tr>
<tr>
<td></td>
<td>• Delivery of treatment</td>
</tr>
<tr>
<td></td>
<td>• Drug testing</td>
</tr>
<tr>
<td>4</td>
<td>Psychosocial components of treatment, including:</td>
</tr>
<tr>
<td></td>
<td>• Psychosocial interventions</td>
</tr>
<tr>
<td></td>
<td>• NICE guideline</td>
</tr>
<tr>
<td></td>
<td>• Practitioner competencies</td>
</tr>
<tr>
<td>5</td>
<td>Pharmacological interventions, including:</td>
</tr>
<tr>
<td></td>
<td>• Prescribing</td>
</tr>
<tr>
<td></td>
<td>• Opioid detoxification</td>
</tr>
<tr>
<td></td>
<td>• Stimulants</td>
</tr>
<tr>
<td>6</td>
<td>Health considerations, including:</td>
</tr>
<tr>
<td></td>
<td>• Blood-borne infections</td>
</tr>
<tr>
<td></td>
<td>• Preventing drug-related deaths</td>
</tr>
<tr>
<td>7</td>
<td>Specific treatment situations and populations, including:</td>
</tr>
<tr>
<td></td>
<td>• Prisons</td>
</tr>
<tr>
<td></td>
<td>• Pregnancy and neonatal care</td>
</tr>
<tr>
<td></td>
<td>• Older current and ex-drug misusers</td>
</tr>
<tr>
<td>Annexes</td>
<td>Covers a range of topics such as drugs and driving, injectable opioid treatment and writing prescriptions, amongst others.</td>
</tr>
</tbody>
</table>

11.4.3 Drug Misuse – Opioid detoxification

This clinical guideline produced by NICE, makes recommendations for the treatment of people who are undergoing opioid detoxification in community, residential, inpatient and prison settings (NICE 2007c). Other substances are only dealt with when they are likely to impact on opioid detoxification. To ensure effectiveness of the recommendations outlined in the guideline, it is recommended that key working takes place to co-ordinate care plans. The guideline is aimed at clinicians and service commissioners. Primarily, the guideline makes recommendations based on the available evidence for the use of agonists, antagonists and adjunctive medications, stating clearly, where and when opioid detoxification is, or is not, appropriate.

The guideline recommends that treatment for opioid detoxification should be primarily pharmacological but that the evidence base suggests that psychosocial interventions, such as contingency management, should be considered for provision during detoxification.
The guideline recommends that after providing information, advice and support a clinical assessment of the service user should be completed. The assessment should document current and previous levels of opioid use, history of treatment and treatment compliance and identify any other substances that are being used (which may interfere with detoxification). Before commencing detoxification, in collaboration with the service user, several factors need to be explored: the level of dependence; the stability of an individual's mental health and other substance use; the pharmacology of the preferred detoxification medication and its interaction effects with other medication being used; and the setting in which the detoxification will occur. Opioid detoxification should take place within a community-based programme with residential detoxification only considered for people with co-morbid physical and/or mental health problems, or for detoxification from multiple substances. The recommended duration for opioid detoxification in an inpatient/residential setting is four weeks and within community settings, twelve weeks.

The first-line pharmacological treatments that should be offered for opioid detoxification are the opioid agonist methadone or the partial agonist buprenorphine. To decide between the two, clinicians are expected to review each client on a case-by-case basis, taking into account if either substance is currently being used or if the service user has a preference.

It is recommended that lofexidine, but not clonidine is routinely offered in opioid detoxification, where such adjunctive medication is needed. Again, there is a list of criteria that practitioners are advised to consider before providing a prescription.

It is recommended that ultra-rapid detoxification from opioid dependency, under general anaesthesia or heavy sedation should not be offered through the NHS due to the high level of risk involved.

### 11.4.4 Methadone and buprenorphine for the management of opioid dependence

This NICE technology appraisal guidance document recommends naltrexone for relapse prevention treatment in highly motivated individuals who have completed
detoxification and are aiming for abstinence (NICE 2007b). The guidance addresses doctors, non-medical prescribers and PGDs. Naltrexone should be provided as part of a programme of supportive care where the user has been fully informed of the possible adverse effects and should only be administered under supervision. Through a process of regular review, if the misuse of naltrexone occurs, treatment should be discontinued. It is recommended that naltrexone only be provided for people who are highly motivated to remain in an abstinence programme.

11.4.6 Drug misuse – psychosocial interventions

This clinical guideline produced by NICE, is a comprehensive non-medical guidance document for the treatment of drug misuse (NICE 2007d). The guideline makes recommendations for the role of psychosocial interventions in combination with pharmacological interventions and as stand-alone interventions in the treatment of people who misuse opioids, stimulants and cannabis. It is applicable across all tiers of interventions recommended for drug treatment, with the level of interventions provided, dependent on an individual's level of need. Typically, Tiers 1 and 2 are 'low-intensity' interventions such as motivational interviewing and self-help while Tiers 3 and 4 are 'higher intensity' interventions such as contingency management or more structured forms of counselling. The guideline is aimed at practitioners and commissioners but may be of interest to service users, advocates and family members. It is acknowledged that the guideline will also influence the work of occupational health and social services.

The guideline covers a wide range of settings. The psychosocial interventions recommended in the full clinical guideline summarises the analysis of the evidence for a broad range of interventions, including contingency management, Cognitive Behavioural Therapy (CBT) and psychodynamic therapy. The quick reference guide of this guideline highlights those interventions that have particularly strong evidence and so prioritises these recommendations.
11.5 Existing list of guidance

Guidance documents on the management of drug misuse in the UK have been developed for specific settings (e.g. community), specific populations (e.g. young people) and for professional groups (e.g. psychiatrists and general practitioners with an interest in addictions). Consequently, there are a large number of guidance documents covering a broad range of topics. The majority of these documents are consistent with key messages contained within the 2007 NICE suite of guidance and the 2007 UK Clinical Guidelines. This section lists current drug treatment guidance in the UK. They are differentiated by whether they address practice issues (Table 11.5) or the drug treatment system (Table 11.6)

Table 11.5: Current UK and national practice treatment guidance

<table>
<thead>
<tr>
<th>Date</th>
<th>Publication Title</th>
<th>Where relevant</th>
<th>Types of Interventions</th>
<th>Groups Addressed</th>
<th>Lead Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10</td>
<td>Updated guidance for prison based opioid maintenance prescribing.</td>
<td>England</td>
<td>Pharmacological</td>
<td>Clinicians working with prisoners</td>
<td>DH</td>
</tr>
<tr>
<td>Mar-10</td>
<td>Guidance and training protocol for the development of the introduction of take home Naloxone</td>
<td>Wales</td>
<td>Pharmacological</td>
<td>Community Safety Partnerships, providers</td>
<td>WAG, National Working Group</td>
</tr>
<tr>
<td>Nov-09</td>
<td>Treatment of Offenders</td>
<td>Wales</td>
<td>Arrest Referral Service, psychosocial and pharmacological</td>
<td>Planners, commissioners and providers</td>
<td>WAG</td>
</tr>
<tr>
<td>Oct-09</td>
<td>Guidance for the pharmacological management of substance misuse among young people in secure environment</td>
<td>England</td>
<td>Prescribing protocols &amp; observation</td>
<td>PCT Prison Health Leads, Senior MPs in young offender institutes, Doctors for LA secure children's homes</td>
<td>NTA</td>
</tr>
<tr>
<td>Jul-09</td>
<td>Towards successful treatment completion - a good practice guide</td>
<td>England</td>
<td>Client-centred</td>
<td>Providers, joint commissioners, service users and advocacy groups</td>
<td>NTA</td>
</tr>
<tr>
<td>Mar-09</td>
<td>Guidance for the pharmacological management of substance misuse among young people</td>
<td>England</td>
<td>Prescribing protocols &amp; observation</td>
<td>Young persons specialist substance misuse service providers, commissioners, doctors, NMPs, PCTs</td>
<td>NTA</td>
</tr>
<tr>
<td>Feb-09</td>
<td>Needle and syringe programmes: providing people who inject drugs with injecting equipment</td>
<td>England</td>
<td>Needle and syringe programmes</td>
<td>NHS, NSPs, DAATs, pharmacies, Las, wider public, voluntary and community sectors, injecting drug users and their families/advocates.</td>
<td>NICE</td>
</tr>
<tr>
<td>Date</td>
<td>Title</td>
<td>Location</td>
<td>Focus</td>
<td>Authors/Agencies</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------------------------------------------</td>
<td>-------------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Oct-08</td>
<td>Good Practice in Harm Reduction</td>
<td>England</td>
<td>Highlights good practice in harm reduction</td>
<td>Drug service treatment providers; Drug treatment commissioners; Users of drug treatment services</td>
<td></td>
</tr>
<tr>
<td>Dec-07</td>
<td>Non-medical prescribing, patient group directions and minor ailment schemes in the treatment of drug misusers</td>
<td>England</td>
<td>Minor ailment schemes, PGD's, NMP's</td>
<td>Chief executives of primary care, strategic health authorities, LAs. Directors of adult social services, GPs, commissioners and service providers.</td>
<td></td>
</tr>
<tr>
<td>Sep-07</td>
<td>Drug misuse and dependence - UK guidelines on clinical management</td>
<td>UK</td>
<td>Psychosocial, Pharmacological</td>
<td>Drug treatment commissioners and clinicians</td>
<td></td>
</tr>
<tr>
<td>Jul-07</td>
<td>Drug misuse - Psychosocial Interventions</td>
<td>England Wales and Northern Ireland</td>
<td>Psychosocial and Psychological</td>
<td>Drug treatment commissioners and clinicians, service users and advocates.</td>
<td></td>
</tr>
<tr>
<td>Jul-07</td>
<td>Drug misuse - Opioid detoxification</td>
<td>England Wales and Northern Ireland</td>
<td>Pharmacological and Psychosocial</td>
<td>GPs, NMPs, PGDs service users</td>
<td></td>
</tr>
<tr>
<td>Jan-07</td>
<td>Naltrexone for the management of opioid dependence</td>
<td>UK</td>
<td>Pharmacological</td>
<td>GPs, NMPs, PGDs, service users</td>
<td></td>
</tr>
<tr>
<td>Jan-07</td>
<td>Methadone and buprenorphine for the management of opioid dependence</td>
<td>UK</td>
<td>Pharmacological</td>
<td>GPs, NMPs, PGDs, service users</td>
<td></td>
</tr>
<tr>
<td>Dec-06</td>
<td>Clinical Management of Drug Dependence in the Adult Prison Setting - Including Psychosocial Treatment as a Core Part</td>
<td>England</td>
<td>Reception screening, pharmaceutical management of opioids</td>
<td>PCT Ces, SHA Ces, SHA and PCT Prison Health Leads</td>
<td></td>
</tr>
<tr>
<td>Aug-06</td>
<td>Psychological Therapy and Psychosocial interventions in the Treatment of Substance Misuse</td>
<td>Wales</td>
<td>Psychological and psychosocial</td>
<td>Commissioners, manager and providers</td>
<td></td>
</tr>
<tr>
<td>May-06</td>
<td>Treating drug misuse problems: evidence of effectiveness</td>
<td>England</td>
<td>Pharmacological, psychosocial and psychological</td>
<td>Providers, commissioners, service users and carers</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Title</td>
<td>Location</td>
<td>Details</td>
<td>Sources</td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>----------------------------------------------------------------------</td>
<td>----------</td>
<td>-------------------------------------------------------------------------------------------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td>Feb-06</td>
<td>Integrated Drug Treatment System - The First 28 days: Psychosocial Support</td>
<td>England</td>
<td>3 phase CARAT (tiers 2 &amp; 3)</td>
<td>NTA</td>
<td></td>
</tr>
<tr>
<td>Jun-05</td>
<td>Retaining clients in drug treatment</td>
<td>England</td>
<td>Retention</td>
<td>NTA</td>
<td></td>
</tr>
<tr>
<td>Feb-04</td>
<td>Northern Ireland Guidelines on Substitution Treatment for Opiate Dependence</td>
<td>Northern Ireland</td>
<td>Substitute prescribing</td>
<td>DH, SSPS</td>
<td></td>
</tr>
<tr>
<td>Jan-04</td>
<td>Reducing Drug-Related Deaths: guidance for drug treatment providers</td>
<td>England</td>
<td>Harm-reduction</td>
<td>NTA</td>
<td></td>
</tr>
<tr>
<td>May-03</td>
<td>Injectable heroin (and injectable methadone) - Potential roles in drug treatment</td>
<td>England</td>
<td>Drug treatment modality</td>
<td>NTA</td>
<td></td>
</tr>
<tr>
<td>Oct-02</td>
<td>Psychostimulants: A practical guide</td>
<td>Scotland</td>
<td>Pharmacological, psychosocial and acupuncture</td>
<td>PSWG, SDF, EIU</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Publication Title</td>
<td>Where relevant</td>
<td>Types of Interventions</td>
<td>Groups Addressed</td>
<td>Lead Authors</td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>May-10</td>
<td>Routes to Recovery: Psychosocial interventions for drug misuse. A framework and toolkit for implementing NICE-recommended treatment interventions</td>
<td>England and Wales</td>
<td>Implementation of psychosocial interventions</td>
<td>Practitioners, service managers and commissioners</td>
<td>NTA and BPS</td>
</tr>
<tr>
<td>Jan-10</td>
<td>Commissioning for recovery. Drug treatment, reintegration and recovery in the community and prisons: a guide for drug partnerships</td>
<td>England</td>
<td>Commissioning</td>
<td>Drug partnerships and commissioning staff in community and prison settings</td>
<td>NTA</td>
</tr>
<tr>
<td>Dec-09</td>
<td>Guidance for the planning and provisions of substance misuse services to children and young people in the care of youth offending services</td>
<td>Wales</td>
<td>Care planning and the delivery of interventions</td>
<td>Youth offending team partnerships, children and young people’s partnerships, Community Safety Partnerships and substance misuse action teams</td>
<td>WAG and Health Challenge Wales</td>
</tr>
<tr>
<td>Dec-09</td>
<td>Substance Misuse Service and System Improvement - National Core Standards for Substance Misuse Services in Wales</td>
<td>Wales</td>
<td>Standards required for treatment</td>
<td>Responsible Authorities of CSPs, providers and citizens</td>
<td>WAG, Health Challenge Wales</td>
</tr>
<tr>
<td>Sep-09</td>
<td>Prisons Integrated Drug Treatment System: Continuity of Care Guidance</td>
<td>England</td>
<td>Assessment of need</td>
<td>Commissioning managers, drug partnership boards, PCTs, and prison stakeholders</td>
<td>DH, Ministry of Justice</td>
</tr>
<tr>
<td>Jul-09</td>
<td>Undertaking needs assessment: drug treatment. Recovery and reintegration in the community and prisons</td>
<td>England</td>
<td>Assessment of need</td>
<td>Commissioning managers, drug partnership boards, PCTs, and prison stakeholders</td>
<td>NTA</td>
</tr>
<tr>
<td>Jul-09</td>
<td>Clinical governance in drug treatment: A good practice guide for providers and commissioners</td>
<td>England and Wales</td>
<td>Clinical Governance</td>
<td>Service providers, commissioners and service users</td>
<td>NTA</td>
</tr>
<tr>
<td>May-09</td>
<td>Residential drug treatment service: a summary of good</td>
<td>England</td>
<td>Tier 4</td>
<td>Commissioning managers, DATs, Tier 4 NHS and voluntary sector treatment providers</td>
<td>NTA</td>
</tr>
<tr>
<td>Date</td>
<td>Title</td>
<td>Location</td>
<td>Skills</td>
<td>Organisation</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------------------------------------------</td>
<td>-------------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------------------</td>
<td></td>
</tr>
<tr>
<td>May-09</td>
<td>Residential drug treatment services: good practices in the field</td>
<td>England</td>
<td>Tier 4 set-up by service review</td>
<td>Commissioning managers, DATs, Tier 4 NHS and voluntary sector treatment providers</td>
<td></td>
</tr>
<tr>
<td>Jan-09</td>
<td>Planning, commissioning and delivering the training and employment pathway for PDU's (Updated April 2009)</td>
<td>England</td>
<td>Practice development</td>
<td>Jobcentre Plus advisors and drug coordinators, commissioners and providers of treatment services</td>
<td></td>
</tr>
<tr>
<td>Dec-08</td>
<td>Auditing drug misuse treatment</td>
<td>England and Wales</td>
<td>Auditing</td>
<td>Drug partnerships, service providers, commissioners and commissioning managers</td>
<td></td>
</tr>
<tr>
<td>Sep-08</td>
<td>Supporting and involving carers: a guide for commissioners and providers</td>
<td>England and Wales</td>
<td>Commissioning</td>
<td>Commissioners and providers</td>
<td></td>
</tr>
<tr>
<td>Sep-08</td>
<td>Improving the quality and provision of Tier 4 interventions as part of client treatment journeys: A best practice guide</td>
<td>England</td>
<td>Quality and provision of tier 4 treatments</td>
<td>Treatment service managers, joint commissioners, providers and users of drug treatment services</td>
<td></td>
</tr>
<tr>
<td>Jul-08</td>
<td>Guidance on good practice for the provision of services for children and, younger people who use or misuse substances in Wales</td>
<td>Wales</td>
<td>Prescribing, education, needle exchange, assessments, detoxification, group, family and individual therapy, self-help, specialised interventions, transition planning</td>
<td>Planners and service providers</td>
<td></td>
</tr>
<tr>
<td>Apr-08</td>
<td>Substance Misuse Treatment Framework Carers and Families of Substance Misusers A Framework for the Provision of Support and Involvement</td>
<td>Wales</td>
<td>User involvement</td>
<td>Adult carers, adult family members, service providers, commissioners</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Subject</td>
<td>Country</td>
<td>Focus Area</td>
<td>Stakeholders</td>
<td>Author</td>
</tr>
<tr>
<td>-------</td>
<td>--------------------------------------------------------------------------</td>
<td>----------</td>
<td>------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Aug-07</td>
<td>Needs assessment guidance for adult drug treatment</td>
<td>England</td>
<td>Needs assessment</td>
<td>Commissioners, providers, clinicians, users and other interested groups</td>
<td>NTA</td>
</tr>
<tr>
<td>Jul-07</td>
<td>Good practice in care planning</td>
<td>England</td>
<td>Care planning practice</td>
<td>Treatment providers, commissioners and service providers</td>
<td>NTA</td>
</tr>
<tr>
<td>Jun-07</td>
<td>Good Practice Framework for the Provision of Substance Misuse Services to Homeless People and those with Accommodation Problems</td>
<td>Wales</td>
<td>Outreach services (Tier 2) &amp; partnership working</td>
<td>Service providers, commissioners, planners, homelessness agencies, housing authorities, CSPs</td>
<td>WAG</td>
</tr>
<tr>
<td>Oct-06</td>
<td>Models of residential rehabilitation for drug and alcohol misusers</td>
<td>England</td>
<td>Residential rehabilitation - group work, life skills, vocational, family, supportive programmes, community treatment, resettlement, withdrawal treatment</td>
<td>Local, regional and supra-regional commissioners, care managers,</td>
<td>NTA</td>
</tr>
<tr>
<td>Jul-06</td>
<td>Models of care for treatment of adult drug misusers: Update 2006</td>
<td>England</td>
<td>Four-tiered framework</td>
<td>Managers, joint commissioners, providers and service users</td>
<td>NTA</td>
</tr>
<tr>
<td>Feb-06</td>
<td>Best practice guidance for commissioners and providers of pharmaceutical services for drug users. Service specification (Tier 2 or 3)</td>
<td>England</td>
<td>Commissioning</td>
<td>Commissioners and providers of pharmaceutical services in primary and secondary care</td>
<td>NTA</td>
</tr>
<tr>
<td>Feb-06</td>
<td>New Strategic Direction for Alcohol and Drugs</td>
<td>Northern Ireland</td>
<td>Service framework</td>
<td>service commissioners, co-ordinators and joint commissioning group, DAT co-ordinators, strategic partnerships, treatment providers</td>
<td>DHSSPS</td>
</tr>
<tr>
<td>Jun-05</td>
<td>Young people's substance misuse treatment services - essential elements</td>
<td>England</td>
<td>Four-tiered framework</td>
<td>service commissioners, co-ordinators and joint commissioning group, DAT co-ordinators, strategic partnerships, treatment providers</td>
<td>NTA</td>
</tr>
</tbody>
</table>
11.5.1 On-going guidance development

Unless otherwise stated, guidance in the UK does not have a pre-determined date for review. However, some guidance, such as the NICE technology appraisals will be reviewed at a set date (month and year). NICE consults with relevant organisations to decide whether the guidance needs to be updated and, if so, how. The time between guidance publication and review will vary depending on available evidence and knowledge of when ongoing research will be reported. Technology appraisals can be reviewed before the review date if there is new significant evidence that is likely to change the recommendations. After gathering relevant information and completing a literature search, a review proposal is produced. NICE’s Guidance Executive considers and signs off guidance documents on a weekly basis. The group consists of NICE executive directors, guidance directors and the communications director. For technology appraisals, the Guidance Executive will use information from the review proposal to decide if the published guidance should be updated. The Guidance Executive then decides on the most appropriate course of action (Table 11.7).

### Table 11.7: Possible actions for updating NICE guidance

<table>
<thead>
<tr>
<th>Guidance needs updating</th>
<th>Guidance does not need updating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appraisal planned to update the published guidance</td>
<td>Guidance is valid and does not require an update because the evidence base is not likely to change substantially, i.e. gets designated as a static guideline</td>
</tr>
<tr>
<td>Appraisal planned that combines the published guidance with the one or more related pieces of published guidance or ongoing appraisals</td>
<td>Defer the update to a future date</td>
</tr>
<tr>
<td>Update the published guidance with another guidance producing centre</td>
<td>Incorporate the guidance into a clinical guideline</td>
</tr>
</tbody>
</table>

Source: NICE

The NTA review their guidelines on a case-by-case basis with different processes for review depending upon the guideline being reviewed.

11.6 Implementation process

Virtually all drug treatment organisations have a statutory or contractual obligation for appropriate clinical governance, and clinicians have professional obligations for standards of care through their established regulatory bodies. This will include proper consideration and application of evidence-based guidance and guidelines for effective treatment. In addition, commissioners of services may reflect elements of current guidance in contracts or service level agreements with providers. Commissioners and providers are also expected to implement services that address specific needs at a local level.

Due to services having the flexibility to implement guidelines in a way that addresses the level of need at a local level, there is no single model for effective implementation of treatment guidelines within the UK.

11.6.1 Guideline adoption

In England and Wales, the NHS must provide funding for recommendations made by NICE technology appraisals within three months of their publication.
Table 11.8: NICE guidance adoption in the NHS

<table>
<thead>
<tr>
<th>Type of guidance</th>
<th>Recommendations for NHS organisations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Guideline</td>
<td>Review current management of clinical conditions and consider the resources and time needed to implement the guideline</td>
</tr>
<tr>
<td>Technology Appraisal</td>
<td>Fund and resource medicines and treatment recommended usually within three months of NICE issuing guideline</td>
</tr>
<tr>
<td>Public Health Guidance</td>
<td>Review current practice and consider the resources and time needed to implement the guideline</td>
</tr>
</tbody>
</table>

Source: NICE

11.6.2 Strategy of dissemination and implementation

In England, *Models of care: Update 2006* does not in itself provide recommendations for implementation and dissemination but the NTA has produced multiple guidance documents for commissioners, service managers and practitioners on how to develop services in line with the models of care framework (see tables 11.5.1 and 11.5.2).

The 2007 UK clinical guidelines do not provide their own framework for dissemination and implementation but, across the UK, a range of documents has been produced, including service frameworks that provide organisations with guidance on how to implement the UK clinical guidelines (see tables 11.5.1 and 11.5.2). The 2007 UK clinical guidelines and NICE clinical guideline and technology appraisals were launched together at regional events from Autumn 2007, with agreement reached between the NTA and NICE on joint dissemination in order to maximise the impact of dissemination and to enable effective and consistent communication.

NICE has produced a range of ‘how to’ guides to help with the implementation of their guidance at a local level with topics such as *How to put NICE guidance into practice* (NICE 2005) (which covers the dissemination and implementation process of their clinical guidelines and technology appraisals) and *How to use NICE guidance to commission high quality services* (NICE 2009e).

For NICE technology appraisals, it is recommended that guidance implementation teams assess the relevance of the guidance to their service, if there will be an impact on the existing health community and if so, where partnership working can be implemented. A baseline assessment should then be completed, assessing the current practice against that recommended in the guidance. If current practice is not in line with the guidance recommendations, then an action plan and cost assessment needs to be produced. The action plan will identify areas needing work and the implementation team will allocate actions and assign responsibility according to the interests of individuals within the implementation team. Funding will need to be provided within three months from the date NICE issues the technology appraisal (unless otherwise stated). Dissemination of the guidance then occurs within the service. The implementation process is reviewed and monitored with feedback of progress being provided to the NHS trust board.

Guidance specific tools have been published, with particular reference to costing tools for implementation. *Drug misuse - naltrexone: costing statement* (NICE 2007e) and *Drug misuse - methadone and buprenorphine: costing template and costing report* (NICE 2007f) are tools to help services assess the financial impact of implementing NICE guidance.
Practical implementation of treatment guidance

The flexibility in the implementation of guidance documents by services and practitioners was demonstrated in a project conducted by Luty et al. (2010),157 which showed that despite guidance documents e.g. ‘Methadone and buprenorphine for the management of opioid dependence’ (NICE 2007a) recommending higher doses of methadone be prescribed, it was more common for practitioners to prescribe lower doses of methadone; only half the teams reported 10 service users on doses over 60mg. These prescribing policies were supported by just over half of the service users, who recommended a maximum dose of 80mg of methadone. Regarding supervised consumption of methadone, just over half of the service users were opposed to the recommendation in the UK Clinical Guidelines (DH et al. 2007) that a pharmacist should supervise initial consumption of methadone. Consequently, the authors suggest that community drug teams may come under pressure from service users to permit take-away doses of methadone as findings from the study suggest that one-fifth of service users who are prescribed methadone are done so on a take-away basis. Even though benzodiazepines for symptomatic relief during opiate detoxification is supported by the 2007 UK Clinical Guidelines, the study found that less than half of the community drug teams would prescribe benzodiazepines for this purpose; the authors suggest that this is because the evidence base for this intervention remains weak. Despite the provision of guidelines for injectable opioids e.g. 2007 UK Clinical Guidelines (DH et al. 2007) and Injectable heroin (and injectable methadone) - Potential roles in drug treatment (NTA 2003), three-quarters of community drug teams would not prescribe injectables of heroin or methadone at all, whilst 60% of service users opposed the use of injectable prescriptions from private facilities.

11.6.3 Factors supporting and complicating implementation

NICE have created a ‘Shared Learning Database’ that enables organisations that have implemented NICE guidance to share tips, ideas and examples of their implementation process.

In 2007, the Department of Health implemented ‘Payment by Results’ for NHS services. This process aims to provide financial gains for services that prove to be efficient and supportive of patient choice and diversity. It aims to encourage sustainable activities that reduce waiting times. As guidance produced in the UK has proven clinical and cost-effectiveness, ‘Payment by Results’ may be a scheme that encourages the implementation of guidelines.

11.6.4 Future developments

NICE currently plans holding a stakeholder consultation on the draft guidance, Psychosis with substance misuse, which is due to be published in March 2011. NICE regularly considers whether there is sufficient evidence to suggest that a review of existing guidance is necessary and expects to consult on plans to consider a review of the technology appraisals, Methadone and buprenorphine for managing opioid dependency and Naltrexone for the management of

---

157 Conducted as a postal and telephone survey, and directed to the prescribing doctors of 140 community drug teams in England and Wales. Prescribing policies for substitute prescriptions, including the prevalence of supervised methadone consumption, the use of higher doses of methadone, injectables and prescribed benzodiazepines, were surveyed from 120 drug teams (giving a 86% response rate). Through a second survey, 104 clients from community drugs teams in Essex commented on various aspects of prescribing policies.
opioid dependence. It will also consider updating the public health guidance on Interventions to reduce substance misuse amongst vulnerable young people. In 2011 NICE is expected to consider the need to review its clinical guidelines on Drug misuse: opioid detoxification (NICE 2007c) and Drug misuse: psychosocial interventions (NICE 2007d).

In addition to guidance specifically addressing drug misuse, the treatment of drug misuse may be covered in broader guidelines such as the recently published clinical guideline, Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors (NICE 2010).

11.7 Comparison with the World Health Organisation guidelines

Pharmacological treatment of opiate dependence
As part of the selected issue, Focal Points are requested to compare national guidelines on pharmacological treatment of opiate dependence with the World Health Organisation (WHO) guidelines, Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence (WHO 2009). There are a number of UK guidelines that cover aspects of the treatment of opiate dependence – relating to different specific treatments or different settings. However, the document Drug misuse and dependence - UK guidelines on clinical management (DH et al. 2007) is consistent with, or incorporates recommendations from, the other main UK guidance documents. It the UK guidelines document most equivalent in scope to the WHO document and so is used as the main comparator in the following discussion.

As in the WHO guidelines, the first-line treatment recommended in the 2007 UK clinical guidelines for opioid dependence is induction and stabilisation on opioid agonist treatment. The relevant section on opioid maintenance prescribing in the 2007 UK clinical guidelines recognises that most will require agonist treatment for longer than just a few months but also that a few patients can achieve abstinence rapidly. The opioid agonists recommended by WHO for the pharmacological treatment of opioid dependence, methadone and buprenorphine, are also the ones recommended within the UK. In the UK, it is recommended that if both methadone and buprenorphine are equally suitable, methadone should be prescribed as first choice (as recommended in the NICE technology appraisal on methadone and buprenorphine – because of the greater cost-effectiveness of the former). However, the 2007 UK clinical guidelines make clear that the choice initially should be made on a case-by-case basis, taking patient and prescriber preferences into account. The WHO guideline is slightly stronger in its statement that, in general, methadone is recommended over buprenorphine. However, both the UK and WHO guidelines do make clear that good outcomes are seen with both drugs and that there may be benefits from making both available.

The 2007 UK clinical guidelines also very closely match WHO recommendations on the appropriate dosage level for methadone and buprenorphine, both initially for induction and subsequently for stabilisation and maintenance. There are some differences of detail. The WHO guideline suggests stabilisation on 8 to 24mg per day of buprenorphine, whilst in the UK, it is recommended that most patients need an average daily dose of 12 to 16 mg for effective maintenance treatment (with some needing up to 32 mg). Also, the WHO guideline states that initial methadone dose should be 20 mg or less, whilst in the 2007 UK clinical guidelines it is suggested that in general, the initial daily dose will be in the range of 10 to 30 mg. In the UK, it is stated that with heavily dependent misusers who are tolerant, and where the clinician is experienced or competent, a first dose can be up to 40 mg but that it is unwise to exceed this dose. A similar caveat in the WHO guideline recognises that some patients with high levels of
neuroadaptation may be given up to 30 mg as a starting dose as long as the risks of fatal overdose are taken into account in balancing risks. The speed of escalation of doses during the induction and stabilisation phases are very similar.

The WHO recommendation of supervision in the early phase of treatment followed by take-home doses in the right circumstances is also a feature of 2007 UK clinical guidelines.

The WHO guideline recommends consideration of the use of naltrexone, following completion of opioid withdrawal in those who are motivated to cease opioid use completely. It suggests it is likely to be most useful for those with a reasonable chance of remaining abstinent, where a significant other can administer and supervise it, and alongside routinely offered psychosocial treatment. This is a very similar recommendation to that given in the NICE technology appraisal on naltrexone. The UK guideline summarise the recommended use of naltrexone in detoxified formerly opioid-dependent people who are highly motivated to remain in an abstinence-based programme, only under adequate supervision, in those who have been fully informed of the potential adverse effects of treatment, and receive the medication as part of a wider programme of supportive care.

For pregnant women who are dependent on opioids, maintenance treatment is generally recommended using methadone in both the UK and WHO guidelines but both also recognise that it is appropriate to consider continuing with buprenorphine treatment if this is already working.

The 2007 UK clinical guidelines on the use of drugs for opioid detoxification are generally similar to the WHO guidelines. Tapering doses of methadone and buprenorphine, as well as the alpha-adrenergic agonists – particularly lofexidine, are recommended by the WHO and in the UK. Both guidelines also advise against the combination of opioid antagonists with heavy sedation. There is a discrepancy in the descriptions of duration of detoxification between the two guidelines. The WHO document refers to typical durations of dose tapers of five days for buprenorphine and 10 days for methadone and it also notes that gradual reduction can reduce the severity and increase the length of opioid withdrawal but reduce the rate of successful completion of withdrawal. For methadone, the WHO guideline does note though that a further 10 to 14 days may be needed before initiation of naltrexone is appropriate. In contrast, the UK guidelines document states that the process of opioid detoxification may vary from person to person, usually lasting about 28 days as an inpatient or up to 12 weeks as an outpatient.

In the UK, it is recommended, in line with the WHO guidelines, that clients receiving pharmacological treatment are routinely offered psychosocial support.
CROATIA

11 History, methods and implementation of national treatment guidelines

In Croatia there are two guidelines that refer to the treatment of drug addiction: the Guidelines for the Methadone Pharmacotherapy of Opiate Dependence and the Guidelines for the Buprenorphine Pharmacotherapy of Opiate Dependence. Both were adopted in 2006 and are targeting opiate addicts as the most significant and problematic group of drug users in Croatia. The main idea behind elaborating these guidelines was to provide professionals in the responsible inpatient and outpatient treatment settings with operational framework that would increase effectiveness of substitution treatment and would prevent possible abuse of medicines concerned. Both guidelines were elaborated by the expert group at the Ministry of Health and Social Welfare.

11.1 History and overall framework

The first comprehensive document that provided a base for establishing systematic and organised treatment of drug addiction in Croatia, in line with the highest professional and quality standards was the National Strategy for Combating Narcotic Drugs Abuse in the Republic of Croatia, which was adopted by the Croatian Parliament in 1996, as the first strategic document in the field. Due to the geostrategic position of Croatia on so-called Balkan route which was especially in the past well known for trafficking in opiates, maritime orientation of the country, circumstances related to the Croatian War of Independence as well as other social factors, problems related to abuse of opiates started to expand in early 1990. That is the main reason why treatment of drug addiction in Croatia is primarily focused on opiate drug addicts as they still today dominate in the total number of drug addicts (2009:80.8%) registered by the treatment system.

Basic determinants of the state policies regarding treatment of drug addicts require the availability of different types of programmes. The therapeutic approaches, as well as forms of intervention and aid, must be adjusted individually so that three determinants of a good state policy regarding addict treatment are abided by, fulfilling at the same time the most important strategic and individual goals (according to the EU strategy on drugs and valid national strategic documents):

- Detection of heroin addict in an early stage of the disease and their contact with the treatment system, so that a therapy may commence;
- Enabling and implementing a treatment in the largest number of patients possible with regard to the total number of heroin addicts in the community;
- Ensuring that the largest number of patients maintain their therapy.

None of the three determinants is possible to accomplish if heroin addicts are not enabled an easily available supply of opiate agonists.

Therefore, the first national guidelines related to the treatment of drug addiction referred to methadone substitution treatment of opiate addiction. The Guidelines for the Methadone Pharmacotherapy of Opiate Dependence (Methadone Guidelines) were adopted in January 2006 by the Croatian Government, upon the recommendation of the Ministry of Health and Social Welfare. The basic starting point for the creation of this document was the National Strategy for
Combating Narcotic Drugs Abuse in the Republic of Croatia (adopted by the Croatian Parliament in 1996). The Methadone Guidelines elaborates position and role of the national system for addiction treatment, the organization of the system, as well as the treatment of heroin addicts itself. In the creation of the Guidelines, the following documents were used: WHO (The Practices of Pharmacotherapy of Opioid Dependence, WHO 2004), EMCDDA (Reviewing current practice in drug-substitution treatment in the European Union, EMCDDA, 2000); Methadone Guidelines, prepared by A. Verster and E. Buning in the scope of the project funded by the European Commission (EuroMeth, June, 2000), NIDA (Thirteen principles of effective drug addiction treatment, NIDA Notes; Vol.14.Nr.5. 1999), European Union Drugs Strategy 2005 – 2012 (Council of the EU 15074/04, Cordrogu 77), document “Improvement possibilities of the heroin addict treatment programme using methadone” (Sakoman, 2000). All these sources confirmed the contemporary scientific findings, and define treatment of addicts as a long-term (even lifelong) process, with an unpredictable dynamics and final result, which is, like all other chronic diseases, a task undertaken by medical experts.

Recognizing the importance and benefits of guidelines in the treatment of drug addicts and in order to introduce new treatment possibilities as well as to ensure its consistent implementation, the Government Committee on Combating Drugs Abuse adopted the Guidelines for the Buprenorphine Pharmacotherapy of Opiate Dependence (Buprenorphine Guidelines) already in December 2006. Buprenorphine is as well as methadone included in the positive lists to medicines that are covered by the Croatian health insurance. Different than in the case of the Methadone Guidelines, starting point for elaboration of this document was the National Strategy for Combating Narcotic Drugs Abuse for 2006-2012 (adopted by the Croatian Parliament on 2 December 2005) and the Action Plan on Combating Narcotic Drugs Abuse for 2006-2009 (adopted by the Croatian Government on 15 February 2006) as new strategic documents in the field. Similar like Methadone Guidelines, this document also describes position and role of the national system for addiction treatment, the organisation of the system, and the treatment of heroin addicts. In the creation of the Guidelines, the following documents were consulted: WHO (The Practices of Pharmacotherapy of Opioid Dependence, WHO 2004), EMCDDA (Reviewing current practice in drug-substitution treatment in the European Union, EMCDDA, 2000), NIDA (Thirteen principles of effective drug addiction treatment, NIDA Notes; Vol.14, Nr.5, 1999), European Union Drugs Strategy 2005 – 2012 (Council of the EU 15074/04, Cordrogu 77). The document stresses: “opiate agonist pharmacotherapy is the backbone of the modern approach to addiction treatment. Compared to methadone, buprenorphine has been confirmed to be a safer option, since its mechanism of action places it in the category of partial opiate agonists of mi receptors in the brain, and, unlike methadone, kappa and delta receptor antagonists. By acting on mi receptors, it efficiently reduces the craving for opiates and prevents abstinence symptoms” (Guidelines for the Buprenorphine Pharmacotherapy of Opiate Dependence 2006, p. 1).

11.2 Existing guidelines: narrative description of existing guidelines

The main objective of the Methadone Guidelines is to reduce the harmful consequences of opiate addiction on the society and to help addicts and their families by early treatment of addicts and in large numbers; reducing number of new addicts attracted by untreated addicts; preventing spread of hepatitis B and C, HIV, syphilis, tuberculosis and other infections; reducing costs of chronic disease treatment (AIDS, hepatitis B and C, tuberculosis and many others); reducing total mortality of addicts and overdose mortality; maintaining work productivity (of the addicts' parents, as well as of the addicts themselves); reducing effect of addiction on life expectancy and
lost years of healthy (productive and quality) life; reducing consumption and demand for illicit substances and drugs; reducing health protection of addicted pregnant women and their children; increasing probability of full recovery and satisfactory social rehabilitation and reintegration; improving treatment of comorbid psychological disorders in opiate addicts; reducing number of secondary criminal offences; reducing profit of organised crime groups; reducing prostitution; reducing corruption and reducing number of traffic accidents and the severity of material damage.

The indication for methadone treatment is a confirmed opiate addiction after a diagnostic procedure, based on the criteria for this disease according to ICD-10 or DSM-IV, with a special emphasis placed on psychological criteria (strong craving or compulsion to take opiates; difficulty in controlling criminal behaviour that can lead to discontinued or reduced use), physiological criteria (characteristic withdrawal symptom upon discontinuing use of the opiate; proof of tolerance, and the subsequent need to increase the dose to achieve the desired effects) and social criteria (progressive neglect of other interests/sources of pleasure, increasingly more time spent in acquiring and consuming of or recovering from the drug; persistent taking of the drug despite the harmful side effects).

The contemporary concept of addict treatment should enable the patient to be in the position of a subject in the therapeutic process. Therefore, both the assessment of a physician according to the best practice for each addict and the co-decision of the addicts themselves are important in the decision on methadone therapy. Among the available treatment modalities there are short detoxification, slow detoxification, short (temporary) maintenance therapy and long-term maintenance therapy.

To, according to the principle of the best practice and these guidelines, indicate a methadone therapy in the treatment of heroin addicts, a physician must have the necessary theoretical and practical knowledge examined in the manner set out by the law, which makes him/her an authorised physician for such a specific form of treatment. Education is implemented according to a special programme, which must include specific knowledge on opiate agonist pharmacotherapy. The Drug Reference Centre of the Ministry of Health and Social Welfare is competent for the creation and implementation of the programme, as well as for examinations. The minister of health, according to the needs in each individual county, on the initiative of the Croatian Institute of Public Health, promulgates the list of authorised physicians. The updated list of authorised physicians is delivered to public health institutes, general practitioners and pharmacies. Physicians and their expert teams oblige the patient to, according to their individual therapy agreement, undergo the recommended therapy, which must include regular visit to his/her chosen general practitioner, who will, according to the written recommendation of the authorised physician, indirectly enable the addicted patient to use methadone and must undergo control examinations by the authorised physician on the set date. In addition, other psychosocial measures have to be provided as well (psychotherapy, social interventions etc.). To start with a methadone treatment programme, the addict must first contact a team of authorised physicians. After a diagnostic procedure and indication of methadone therapy, the authorised physician writes a finding for the general practitioner, which must contain the following elements: date of the finding; name and surname of the physician to which the therapy recommendation is sent; type of preparation (tablet or solution) and the dose of the drug; whether the drug is administered under supervision, or by the patient, or by family members; duration of the therapy and dates of control examinations. The client may request and, with or against the physician’s recommendation, discontinue the programme permanently or temporarily. The programme may be discontinued temporarily or for a longer period of time by the decision of an authorised specialist. The physician, responsible for the indirect administration of methadone, according to
the regulations on dispensing “narcotics”, writes a prescription and ensures the dispensing of the drug, and afterwards the keeping of the necessary quantity of the drug. The addict must not receive methadone in a pharmacy by him/herself. The physician can authorise a person who will do that instead of the addict. That can be a reliable member of the addict's family. In such a case, the prescription should contain the name and surname of the authorised person with the ID number. The patient must take the drug in the clinic, under the supervision of the medical staff. Methadone may be administered to the patient directly and on a one-time basis by all physicians as a form of emergency intervention in case of an acute abstinence syndrome. The Ministry of Health, according to a special plan, supervises the process of indicating, prescribing and dispensing methadone. The expert supervision of the addict treatment programme that includes specific opiate agonist pharmacotherapy will be implemented by the expert team of the Drugs Reference Centre and Croatian Institute for Public Health. Until the Reference Centre is established, the expert supervision will be implemented by the Croatian Institute for Public Health in cooperation with appointed experts and the Ministry of Health.

Buprenorphine was introduced in the treatment of opiate addicts in Croatia with the objective to expand treatment possibilities. Although it has not yet been scientifically confirmed which addicts will benefit the most from a methadone therapy, and which from buprenorphine therapy, the Buprenorphine Guidelines emphasise that there are several proven facts which make the drug essential in therapy today, with a comparative advantage over methadone: high-dose tolerance for buprenorphine is better than high-dose tolerance of methadone; patients develop tolerance to buprenorphine in much fewer cases; buprenorphine is much less addictive than methadone; buprenorphine use bears an extremely small risk of overdose death; many addicts who are undergoing methadone addiction therapy today could benefit from Buprenorphine; buprenorphine may be administered three times a week; patients may visit their physician only once a week. It has to be stressed that Buprenorphine Guidelines contains similar provisions in more general issues like objective of the therapy, indications, treatment modalities, physicians authorised for substitution treatment etc, which are adapted to the specificities of buprenorphine therapy.

11.3 Implementation process

When talking about who directly initiates and implements the procedure, there should be differentiated inpatient and outpatient settings. In hospitals that would be specialist psychiatrists, as a part of the detoxification process in specialist hospital wards; specialist psychiatrists and other physicians as consulting physicians in other hospital wards where patients are treated for other diseases, or where there are pregnant women and infants; specialist psychiatrists and other authorised physicians in prison hospitals (including prisons, detentions, penitentiaries and penal institutions). In outpatient treatment there is authorised psychiatrists and other authorised physicians employed in the addiction prevention services of public health institutes and their branches (prevention and outpatient treatment on the municipal level); authorised psychiatrists who are a part of polyclinical, specialist and consulting health care in hospitals; authorised psychiatrists and other authorised physicians with a private practice.

To start with a substitution treatment programme, the addict must first visit an authorised physician. There are several modes of involving patients in the programme and keeping them in it.

- Visiting an outpatient treatment service, also possible directly (without a referral and fees). The patient must be indentified, and then he/she completes a compulsory questionnaire (for the purposes of registry, epidemiological monitoring, national registry
and statistics). If after a diagnostic procedure buprenorphine is indicated, the addict may start the therapy, according to the written recommendation (letter to the physician), at his/her chosen general practitioner, and only exceptionally at some other institution, in a prescribed manner.

- Visiting the clinic of an authorised physician, who is at the same time the chosen general practitioner. This mode enables the addict to be examined, to get a prescription for the drug and to start a buprenorphine therapy, all in one place. If the physician deems the patient's case to be too complicated, he/she will ask for another opinion and request that the initial administration of buprenorphine be started at the local Centre, and continue in his practice. The physician is obliged to complete a compulsory questionnaire for the records and send it to the Croatian Institute for Public Health.

- Visiting the private psychiatric practice of an authorised physician (psychiatrist). After an examination and decision on whether to start the therapy, the psychiatrist first completes the compulsory questionnaire for the records, writes the medical findings and prescription for the first package of the drug, and then induces the addict to the programme (all the costs are borne by the patient). After the first week, when the patient has stabilised on an appropriate dose, the treatment may continue in at the practice using the procedure according to the decision of the authorised physician, or the patient may be referred to his/her chosen general practitioner with his/her medical documents to resume the recommended treatment directly.

- Being referred by the chosen general practitioner to the clinic of an authorised psychiatrist of a polyclinical institution. After an examination and decision on whether to start the therapy, the psychiatrist first completes the compulsory questionnaire and writes the medical findings on the planned procedure. The initial administration of buprenorphine, lasting from a day to a week, depending on a clinical decision and the severity of the case, will be implemented in the polyclinic, at the local Centre, or (in simpler cases) in the clinic of the chosen physician. After a successful initial administration, further treatment will be implemented by the chosen general practitioner in cooperation with the authorised physician.

11.4 For countries that have treatment guidelines: comparison with the WHO guidelines

In addition to the information provided in the questionnaire on coherence with WHO guidelines (see Table 11.1), in the text below there is more detailed description of key issues.

When it comes to types of programmes and criteria for administering methadone / buprenorphine, according to the national guidelines concerned the contemporary concept of addict treatment should enable the patient to be in the position of a subject in the therapeutic process. Therefore, both the assessment of a physician according to the best practice for each addict and the co-decision of the addicts themselves are important in the decision on methadone therapy. Short detoxification is a procedure which eases the abstinence syndrome in patients following discontinued use of heroin (other opiate agonists) by gradually reducing the daily methadone doses over the period of a month. It is indicated in therapy when a complete abstinence, followed by abstinence maintenance, is agreed upon as the goal of the therapy. Slow detoxification is a procedure which eases the discontinued use of opiates in patients by gradually reducing the daily methadone doses over the period up to six or more months. It is indicated if previous attempt or attempts at a rapid detoxification failed. The procedure is recommended when a complete abstinence from opiate agonists and abstinence maintenance are agreed upon.
as the goal of the therapy, and when it is assessed that a rapid detoxification process is not possible due to the severity of the addiction. Short (temporary) maintenance therapy on a sustained daily methadone dose includes a procedure in which the daily dose of methadone given to the patient remains the same for up to six months. It is indicated as the initial treatment of addicts who may lack the cannot (personal capacity and support of the environment) quit drugs completely, or where an attempt at a detoxification may result either in discontinued treatment or continued heroin use; in patients who are unable to establish and maintain abstinence after a previous detoxification attempt; in patients who, after detoxification and maintaining heroin abstinence, indicate a progressive craving for the drug, and thus compensate for the heroin abstinence by abusing large quantities of psychoactive drugs, illicitly obtained methadone and other types of drugs and/or alcohol; as a temporary form of treatment which guarantees the continuation of the programme and facilitates an improvement of the patient's social status and living conditions, after which another detoxification process may be attempted; in addicts who, during detoxification, insist that the daily methadone doses is maintained because they feel unwell or fear recidivism. Long-term maintenance therapy is a process which enables the addict to take appropriate (with regard to tolerance) daily doses of methadone over the period of more than six months. Some of the patients undergo such maintenance treatment for the remainder of their life. It is indicated when the clinical features of the addiction are so severe that this form of treatment is thought to be the best for both the addict and his/her environment (family, social community); in addicts who could not be motivated to quit drugs and adopt a “drug-free” therapy goal; in pregnant women addicted to opiates; in HIV patients addicted to drugs; in addicts with a comorbidity.

The daily dose must be sufficient to maintain the stability of the patient and prevent withdrawal symptoms (abstinence syndrome) for 24 hours, meaning it has to be adjusted to the individual needs of each addict. The daily dose\(^{158}\) of methadone between 10 and 120 mg is enough for the majority of addicts. In special circumstances, when a dose greater than 120 mg is required, the decision is made and the medical finding signed by two authorised physicians. The recommended initial dose should not exceed 30 mg. The daily dose of buprenorphine between 1 and 8 mg is enough for the majority of addicts. The initial dose with which the induction of buprenorphine begins is usually 2 mg, and is taken (sublingually) under direct supervision. The patient is then placed under observation for 1-2 hours (necessary to observe the initial action of the drug and to intervene in case of an abstinence syndrome (due to the antagonistic action of buprenorphine on “pure” opiate agonists like heroin and methadone)). Initially, during the titration of the dose, the authorised physician must examine the patient more frequently. The Methadone Guidelines say that the first examination should be carried out after 3 to 4 days, when the maximum concentration of methadone in blood is achieved due to accumulation with equal doses. The second examination should follow after a week, and then according to the patient’s condition. According to the Buprenorphine Guidelines, the first examination should be carried out on the first day, and in any case after 3 to 4 days. In the first two weeks the patient should be examined at least three times, and i that time the maximum concentration of buprenorphine in blood will be reached with equal doses. This will also establish a cooperation with the patient and help determine the optimal dose.

When the addict stabilises his/her therapy routine and shows improvement in abstinence, cooperation and positive changes to his/her behaviour, the manner of administering methadone may be altered in the sense that the addict comes and takes the drug under direct supervision three times a week, and later once a week. Before travelling outside the place of residence or

\(^{158}\) Croatian guidelines do not specify an average maintenance dose but rather provide a range of recommended dose.
abroad, pursuant to the Act on Combating Drugs Abuse, the drug may be given to the patient with the accompanying medical documentation in advance for the period prescribed by an authorised physician (15 days at most). In special circumstances, a physician may make the drug available in advance for a longer period of time, especially if there is a very reliable cooperation with a family member.

Physicians and their expert teams oblige the patient to, according to their individual therapy agreement, undergo the recommended therapy, which must include at least the first two or more following elements: to visit regularly his/her chosen general practitioner, who will, according to the written recommendation of the authorised physician, indirectly enable the addicted patient to use methadone; to undergo control examinations by the authorised physician on the set date; to undergo a sporadic abstinence control: analysis of urine, saliva, hair sample at the premises or in a biochemical laboratory, conducted with the addict’s consent; psychotherapy; family procedure; education on the disease and the possibilities of recidivism prevention; measured of preventing infections (HIV, hepatitis, syphilis), including testing on the premises or referrals for testing in a competent health institution; social interventions; special re-educational procedure, if needed; comorbidity therapy; self-help programmes (former addict clubs or NGO programmes).

Table 11.1 – Comparison of national treatment guidelines with respective WHO guidelines

<table>
<thead>
<tr>
<th>Name of Assessors:</th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
<th>Specify</th>
<th>No answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office for Combating Drugs Abuse of the Government of the Republic of Croatia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 | Choice of treatment

1.2 For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment. Do the present guidelines include this recommendation?

1.3 For opioid-dependent patients not commencing opioid agonist maintenance treatment, consider antagonist pharmacotherapy using naltrexone following the completion of opioid withdrawal. Do the present guidelines include this recommendation?

2 | Opioid agonist maintenance treatment

2.1 For opioid agonist maintenance treatment, most patients should be advised to use methadone in adequate doses in preference to buprenorphine. Do the present guidelines include this recommendation?

2.2 During methadone induction, the initial daily dose should depend on the level of neuroadaptation; it should generally not be more than 20 mg, and certainly not more than 30mg. Do the present guidelines include this recommendation?

2.3 On average, methadone maintenance doses should be in the range of 60–120 mg per day. Do the present guidelines include this recommendation?

2.4 Average buprenorphine maintenance doses should be at least 8 mg per day. Do the present guidelines include this recommendation?
### 2.5 Methadone and buprenorphine doses should be directly supervised in the early phase of treatment.  
Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
<th>Not Addressed</th>
</tr>
</thead>
<tbody>
<tr>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2.6 Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review.  
Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
<th>Not Addressed</th>
</tr>
</thead>
<tbody>
<tr>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2.7 Psychosocial support should be offered routinely in association with pharmacological treatment for opioid dependence.  
Do the present guidelines include this recommendation?

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
<th>Not Addressed</th>
</tr>
</thead>
<tbody>
<tr>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 3 Management of opioid withdrawal

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
<th>Not Addressed</th>
</tr>
</thead>
</table>
| 3.1 For the management of opioid withdrawal, tapered doses of opioid agonists should generally be used, although alpha-2 adrenergic agonists may also be used.  
Do the present guidelines include this recommendation? | □   | X  | □              | □             |
| 3.2 Clinicians should not routinely use the combination of opioid antagonists and minimal sedation in the management of opioid withdrawal.  
Do the present guidelines include this recommendation? | x   | □  | □              | □             |
| 3.3 Clinicians should not use the combination of opioid antagonists with heavy sedation in the management of opioid withdrawal.  
Do the present guidelines include this recommendation? | x   | □  | □              | □             |
| 3.4 Psychosocial services should be routinely offered in combination with pharmacological treatment of opioid withdrawal.  
Do the present guidelines include this recommendation? | x   | □  | □              | □             |

### 4 Pregnancy

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
<th>Not Addressed</th>
</tr>
</thead>
</table>
| 4.1 Opioid agonist maintenance treatment should be used for the treatment of opioid dependence in pregnancy.  
Do the present guidelines include this recommendation? | x   | □  | □              | □             |
| 4.2 Methadone maintenance should be used in pregnancy in preference to buprenorphine maintenance for the treatment of opioid dependence; although there is less evidence about the safety of buprenorphine, it might also be offered.  
Do the present guidelines include this recommendation? | □   | X  | □              | □             |

*Source: EMCDDA*
TURKEY

HISTORY, METHODOLOGY AND IMPLEMENTATION OF NATIONAL TREATMENT GUIDELINES

Treatment guidelines for treatment of addiction have been included in the agenda of the Scientific Commission on Drug Addiction Treatment Procedures of the Ministry of Health in the recent years and studies were launched in this area.

1. The first output on this issue has been the “Drug Addiction Diagnosis and Treatment Guideline” issued in 2010 by the MoH Directorate General for Curative Services, edited by Prof. Dr. Zehra Arikan and Assoc. Prof. Nesrin Dilbaz. The preparation of this guideline was initiated in 2008 and the chapters were written by the members of MoH Scientific Commission on Drug Addiction Treatment Procedures and the experts appointed by this commission.

The guideline has the following content:

1. Protection and treatment principles in drug addiction
2. Toxicology analyses for detection of drug use
3. Opiate addiction
4. Alcohol abuse
5. Methyl alcohol intoxication
6. Mental and behavioural disorders due to sedative or hypnotic use
7. Mental and behavioural disorders due to cannabis use
8. Mental and behavioural disorders due to cocaine use
9. Mental and behavioural disorders due to solvent use
10. Mental and behavioural disorders due to caffeine and other stimulants
11. Hallucinogens
12. Mental and behavioural disorders due to tobacco (nicotine) use
13. Disorders related to the use of other substances
14. Poly-drug use
15. Substance intoxication
16. Motivational counselling
17. Challenges in addiction treatment and managing them
18. Self-help groups
19. Substance addiction, remission, relapse and its prevention
20. Psychotropic drug interactions
21. Laws on alcohol and illicit drug use
Annex-1 Notification on Training of Personnel to Serve in Drug Addiction Centres
Annex-2 Regulation on Drug Addiction Treatment Centres
Annex-3 Drug addicts treatment notification system in Turkey Tests used in alcohol addiction
Annex-4 CAGE test
Annex-5 Michigan Alcoholism Screening Test (MAST)
Annex-6 The Alcohol Use Disorder Identification Test (AUDIT)
Annex-7 Short alcohol withdrawal scale
Annex-8 Addiction Severity Index
The aim of this guideline is to serve as a fundamental reference book for the physicians treating addicts in their diagnosis and treatment practices.

2. Our country introduced Probation practices with a new legal arrangement in 2006. Those who are apprehended due to crimes related to substance use are referred to treatment under a probation order by the courts as per Article 191 of Turkish Penal Code (TPC).

The book entitled “Probation Addiction Program” written by Kültegen Ögel, Figen Karadağ, Yeşim Can, Ender Alıntıoprak, Hakan Coşkunol and prepared by the Alcohol and Substance Use Disorders Working Group of the Psychiatric Association of Turkey has been published in April 2010. The approval of MoH, Scientific Commission on Drug Addiction Treatment Procedures has been obtained.

This book is a guide that has been prepared in connection with the Probation order practices. A treatment program consisting of six sessions has been prepared and these structured sessions aimed to standardize the practices in the field.

3. The Buprenorphine/Naloxone preparation used for treating opiate addiction was introduced for use in our country in 2010. The MoH, Scientific Commission on Drug Addiction Treatment Procedures decided for the preparation of a guideline for detoxification and maintenance treatment and Prof. Dr. Hakan Coşkunol and Assoc. Prof. Dr. Defne Tamar Gürol were assigned for the preparation of this guideline. The preparation work for this guideline is still ongoing and the guide is planned to be printed within 2010.

“Drug Addiction Diagnosis and Treatment Guideline”, which has been prepared to ensure application of diagnostic and treatment approaches required by modern medicine on drug addiction in our country, has been approved by the Publication Board to be printed. Following the final editorial work, the book was agreed to be approximately 300 pages and printed in A4 format. Planned to be printed in 1000 copies, the book will be distributed to psychiatry clinics, drug addiction treatment centres and the relevant places providing services in the area of addiction. This guideline, which will be used in trainings and by those serving in this field, is intended to bring unity in practice and increase in the quality of service.

There are no treatment protocols on drug addiction in Turkey. The Scientific Commission on Substance Addiction Treatment Procedures has only recently started its work on this field. However, with an aim to cover the information need of healthcare staff working in the area of drug addiction, the publication of Drug Addiction Diagnosis and Treatment Guideline has been planned and the publication work has progressed to final stages.

This book, aimed to be published in 2010, is composed of 21 chapters following the DSM-IV-TR (Disorders related to Substance Use) and ICD10 (F10-F19 Mental and Behavioural Disorders due to Psychoactive Substance Use) diagnostic criteria.

Scientific Commission on Drug Addiction Treatment Procedures members and the staff of Medical Services Division of Curative Services General Directorate have contributed to the work of 13 authors and editors in the preparation and publication of this book.

Drug Addiction Diagnosis and Treatment Guideline has been written for psychiatrists, general practitioners, family doctors, psychologists, social services experts and nurses working in the area of addiction.
The aim of this book is to help the diagnosis and treatment of drug use disorders. The diagnosis classification is done according to ICD10, which is officially adopted by our Ministry. The book will facilitate the practical work serving as a manual containing the diagnosis and treatment data for all drug use disorders. Moreover, considering the small availability of Turkish publications, this book will also fill a gap in this field.
NORWAY

11. History, methods and implementation of national treatment guidelines

Senior adviser Gabrielle Welle-Strand and senior adviser Martin Blindheim, Norwegian Directorate of Health

11.1. History and overall framework

Up until 2004, the legal basis for treatment for drug and alcohol problems in Norway was the Act relating to social services. In 2004, treatment for drug and alcohol problems was transferred to the specialist health services with the aim of integrating and normalising such treatment in the general health services on a par with other treatment at specialist level. At the same time, persons with drug or alcohol problems were given status as patients and thus acquired statutory patient rights.

In 2005, the Storting (Parliament) and the Ministry of Health assigned the Directorate of Health the task of drawing up guidelines for all drug and alcohol treatment at specialist level. The Directorate plans to complete this work in 2015. Guidelines will be prepared on the basis of the principles of evidence-based medicine following set criteria.

Work on the first guidelines, the National guidelines for opioid substitution treatment – OST, was initiated in 2006. The main reason why substitution treatment was the first topic chosen was the amount of attention it received in the media and from politicians and experts. This is partly because of the disproportionally high number of overdose fatalities in Norway. At the same time, however, substitution treatment has been a very controversial treatment form. An evaluation of the treatment offered in OST in 2003 uncovered undesirable regional differences. This was an important reason for work on the guidelines being initiated.

Methadone treatment was tentatively tested in a few projects around 1970, but, for the most part, Norway chose to develop a treatment system without the use of medication and characterised by an unwillingness to regard addiction as an illness. It was not until the HIV epidemic was detected among injecting users that a serious debate about substitution treatment started. On the basis of two Oslo-based trial projects, methadone treatment was made nationwide in 1998, following a decision by the Storting in 1997. From 2002, buprenorphine was also used systematically. The decision made it clear that substitution treatment was intended to be limited to a small number of hardcore heroin addicts, and as a supplement to other treatment without substitute medication. The reality proved to be different, and by the end of 2009, nearly 5,400 patients were receiving substitution treatment in Norway.

Norway was thus relatively slow to develop guidelines for drug and alcohol treatment. The first guidelines for OST were completed in 2010 after more than four years’ work. A further three

---

159 However, several guides have been produced for the municipalities and health service, including a guide relating to referrals to interdisciplinary specialist treatment for drug and/or alcohol problems and a guide to early intervention.
guidelines are being developed; one on detoxification, one on the treatment of persons with drug or alcohol problems and concurrent mental illness, and one on substitution treatment for pregnant women and follow-up of children and families until the children reach school age. All the work on the national guidelines is based in the Directorate of Health, and all the guidelines contain knowledge-based recommendations.

11.2. Existing guidelines: narrative description of existing guidelines

National guidelines for opioid substitution treatment of opioid dependency

The target group for the guidelines consists of service providers who work with patients receiving substitution treatment from the specialist health service, both in municipalities and at pharmacies, correctional service staff, patients in OST and other drug addicts, plus their family members. The patient target group consists of opioid addicts. The objective of the guidelines is to make OST a normal, integrated part of the health service, to ensure that patients receive comprehensive treatment, and to help to ensure that the treatment offered is the same throughout the country. The guidelines have been prepared on the basis of the collation of international research and on clinical experience from Norway. The Regulations relating to OST issued by the Ministry of Health and Care Services on 1 January 2010 form the legal basis for the OST guidelines (see Chapter 1.1). The Regulations regulate the objective, admissions, discharges and control measures. OST is an interdisciplinary specialised treatment that includes substitution treatment as one of several measures in a comprehensive rehabilitation process. The substitute medications used are buprenorphine (preferably with naloxone) and methadone. The guidelines entered into force on 1 February 2010.

11.3 New guidelines under preparation

National guidelines for pregnant women in opioid substitution treatment and follow-up of families until the children reach school age

The target group for the guidelines consists of service providers working with pregnant women in OST and families with children who have been exposed to OST medication during pregnancy, both in the municipalities (health, social and child welfare services) and in the specialist health service (obstetrics, neonatal medicine, child and youth psychiatry, and interdisciplinary specialised treatment). The purpose is to provide clear, knowledge-based recommendations for the treatment and follow-up of pregnant patients in OST during pregnancy and while in hospital, and for follow-up/treatment of the child and the family from the time of birth until the child reaches school age. The main goal is for the family to receive individually-adapted and knowledge-based follow-up from a support system that provides professional and respectful follow-up, to ensure an optimal development process and a safe care situation for the child and the family. The guidelines will be completed during the first six months of 2011.

National professional guidelines for examining, treating and following up persons with drug or alcohol problems and concurrent mental illness
The guidelines will primarily target professionals and managers in the municipalities, plus health personnel and managers in the specialist health service, especially in the areas of mental health care and interdisciplinary specialised treatment. The guidelines will also be useful to other services such as the prison health service, the State Housing Bank and voluntary organisations. In addition to patients with serious mental problems with concurrent drug or alcohol problems, the guidelines will also address hyperkinetic disorders/ADHD, eating disorders and serious anxiety and personality disorders. The guidelines will cover three main areas:

1) Information about mental health problems and concurrent drug or alcohol problems
2) Recommended methods for mapping and diagnosing mental health problems and concurrent drug or alcohol problems
3) Recommended psychosocial treatment and follow-up.

The guidelines will be completed during the first six months of 2011.

**National professional guidelines for detoxification in connection with different forms of drug or alcohol dependency**

The target group for the guidelines consists of employees in interdisciplinary specialised treatment services and other parts of the specialist health service, employees in the primary social and health services, managers/administrators in the social and health services and users/family members. The guidelines aim to describe the various purposes of detoxification, what types of substances (including addictive medicinal drugs) require detoxification, and at what level of the service detoxification shall/can be offered. The guidelines will also contain a description of which detoxification methods should be used in connection with various conditions, and when there is a risk of serious drug/alcohol-induced poisoning conditions that require treatment/monitoring by ambulance personnel and in an observation ward/intensive care unit, plus therapeutic measures that support the detoxification process. Work on the guidelines started in autumn 2010.

**11.4 Implementation process**

The implementation of national guidelines starts as soon as a group has been appointed to work on them. When appointing a working group that will develop guidelines together with the Directorate of Health, it is emphasised that the members of the group represent the most important target groups for the guidelines. At the same time, the participants must also come from different parts of the country, different professions and different service levels, including research and user organisations. Similar considerations form the basis for the appointment of reference groups, but these groups can be put together on an even broader basis. Consultations are held when it is necessary to discuss specific areas in connection with guidelines. During work on the guidelines, information about how the work is progressing will be distributed on a broad basis, and a dedicated website will be established in connection with the work on the guidelines. Once the guidelines are completed, the implementation work is intensified by holding seminars and lectures for relevant target groups around the country.

In connection with the guidelines on drug or alcohol problems and concurrent mental health problems, a more systematic implementation project was conducted. The first part of the project
involved identifying professional groups and organisations responsible for following up and treating this group of patients. It was then analysed how these professionals handle this patient group today and how big a change the new guidelines will entail (a GAP analysis). A national survey was conducted, and 154 managers and 1,047 clinicians were interviewed. On the basis of this survey, possible obstacles and enablers were identified in relation to the implementation of the guidelines.

11.5 Comparison with the WHO guidelines

The national professional guidelines for OST differ from the WHO guidelines on a few important points (see annex 1):

**Substitution is not the first choice in the treatment of opioid dependency**

The Regulations state that: ‘Opioid substitution treatment shall not, as a rule, be the first choice of treatment for opioid dependency unless it is the most appropriate and adequate treatment option based on a professional assessment.’

This provision must be seen as a statutory requirement that has been incorporated into the guidelines, but without a knowledge-based assessment.

The reason for not choosing substitution treatment as the first option is based on

- the extensive opposition to substitution treatment that has traditionally existed in Norway, and the decision by the Storting that such treatment was to be a supplement to treatment without substitute medication,
- relatively good access to long-term in-patient treatment,
- the view that substitution treatment in many cases represents a life-long treatment form that is demanding, especially for young people.

**Choice of medication**

The guidelines state: ‘Buprenorphine should be the first choice in substitution treatment. Buprenorphine should be prescribed in combination with naloxone.’

The reason for this is a wish to limit the number of overdose fatalities resulting from use of the substitute medication. Overdose fatalities involving buprenorphine are unusual compared with methadone. Based on an assessment of what is justifiable in relation to both the patient’s safety and the safety of third parties, increased use of buprenorphine is preferred to methadone. An individual assessment, including consideration of justifiability, will nonetheless form the basis for the choice of substitute medication. The increased costs incurred in connection with such a recommendation are deemed to be counterbalanced by lower overdose fatality rates. Another reason why buprenorphine is the first option is that it is much easier to change from buprenorphine to methadone than vice versa, should that be an option.

**Choice of dose**

The choice of start-up regime and dose of substitute medication differs somewhat from the WHO guidelines:
In treatment with methadone, a daily increase in dosage of 10 mg is recommended during escalation. A lower dose than 60 mg is not recommended. There is no specific recommendation for the upper dosage limit. However, the dosage issue is considered in connection with the annual national monitoring of substitution treatment. A daily dose of between 60 and 120 mg is recommended in that connection. In treatment with buprenorphine, 16 mg is recommended as a daily stabilisation dose.

Apart from the above-mentioned recommendations, the recommendations in the Norwegian guidelines correspond well with the WHO guidelines. See Annex 1.