

European Monitoring Centre for Drugs and Drug Addiction

GUIDELINES FOR THE TREATMENT OF DRUG DEPENDENCE: A EUROPEAN PERSPECTIVE



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## Introductory note and acknowledgements

In-depth reviews of topical interest are published as Selected issues each year. These reports are based on information provided to the EMCDDA by the EU Member States, the candidate countries Croatia and Turkey, and Norway as part of the national reporting process.

The most recent Selected issues are:

- Cost and financing of drug treatment services in Europe: an exploratory study;
- Treatment and care for older drug users;
- Problem amphetamine and methamphetamine use in Europe;
- Trends in injecting drug use in Europe;
- Drug offences: sentencing and other outcomes;

All Selected issues (in English) and summaries (in up to 23 languages) are available on the EMCDDA website: http://www.emcdda.europa.eu/publications/selected-issues

The EMCDDA would like to thank the following for their help in producing this Selected issue:

- the heads of Reitox national focal points, their staff and the national experts on guideline development;
- the services within each Member State that collected the raw data;
- the members of the Management Board and the Scientific Committee of the EMCDDA;
- the Publications Office of the European Union.

#### **Reitox national focal points**

Reitox is the European information network on drugs and drug addiction. The network is comprised of national focal points in the EU Member States, Norway, the candidate countries and at the European Commission. Under the responsibility of their governments, the focal points are the national authorities providing drug information to the EMCDDA.

The contact details of the national focal points may be found at: http://www.emcdda.europa.eu/about/partners/reitox-network





## Introduction

The last two decades have witnessed an increase in the development of treatment guidelines in the European drugs field. This has largely built on a body of evidence on the treatment of drug dependence that has developed since the 1980s, alongside a growing interest in, and understanding of, the effectiveness of interventions. A range of tools became available to translate evidence into satisfactory and sustainable results, among them: guidelines and standards, education and training, implementation and assessment, monitoring, and accreditation systems based on quality standards.

The focus of this Selected issue is drug dependence treatment guidelines - one of the main measures used to improve and guarantee the quality of drug treatment provision. The focus on drug dependence treatment is timely and appropriate, as current estimates suggest that at least 1.1 million people were treated for illicit drug use in the European Union, Croatia, Turkey and Norway during 2009 (1). This is the consequence of a major expansion of specialised outpatient services during the last twenty years, with the significant inclusion of primary healthcare, self-help groups, general mental health services, and outreach and low-threshold service providers. While more than half of clients received opioid substitution treatment, a substantial number received other forms of treatment for problems related to opioids, stimulants, cannabis and other illicit drugs. The main modalities used for the treatment of drug problems in Europe are opioid substitution, detoxification and psychosocial interventions. Drug dependence treatment services are provided in a variety of settings: specialised treatment units (including outpatient and inpatient centres), mental health clinics and hospitals, units in prison, lowthreshold agencies and by office-based general practitioners. Particularly in western Europe, there appears to have been a gradual shift away from a view of drug dependence treatment as the responsibility of a few specialist disciplines providing intensive, short-term interventions towards a multidisciplinary, integrated and longer-term approach. Evidence suggests that continuous care and integrated treatment responses may be aided by the development and use of guidelines, care protocols and case management by all the relevant service providers (Haggerty et al., 2003).

This publication sets out to introduce the topic of treatment quality improvement by the development of guidelines (and other documents), and to provide an overview of the existing national guidelines for the treatment of drug dependence in Europe.

### Sources of information

This Selected issue is based on the scientific literature and on data on drug dependence treatment guidelines in 30 European countries (27 EU Member States, Croatia, Turkey, Norway), collected in three phases between 2008 and 2010.

A structured questionnaire completed by the Reitox national focal points was initially used to gather information about quality assurance and guidelines in the area of drug dependence treatment in Europe. National focal points also devoted a chapter in their national reports to a description of their countries' guidelines and the context in which these were conceived. Results from both the questionnaires and the national reports were analysed and reported in a consultancy study. In addition, a meeting organised by the EMCDDA in February 2010 convened experts in the field of guideline development from 30 European countries as part of the process for the development of the present Selected issue.

#### Structure of this publication

The next section of this Selected issue introduces the issues relating to the methodology of guideline development and provides definitions of key terms. It then goes on to introduce the evidence on the impact of guidelines on drug dependence treatment services. Another section deals with the evolution of national treatment guidelines in Europe. This is followed by an examination of the wide range of European guidelines that are available on the EMCDDA Best practice portal, alongside lessons from national experiences of using the evidence base to construct guidelines, their implementation and plans for development. Finally, national guidelines on opioid substitution treatment are compared to those published by the World Health Organisation (WHO, 2009).

(1) Based on a range of different sources, including the EMCDDA treatment demand indicator. See Table HSR-10 in the 2011 Statistical bulletin.

## Setting the scene: national treatment guidelines

# What are guidelines and how are they developed?

Guidelines usually contain a series of recommendations for practice that are based on a clear methodology, alongside an appraisal, synthesis and grading of the available evidence (Field and Lohr, 1992). Guidelines are primarily characterised by the validity of this methodological process (Brouwers et al., 2010), which should ensure that evidence from studies, carers' experience and clients' values and preferences are all taken into account.

Evidence-based guidelines are produced by convening multidisciplinary groups of experts who systematically assess the quality of the available evidence and classify the recommendations according to the level of supporting evidence. In general, evidence-based guidelines are published by independent organisations that are able to assemble experts who are free from conflicts of interest and who represent different fields and professions. These groups generally involve as many stakeholders as necessary to ensure they appropriately address all the different aspects of a question, including patients' preferences and practical concerns arising from the experience of the carers.

A number of tools have been developed to assess the quality dimensions in guidelines, the most recent being the 'Appraisal of guidelines for research and evaluation' (AGREE Collaboration, 2003), which was created to address the issue of variability in guideline quality by assessing methodological rigour and transparency. The updated version, 'AGREE II' (AGREE Next Steps Consortium, 2009), is composed of six domains aimed at assessing whether or not the scope and purpose of the guidelines is clearly indicated; the stakeholders' involvement is sufficient to represent the views of the intended users; the process of development was rigorous; the presentation and text are clear; and the guidelines are fit for purpose and free from conflicts of interest.

#### **Glossary of terms**

Accreditation is the process by which an institution delivering a service is independently assessed for quality against some pre-defined criteria. Accreditation requires a set of minimum standards, which are set by the accrediting body.

Benchmarking is the process of comparing service processes and performance metrics to best practices from other services. Dimensions typically measured are quality, time and cost.

Clinical pathways are structured, multidisciplinary plans of care designed to support the implementation of clinical guidelines and protocols.

*Guidance* is a general term that covers documents such as guidelines and quality standards.

Guidelines are 'statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options' (Institute of Medicine, 2011). They are designed to assist carers' and clients' decisions about appropriate interventions in specific circumstances.

*Protocols,* in general, are documents that specify the procedures to follow to perform some tasks, typically those used to conduct a study.

Standards and quality standards are principles and sets of rules based on evidence (Brunsson and Jacobsson, 2000), used to implement the interventions recommended in guidelines. They can refer to content issues, processes, or to structural (formal) aspects of quality assurance, such as environment and staffing composition. In some cases, standards are legally binding. The essential requirement for developing evidence-based guidelines is the availability of good quality studies addressing – and possibly answering – the pre-specified questions that have been identified by the group of experts working on the guidelines. When the evidence is scarce or contradictory and the clinical questions relatively focused and urgent, consensus conferences (Fink et al., 1984) are a possible option. During a consensus conference, a group of experts debate a series of presentations on available evidence and possible gaps. A jury composed of only some of the members of the group then vote on the final recommendations.

The RAND method of assessment of the appropriateness of medical technology (Brook et al., 1986) gathers consensus on the areas for which it is more difficult to resolve dichotomous judgments; when it is not possible to collect all the information needed to tailor the interventions to 'real world' patients from the available studies; and, when the information from those studies needs to be integrated into existing multidisciplinary knowledge. The technology assessment methodology follows the same general steps as a review of the literature, but it is more concerned with the consequences of interventions in terms of the benefits and costs of healthcare and policy decisions (Liberati et al., 1997). Therefore, a variety of stakeholders play a crucial role in the identification of problems in the available data, the judgments and implications of studies' findings.

### Are guidelines always needed?

Some general conditions have been identified as a prerequisite to developing guidelines. They are needed when there is proof that an intervention is heterogeneously provided to those receiving care, when there is controversy over the effectiveness of an intervention and when there is a need for integrating new evidence into a body of existing knowledge. If individuals with the same problems are receiving different care depending on, for example, their doctor, health service, geographical location, gender, age or ethnicity, the development and/or adaptation of existing guidelines will make it more likely that all patients are cared for in the same manner (Woolf et al., 1999). If, on the other hand, it is clear that interventions are provided consistently to all patients, the impact is as intended and existing good practice is well-integrated into services' routines, no guidelines are needed for improvement.

# Grading of recommendations assessment, development and evaluation

Guidelines are composed of recommendations for action. Each of these recommendations should be based on some level of evidence from studies and should have an indication of its strength, which clarifies how and when this is applicable to the target population. The level of evidence is determined by a synthesis of relevant studies' design, number of participants studied and the number of studies sharing the same results.

Although the level of evidence influences the strength of a recommendation, there are conditions under which, even where there is a lack of evidence from studies, the appointed group of experts may attribute a high strength to some recommendations. This is the case for some interventions, such as hydration for hospital patients or blankets to prevent heat loss in trauma patients, that are supported by practical experience evidence and do not need to be based on experimental evidence. Guidelines may therefore include a statement such as 'we recommend that this intervention is offered to most patients, even though there are no studies which prove or refute the effects, and this recommendation is based only on expert opinion'. Another example is where patients cannot be directly studied for ethical reasons (such as exposing newborn babies to different drug therapies). In such cases, the recommendations can be based on the results of studies on other types of patients. In practical terms, this system, which separates level of evidence from strength of recommendations, produces two separate – but not completely independent - scores.

In 2000, a collaboration was established of people interested in addressing the shortcomings of the grading systems used in guideline development, 'The grading of recommendations assessment, development and evaluation' (GRADE) working group (Guyatt et al., 2011). Over the years, this group has developed and continuously updated a common, sensible and transparent approach to grading the quality of evidence and the strength of recommendations. The EMCDDA has officially adopted this method to grade the level of evidence of the interventions that are summarised and published on the Best practice portal. Developing guidelines is a time-intensive and often expensive activity, and one that does not automatically lead to an improvement in the quality of treatment. There can be debate and controversy over the methods used and the choice of experts involved in their development. There can be disagreement as to whether guidelines should be specific and focused or broad and highly inclusive. The recommendations can be unfit for purpose because they are too complex and difficult to understand or, conversely, because they oversimplify the issues and do not use sufficiently technical language.

# Identifying and prioritising topics for guideline development

There are at least three approaches for prioritising the topics for guideline development, based on the epidemiological model, the request model and the economic model (Programma Nazionale Linee Guida, 2002).

The epidemiological model prioritises topics on the basis of observation of the incidence and prevalence of a health or drug use problem in the general population, the mortality caused by such a problem, importantly, the potential availability of effective interventions and the variation in practices that implement them. The main limitation of the epidemiological approach is that it focuses only on the occurrence of health or drug problems, neglecting to consider their social and contextual components.

The request model takes into consideration the perception of clients about a potential risk to which the health or drug treatment system should react. A typical example is the identification of a new strain of seasonal influenza and the alarm this causes. In this case, the development of guidelines serves mainly to attract the attention of health carers to a potential risk to the general population. The third approach is based on an economic model. The rationale is that the allocation of resources corresponds to a subtraction of the same resources from other destinations. The model therefore considers the marginal costs of healthcare interventions. A typical example is those guidelines that specify in detail which patient characteristics ensure the success of a specific intervention, in order that it can be provided only to those patients who can benefit from it.

Improvements in the evidence base leading to new insights may also be a reason to develop guidelines.

### The impact of guidelines: the evidence

Guideline development has become a priority for many health service decision-makers, and it is a widely recognised instrument for quality assurance in the area of treatment provision (Lugtenberg et al., 2009). However, guidelines can be diverse in quality, and, if not based on evidence, they can even be counterproductive (Brouwers et al., 2010). The impact of guidelines on the improvement of the prognosis at patient level is not yet clear. In a recent debate promoted by the British Medical Journal about the effectiveness of guidelines (Grol, 2010), it was pointed out that to ensure clinical guidelines have an impact on actual care and practice, activities beyond the mere production and dissemination of guidelines should be instigated. In particular, performance measurement and quality improvement programmes should accompany the dissemination of guidelines. According to surveys, guidelines are applied to clinical practice in only 50-70% of day-to-day decisions, and the main reason given for not applying them is that they are of limited relevance to patients and healthcare staff (Parchman et al., 2011).

Reported criticisms about guidelines include that they are concerned with only 'ideal patients', free from co-morbidities and complications, and that they are developed by single-discipline specialists, without taking into consideration the preferences of 'real world' patients (Krahn and Naglie, 2008).

## Evolution of national treatment guidelines in Europe

The first guidelines in the medical field were probably published in the United States in the early 1930s (American College of Surgeons, 1931). A search in library catalogues (Weisz et al., 2007) found 25 guidelines published between 1945 and 1959 and 35 between 1960 and 1974. The majority of these were from the USA, with a small number from the United Kingdom.

In the mid-1940s, some reflections on the need for basing the National Health Service (NHS) on scientific methods were undertaken in the United Kingdom and an important input came from Archibald Cochrane (1971) with his influential book 'Effectiveness and efficiency. Random reflections on health services'. Cochrane strongly emphasised the role of randomised controlled trials to 'open a new world of evaluation and control' which would be 'the key to a rational health system' (p. 11).

In 1990, the Journal of the American Medical Association published a discussion on the need for developing clinical guidelines. It argued that clinical decision-making should be based on logical sequences of actions (Eddy, 1990). The plea for evidence-based medicine spread to the United Kingdom at the beginning of the 1990s, in parallel with the founding of the Cochrane Collaboration, an international organisation aimed at preparing, maintaining and disseminating systematic reviews of the effects of health interventions. In a short period of time, the availability of publications on syntheses of evidence-based medicine increased dramatically.

The development of clinical guidelines spread to other European countries during the 1990s, and guidelines for the treatment of drug dependence followed the trend in the medical field. The number of countries where national treatment guidelines were developed increased very rapidly after 1998. Today, nearly all the countries monitored by the EMCDDA (EU Member States, Croatia, Turkey, Norway) have such guidelines.

#### From voluntary to mandatory

The United Kingdom is an example of how clinical guidelines were initiated as a bottom-up and voluntary approach, in which groups of professionals developed their own documents to guide their activity. With the progressive adoption of evidence-based medicine, methods used to create guidelines became more complex and the activity passed to independent institutions created for the purpose (Berti and Grilli, 2003).

Clinical guidelines began to become mandatory with the introduction of clinical governance, a general approach to monitoring and improving the quality, safety and effectiveness of clinical interventions (Harris and Taylor, 2009). This approach included performance indicators and other instruments to control and monitor effective guideline application (Harrison and Smith, 2003).

#### Typical content of guidelines

The guideline title may indicate the target group that is being considered, the professionals being addressed and/or the results that are expected, such as 'Guidance for the pharmacological management of substance misuse among young people in secure environments' (National Treatment Agency, 2009).

The aims and purpose are provided, along with the credentials of the authors and the panel of experts (including any declarations of conflicts of interest). Usually, a brief section introduces the epidemiology and description of the drug use or health problem being considered.

A list of recommendations is provided in the form of brief statements about what to do in some circumstances with some clients. For each recommendation, values are given that indicate the level of evidence that supports the recommendation and its strength (see box 'Grading of recommendations assessment, development and evaluation').

A methods section describes in detail how the literature to support the recommendations was retrieved and assessed, how the information was extracted and how consensus among the panel of experts was reached.

Appendices can be included and may contain, for example, further details of the studies that were examined, a questionnaire or checklist to apply the recommendations, and a literature list. The date of the search for literature and planned updates are also often included.

#### The increasing availability of guidelines

Over the last two decades, as discussed earlier, an increasing number of treatment guidelines have been produced (Institute of Medicine, 2011) along with other types of guidance that are aimed at assisting 'practitioner and patient decisions about appropriate healthcare for specific clinical circumstances' (Field and Lohr, 1992, p. 38). This development has been associated with other phenomena facing healthcare systems, especially an increase in the demand for care and a rise in the cost of providing it. For example, the ageing of the population, progress in medical treatment and, linked to that, new and more expensive technologies, have put considerable pressure on the healthcare system as a whole. This situation and the evidence of variations in service availability, delivery and quality have made quality a core issue within an increasingly competitive environment. Benchmarks and systematic assessments in the healthcare system concurred to stimulate the development and adoption of guidelines as a way of assuring guality in treatment provision.

This issue concerned all the health fields, including, more recently, drug addiction. While, until 2000, only six of the 30 countries monitored by the EMCDDA had at least one national guideline for drug addiction treatment, by 2010, 27 had such instruments, and the remaining countries used other means (regional guidelines, standards or accreditation systems) for quality development. So, not all European countries have adopted national treatment guidelines for drug addiction. In a few cases, this is simply due to the regional partition of health government, which facilitates local approaches to guidance. In other cases, independent organisations provide treatment for the entire country, using their own guidelines.

Another example is the roll-out of substitution treatment across Europe, which took place mainly in the 1980s and 1990s, to be followed in the 2000s by the adoption by most countries of national guidelines (Figure 1).

# The main motivations for developing guidelines

The main reason for investment in the development of drug addiction treatment guidelines in Europe was the link between injecting drug (mainly heroin) use and the associated risk of HIV and AIDS. This was addressed by a widespread introduction of pharmacological treatment for drug addiction and led to the need for recommendations for appropriate care.

In some countries, an evidence-based approach to guideline development was adopted soon after drug addiction was considered a health condition to be treated with substitute pharmaceutical drugs. In Europe, the first national treatment guidelines for drug addiction were issued in the United Kingdom and Ireland during the 1980s. The severity of the HIV/AIDS epidemic led southern European countries such as Spain, France, Italy and Portugal to adopt interventions that had proved effective elsewhere. These countries reflected on their own experiences of the implementation of such interventions and draft treatment guidelines only after the emergency diminished.





NB: N = 30 countries.

Source: Reitox national focal points

A number of countries saw guideline development as part of a broader quality assurance strategy that includes the provision of education for healthcare workers, implementation of standards and certification of quality. Advanced management tools for goal-setting, such as the 'balanced scorecard' normally used in management (Kaplan and Norton, 2006), have also been adopted by some treatment centres.

Government bodies stimulated the production of national guidelines as a means to reduce variations in treatment provision and clarify criteria for treatment access in the northern European countries.

## A bookshelf of European drug dependence treatment guidelines

As of June 2011, 143 national drug dependence treatment guidelines from 30 countries in Europe were collected and made available on the EMCDDA's Best practice portal. The majority of these guidelines were published or updated after 2000. Guidelines are available in 22 European languages, with around a third in English (56), followed by German (10), Dutch (9), Czech (9), French (8) and Hungarian (8).

#### Interventions and substances

Just over a third of these 143 guidelines focus on opioid dependence (Figure 2). Specific attention is given to opioid substitution treatment with methadone or buprenorphine by 40% of the total number of guidelines and, in two cases, on the use of pharmaceutical heroin in the framework of medium to long-term treatment. Psychosocial interventions often accompany these pharmacological treatments: in some guidelines, there are detailed recommendations on these interventions.





NB: Categories are not mutually exclusive. Source: Reitox national focal points. Detoxification from opioid dependence is the third most common topic for drug treatment guidelines across the European countries (<sup>2</sup>), and the medications suggested for this purpose are methadone, buprenorphine, lofexidine, alpha-2 adrenergic agonists (such as clonidine) and benzodiazepines for the control of withdrawal symptoms.

Interventions aimed at the social reintegration of patients are also addressed by guidelines developed in just over a quarter the countries (<sup>3</sup>) and 10% of the guidelines focus on harm reduction, often as a broad umbrella strategy for several interventions.

Some guidelines address broad categories such as 'drug dependence' or 'psychoactive substances'. Addressing drug dependence as a whole without substance specification is more common in the guidelines on psychosocial interventions, social work, social reintegration and community care. Approximately 10% of guidelines have alcohol as one of their major topics and slightly fewer address (misuse of) medicines, for example sedatives.

Although the majority of guidelines focus on opioids (Figure 3), some address issues related to other substances: Germany and the Netherlands, for example, devote specific guidelines to cannabisrelated problems; Germany and Hungary have guidelines for the treatment of amphetamine-related disorders; and the guidelines from Germany and France include strategies for the care of cocaine users.

#### Guidelines for psychosocial interventions: a toolkit

A psychosocial toolkit recently published by the British Psychological Association and the National Treatment Agency for Substance Misuse, in which the key competences for each psychosocial intervention are presented and discussed. The toolkit, which is aimed at practitioners working with adult drug service users (with or without co-morbid mental health problems), is complemented by a specimen training curriculum for each intervention, protocols for implementation, audit criteria and adherence measures (Pilling et al., 2010).

(2) In guidelines from Belgium, Bulgaria, Czech Republic, Denmark, Germany, Estonia, Ireland, Latvia, Hungary, Netherlands, Austria, United Kingdom.

(<sup>3</sup>) Bulgaria, Czech Republic, Germany, Estonia, Hungary, Portugal, Slovenia, United Kingdom.



#### Figure 3: Number of guidelines by type of substance

NB: Categories are not mutually exclusive. Source: Reitox national focal points.

### Target population and client groups

The target population is the group of people who are expected to read and implement the guidelines in their daily activity – primarily service providers and professionals. However, only just over one quarter of countries address healthcare planners in their guidelines (<sup>4</sup>): overall, the results of the present analysis reveal that drug addiction treatment guidelines in Europe are primarily intended to be of practical use for individuals and organisations directly involved in providing care for drug users.

Each country has several sets of guidelines and in terms of clients (or, as defined in the medical literature, 'case definitions'), they all have at least one set that addresses a specific client group. Two thirds of countries refer to long-term dependent drug users, but overall, the type of client the guidelines address varies considerably and includes prisoners, women, young drug users and dependent drug users with co-occurring disorders. In 2009, an EMCDDA consultation study asked for specific guidelines dealing with migrants and sex workers, but none were found in the guidelines examined.

Around a quarter of the countries have developed guidelines about treatment in prison or other secure settings. For example, the Czech Republic has published a set of standards for prison drug services that are provided by external organisations; 15 guidelines, from almost a third of the countries, addressed people with co-occurring disorders besides drug use; and one third of the European countries have developed guidelines specifically tailored to the treatment needs of young drug users and dependent drug users with co-occurring disorders.

#### Guidelines on treatment for cocaine dependence

The Haut Autorité de Santé in France recently published guidelines to deal with cocaine use. They are aimed at identifying and recruiting problem cocaine users into treatment, providing information on the consumption of cocaine and on how to reach specific client groups, such as pregnant women, adolescents and young people, and persons with risky sexual behaviours. Treatment pathways for cocaine users, and diagnostic criteria for dependence are presented, and the possible complications and how to treat them are discussed. The guidelines include strategies to reduce the risks associated with cocaine use, and a range of psychosocial interventions are presented, along with information on the pharmacological treatment for withdrawal symptoms (Haute Autorité de Santé, 2010).

## Developing national guidelines: lessons from experience

This section describes how the European national treatment guidelines are developed at national level, the level of evidence they use and countries' implementation strategies, including how the consultation process with different stakeholders is managed.

In their guidelines, around a third of countries referred to the existence of standardised guideline drafting procedures or to other, more general arrangements, such as laws on the guideline drafting process (Latvia, Lithuania, Hungary) or official quality standards that are in place at national level. Over one third of the countries reported using international treatment guidelines, such as those from the World Health Organisation or those published in other countries. Some of these countries adapted others' guidelines to their national context, while others used them as a base to build upon (<sup>5</sup>).

The majority of the countries explicitly stated the main objective for drafting treatment guidelines at national level. The most common objectives were to harmonise treatment services and/or to improve the quality of treatment. Other objectives included the need to create standards for accreditation/certification procedures, to improve the cost-effectiveness of treatment services and to monitor treatment quality.

It was generally acknowledged that evidence should be the basis for treatment guidelines, and most countries reported a process, or combination of processes, to ensure that the available evidence was included in their guidelines. Ten countries explicitly mentioned that the available evidence formed the basis for their guidelines, and the Netherlands reported on specific trials that were conducted to create the necessary evidence base for future guidelines. Most countries' guidelines were issued for only a fixed period of time, thus enforcing regular updating. Other evidence-related features of guidelines included systematic scientific reviews, expert consensus and the importance of experience and good practice. Six countries stated that their guidelines, once drafted, were reviewed by a panel of independent experts before being formally adopted. In the United Kingdom, one of the tasks of this independent panel was to make sure that all contributions from all relevant stakeholders were considered by the working group drafting the guidelines.

However, only just over one quarter of the countries provided detailed information on the need to establish clear links between the recommendations and the evidence available and only five of these indicated that recommendations need to be explicitly linked to the evidence according to its reliability or acknowledged scientific value.

As for the stakeholders involved in drafting guidelines, the situation varied greatly among European countries. In most, health authorities were the main stakeholder involved, usually through the national departments of health. Health authorities initiated the process and were responsible for developing the guidelines by appointing working groups, and/or by granting the final approval of the guidelines. However, in some countries, these responsibilities lay with independent professional organisations, such as medical councils, national government bodies or independent scientific associations; in such cases, representatives of national health authorities had a less prominent role in guideline development, as regular working group members or observers.

In the Netherlands and the United Kingdom only, patient/carer organisations have a formal role in the development process, although in many other countries they are included at a later stage or given the opportunity to comment on draft guidelines. The other stakeholders involved are mainly healthcare professionals, psychiatrists and psychologists, but universities and quality experts are also mentioned as contributors to the final output of the guideline working groups.

Five countries have a mandatory consultation procedure during the drafting of treatment guidelines. In the Czech Republic, France and Sweden, this is conducted among the relevant professional or expert communities; in Portugal it involves the central and local governmental services that deliver treatment; and, in the United Kingdom, it involves an extensive group of stakeholders and at least one public consultation before the guidelines are formally adopted.

(5) Adapting guidelines (ADAPTE Collaboration, 2011) to a specific context requires that a local group of stakeholders identify specific questions, searching for, retrieving and assessing available guidelines, and preparing the draft adapted guideline.

#### A project for European minimum quality standards

The EQUS study, commissioned by the European Commission ('), convened a number of experts and stakeholders from all over Europe and beyond, in order to propose lists of minimum standards based on evidence and consensus. The results are expected to be available by the end of 2011, and will be used by the Commission to draft a proposal to the Council by 2013 (<sup>2</sup>).

- 'Development of an EU framework for minimum quality standards and benchmarks in drug demand reduction' (available at http:/ec.europa.eu/home-affairs/tenders/2009/312290/tender\_en.pdf).
- (2) For further information, see the EMCDDA Best practice portal (http://www emcdda.europa.eu/themes/best-practice/standards).

Five countries refer to follow-up approaches after the implementation of national treatment guidelines, which can provide information for the updating process and the development of new guidelines. The follow-up work comprises general feedback on implementation (Greece), surveys of general practitioners (Ireland) or municipalities (United Kingdom) and perceptions of guidelines among professionals during the pilot phase of their implementation (Czech Republic). The Netherlands has a dedicated follow-up programme in place to help improve the redrafting process.

#### The evidence base for guidelines

The 20 national guidelines on opioid substitution treatment that were available on the EMCDDA's Best practice portal in April 2011 were examined to see whether bibliographic references to specific studies formed the evidence base for the recommendations.

Surprisingly, a number of the selected guidelines did not even provide a bibliography or reference section. However, the remainder show consideration of the recent evidence base. For example, the guidelines from Latvia cite a considerable number of studies in the bibliography (20 studies in 26 references), 70% of them published in the five years before the guidelines' publication. Guidelines from Belgium, the Netherlands and the United Kingdom also show that the evidence base for recommendations consists of a high number of studies.

Across the guidelines on opioid substitution treatment, the highest proportion of references is to randomised control trials and to the Cochrane library as a general resource for evidence on treatment. This is especially the case in the guidelines from Germany and the United Kingdom.

#### Implementation: what helps and what hinders?

Across Europe, it has been recognised that developing guidelines is an important step towards improvement of practice, although the real difference is made when there is a valid implementation programme. However, the implementation process is not always straightforward, and changes and innovations can meet resistance. The main barriers to the implementation of guidelines can be related to social, organisational and economic context, individual reactions by professionals, and sometimes resistance at client level (Grol, 2010).

Not all the countries reported their strategies to implement national treatment guidelines, and those that did reveal varying experiences. Most countries applied a bundle of measures during the implementation of their guidelines. Some examples follow, but these should not be taken as the only implementation strategies of the countries mentioned.

An approach followed by Belgium, the Czech Republic, Cyprus, Luxembourg and Norway can be described as tackling the attitude of professionals and the social and organisational context of drug treatment services. Through studies aimed at identifying possible barriers and ways forward, these countries created implementation manuals and standards. In Denmark, the implementation of guidelines was assessed using a set of indicators for quality assurance. In Ireland, the tasks of the Methadone Prescribing Implementation Committee include overseeing guideline implementation.

Another vehicle for ensuring adherence to guidelines is by involving key professionals in the promotion of change (Grol and Wensing, 2004). This seems to be the main strategy adopted by Finland, Germany, Latvia and Slovenia, where the medical associations or the coordinators of treatment centres prepared the guidelines and disseminated them among their members.

Continuous learning in terms of guidelines and their implementation is a shared feature across Europe. For instance, in the Baltic States, the guidelines are included in the training of psychiatrists and in ongoing training courses for medical practitioners. Some countries, including Hungary and Austria, created a legal framework for service providers to implement the guidelines, and these are made available by the relevant ministries in their official publications and on their websites.

In the Netherlands, one of the leading countries in research on implementation, an evaluation instrument for physical and mental health (KRIE) was created that assesses the 'implementability' of guidelines (Fleuren et al., 2009). A series of studies (Sinnema et al., 2009; Smolders et al., 2006) came to the conclusion that after having invested in the development of guidelines, future efforts should be directed towards an increased implementation rate, particularly by the use of computer software programmes, for boosting the efficiency of care processes and for advice, evaluation and feedback. Investment in interactive workshops also proved effective in terms of implementation.

#### Strategies for effective guideline implementation

Grol and Wensing (2004) list the following strategies to overcome obstacles to change in healthcare services:

- 1. Innovation: a proposed innovation has to be attractive, feasible and likely to improve practice.
- Individual professionals: awareness and motivation to change should be promoted.
- 3. Patient level: compliance should be promoted.
- Social context: the culture of the professional network and the opinions of colleagues and leadership have to be changed.
- Organisational context: organisational processes to ensure the necessary capacity, resources and staff must be in place.
- 6. Economic and political context: financial arrangements, regulations and policies need to be created.

A milestone project for assessment of implementation is 'Scoring results', which adopted five phases for a successful process: orientation, insight, acceptance, change and maintenance (Grol and Wensing, 2004). The adherence to implementation is measured as a percentage of

organisations that routinely applied a set of six guidelines. This gave positive results for two guidelines on drug treatment: methadone maintenance scored 90% and detoxification in inpatient and outpatient settings scored 64%.

A recent study conducted in the United Kingdom (Luty et al., 2010) showed that there was a huge investment in the implementation of guidelines. The National Institute for Health and Clinical Excellence (NICE) has produced a range of 'how to' guides to help with the implementation of their guidance at a local level. An interesting initiative for dissemination is the 'Shared learning database' that enables organisations that have implemented NICE guidance to share tips, ideas and examples of their implementation process. The UK is also trialling new approaches to payment-by-results to test whether paying on the basis of the outcomes achieved can further incentivise the delivery of recovery for those who are dependent on drugs and/or alcohol. Eight local areas will be testing the approach over two years and a formal evaluation is being put in place (<sup>6</sup>).

# Plans for developing guidelines for treatment of drug dependence in Europe

Overall, there is a sense of coherence in the identification of tools and topics for the future. The countries appear to follow a common pathway when developing guidelines, starting with the medical treatment of opioid dependence. Once guidelines for this treatment provision are produced, they focus on more detailed issues that the guidelines should address (such as subgroup populations), as well as a more sophisticated analysis of impact and hypotheses for further development.

For most countries, updating and/or redrafting guidelines is an ongoing process. Hungary, for example, adopted a statement that healthcare guidelines are to be reviewed every two years. A SWOT (strengths, weaknesses, opportunities and threats) analysis of the last 15 years of activities has been undertaken in the Czech Republic. It concludes that in spite of the advances made in standards and quality accreditation, more efforts could be put into guideline development. The tools identified for future development include manuals targeted at practitioners, focusing on how to apply the recommendations from evidencebased guidelines. Belgium is planning to use these after their current pilot study in their substance use services.

Countries have chosen to focus new guideline development in a range of different areas. Non-medical treatment with psychosocial therapy and rehabilitation has been identified as a topic for further development in Germany. In Estonia, the quality of methadone substitution treatment has been identified as a topic for further development, in collaboration with the United Nations Office on Drugs and Crime (UNODC). In Portugal, the most recent guidelines dealt with harm and risk reduction in private/public partnerships. In the United Kingdom, the next update will focus on detoxification and psychosocial interventions, and new guidelines will consider pregnancy and the complex social factors surrounding drug use.

An important reflection on the need for focused (rather than general) guidelines addressing subgroup populations is underway in the Netherlands, where future activities are envisaged as the adaptation of existing guidelines to the needs of specific groups of patients. A platform for evidence-based guideline development (EBRO) has been created and an open discussion has been launched on the drawbacks arising from an excessive proliferation of tools for quality, which risks shifting the attention from the patients towards the actual management and production of guidance. In Sweden, the need for more involvement of patients in the quality process was identified, and also that this can only be achieved if the health and social care system perceives itself as a learning organisation with flexible borders.

# National and WHO guidelines for the treatment of opioid dependence: differences and similarities

After an open discussion about the quality of its own guidelines, the World Health Organisation (WHO) put procedures in place for developing transparent, evidence-based guidelines, adopting standard methods for the synthesis of the evidence and the grading of recommendations (Barbui et al., 2010). Using these methods, 'Guidelines for psychosocially assisted pharmacological treatment of opioid dependence' was published (WHO, 2009). The WHO guidelines contain a series of recommendations based on evidence from systematic reviews and meta-analyses, along with evidence from other sources, technical considerations, resource implications and the risks and benefits of different alternatives. The strength of each recommendation is based on consideration of the effectiveness of the intervention, the level of the evidence to support it and the resource implications.

The WHO guidelines are grouped according to their target audiences: recommendations for health systems at national and sub-national levels; for treatment programmes; and for treatment of the individual patients. For the purpose of this section, the 15 recommendations for the treatment of the individual opioid dependent user were selected and compared with some of the recommendations included in European countries' national guidelines for the treatment of opioid dependence.

On the EMCDDA's Best practice portal in July 2011, 57 of the national guidelines from 24 countries contained recommendations on opioid substitution treatment. Only 18 of these were published after the WHO guidelines, so the following discussion should not be interpreted as an assessment of the impact of the 2009 WHO guidelines, but rather as a preliminary overview of the convergence or otherwise of some of the recommendations from across Europe.

In terms of choice of pharmacological treatment for opioid dependence, the WHO guidelines recommend that clinicians offer detoxification (withdrawal) and substitution treatment (with agonist medications such as methadone or buprenorphine). These two key WHO recommendations are reflected in just over a third of the selected 57 sets of guidelines. In addition, there are some national guidelines for the treatment of opioid dependence which contain recommendations that are not completely in line with the WHO advice, for example suggesting only provision of drug free treatment. A number of other guidelines do not address this issue.

There are differences concerning the choice of methadone or buprenorphine to treat those dependent on opioids. Some countries do not indicate a preference: in two of them, buprenorphine is not (or has only recently been) available, whereas in a number of countries, buprenorphine is the first choice for opioid substitution treatment. The guidelines specify the dosage that should be given in the induction period (at the beginning of treatment). Some of the countries follow the same conventions, while others do not or leave the decision to the relevant medical doctors. Almost all the countries' guidelines agree on the need for direct supervision of methadone and buprenorphine doses in the early phase of treatment, and specify conditions under which take-away doses can be given to treatment clients. Among the countries that address pregnant drug users in their guidelines, there is some agreement that they should be offered opioid agonist maintenance, and there is a preference for methadone. It is worth noting, however, that there is some new evidence to suggest buprenorphine may also be a valid option for this group (Jones et al., 2010).

Management of opioid withdrawal with opioid agonists or alpha-2 adrenergic agonists is recommended in the majority of the European guidelines, but there are differences concerning the use of minimal or heavy sedation. In some cases, the options are only listed, without an indication of preference. However, the WHO guidelines warn about the risks of this intervention: they recommend that the combination of minimal sedation with opioid antagonists should not be used routinely, and heavy sedation with opioid antagonists should never be used. For clients not undergoing maintenance treatment, the WHO guidelines recommend the use of antagonist drugs such as naltrexone (which blocks the effect of heroin in the user's body) after detoxification. This recommendation appears in eight countries' guidelines. Six do not mention this option and three have slightly different recommendations, mainly due to naltrexone being unavailable in the countries they cover.

Almost without exception, the national guidelines concur with the WHO recommendations that psychosocial support should be routinely offered alongside pharmacological treatment during long-term treatment and detoxification programmes for opioid dependence.

In summary, despite the differences in the rationale for, and the process of developing guidelines in Europe, in the subsample of 57 sets of guidelines on psychologically assisted pharmacological treatment for opioid dependence examined for this Selected issue, there is much agreement regarding the general aspects of this treatment – provision of detoxification, maintenance, supervision during the induction period, regulation of take-away doses, and psychological assistance and individual assessment during treatment. And, while there are signs of convergence regarding the WHO guidelines, only one third of the guidelines contain the two key recommendations on detoxification and opioid substitution treatment. Moreover, there is much diversity in terms of clinical recommendations concerning the dosages and combinations of pharmaceutical drugs to be used during treatment.

## Conclusions

This Selected issue has identified a major increase in the availability of guidelines for treating drug use and dependence across Europe. Overall, the 143 sets of guidelines from across Europe reveal a commitment to improving the quality of treatment, helping practitioners to make more informed choices and, significantly, putting the clients at the centre of the therapeutic process. Currently, guidelines are available in 24 European languages, and when similarities and differences are considered against the varied historical and cultural backgrounds that characterise Europe, the value of the effort made to reach a common strategy and to share best practice becomes clear.

There is a relationship between the year a country introduced opioid substitution treatment and the year in which the production of clinical guidelines for the treatment of opioid dependence started. The number of drug users receiving substitution treatment in Europe has increased almost 10-fold since the beginning of the 1990s (EMCDDA, 2010), which is the period in which guidelines were increasingly produced. The majority of the existing guidelines focus on the pharmacological treatment of heroin dependence. This seems logical, as guidelines originated in the medical discipline, in which experimental studies that inform clinical recommendations are also conducted. However, there are numerous examples of guidelines that also cover other interventions, drugs other than heroin and address the treatment of groups of drug users other than those dependent on heroin. A comparison between the national guidelines on opioid substitution treatment and the evidence-based recommendations provided by the World Health Organisation reveal considerable convergence, with the exceptions of options for the first choice of pharmaceutical drug to treat dependence and the level of detail in recommendations on dosages.

The scientific literature underlines that new treatment guidelines are not always needed and that adaptation of pre-existing evidencebased guidelines may be a feasible alternative. In the context of an increasingly shared effort to improve quality, a consensus around minimal standards appears to be an option to try to achieve homogeneity of intervention provision, while allowing for national choices and differences. It is important to note that guidelines are developed and published at different levels: local, national, EU and global. High quality evidence is by definition valid and exportable to any context, but adaptation at each level is nonetheless essential for successful implementation. The adaptation process at local level, for example, needs to take into account the specific environment, local organisations, culture, resources and clients' preferences (Graham et al., 2002). Guideline implementation strategies are recognised as key to improving the quality of treatment and to changing practice. The European countries reporting on these depict a range of well thought-out strategies that are worth describing in more detail than the present publication allows.

The present overview cannot provide a full picture of the wealth of experiences and strategies to improve treatment quality at national level in Europe. Rather, it can be considered as an introduction to the guidelines from the 30 participating European countries published on the EMCDDA's Best practice portal. The EMCDDA will continue to collect national guidelines and make them available, thanks to the invaluable collaboration of the network of national focal points and their nominated experts.

Monitoring and reporting and the strategies for promoting best practice and ensuring treatment quality at national level is a long-term activity, and one that requires considerable investment and networking of key stakeholders. The present publication is a first step. Despite its limitations, it is necessary to continue on this track to disseminate information on the valuable national efforts, creativity and results.

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