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Abstract

The present chapter is aimed at enabling the readers to master the methods to ascertain whether an evidence-based recommendation is appropriate for real-world patients in specific contexts. Nowadays it is crucial to develop an individual capacity for critical assessment and to know where to search for updated and reliable sources of evidence. The methods, the processes, and the practical meaning of the most popular tools for the promotion of quality are presented with links to current projects and free of cost resources for professionals. The ultimate goal of the evidence-based medicine is to provide the patients with the best possible interventions. To reach this goal, knowledge has to be translated into practice. Guidelines and standards are popular instruments to disseminate and implement evidence-based recommendations. Nevertheless to implement them into specific contexts, some decisions are needed. The chapter includes a description of the main approaches used to adapt or adopt guidelines and standards.

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Quality is never an accident. It is always the result of intelligent effort. There must be the will to produce a superior thing.

John Ruskin

85.1 Introduction

The promotion of quality and the exchange of good practice are recognized as an important strategy both to improve the effectiveness of drug-related interventions and to ensure the efficient use of limited resources. Guidelines and standards in particular are among the most frequently used tools for the promotion of quality through the translation of knowledge into the daily practice of treatment of drug addiction. But it is not always needed to publish new guidelines and standards; often the existing good quality guiding documents can be adapted to suit a specific national or local context. New disciplines have emerged focusing on methods for successful knowledge transfer to action, such as implementation science, translational science, and knowledge mobilization. A common recommendation is that the only way to a successful implementation is the promotion of participation among all the stakeholders, starting with the medical doctors and the health professionals and including the decisions makers, the patients and their families, and the public in general.

It is therefore important that the professionals in the treatment of drug addiction are familiar with the terminology and the methods of the quality promotion as these are increasingly part of their daily activity.

The contents of the evidence base change rapidly as soon as new studies are conducted and contribute with new results. This is why it is important to master the methods to ascertain whether a recommendation is appropriate for real-world patients in specific contexts. It becomes crucial to develop an individual capacity for critical assessment and to know where to search for updated and reliable sources of evidence.

To this purpose the present contribution was conceived. The evolution from evidence base to implementation is described giving some details about the terminology and references for further reading. The methods, the processes, and the practical meaning of the most popular tools for the promotion of quality are also presented with links to current projects and free of cost resources for professionals. In particular it is explained how time and resources can be saved by *adapting* or *adopting* already published evidence-based guidelines to specific needs and contexts. The current initiatives for the development of quality standards in drug addiction treatment at international and at national level are described and compared, and for each of them, the links for free downloading of documents are included. To complement the information on implementation, we included a description and references to some recent initiatives in the medical field in which the participation of drug addiction treatment professionals is crucial but still not sufficient. In fact all those initiatives are studying strategies to effectively communicate with decision makers and patients. In a conclusive part, two examples of use of standards are compared more in depth, in one case as part of an accreditation system and in another as a support for implementation and measuring of quality criteria.

85.2 From Knowledge to Implementation

85.2.1 Knowledge Translation into Practice: From Evidence to Change

The overall aim of good practice sharing and standards development is the achievement of improvement in the quality of treatment. Clearly quality is not an abstract concept but rather an umbrella definition for series of measurable achievements in the health and well-being of the treated patients.

“*Primum non nocere*” – first of all do not harm – the phrase attributed to the Hippocratic Oath, reminds that the first aim of a health intervention is to avoid harm.

And it is exactly with this intention that the pioneers of the evidence-based medicine called the attention on the discrepancies between research results and medical practice, which would have cost human lives (Cochrane 1999). According to their claims the timely application to practice of the results from clinical research would have saved many lives and reduced subsequent costs to the society (Egger and Smith 1997). For example, randomized controlled trials proving the effectiveness of systemic glucocorticosteroids administered to pregnant women at risk of preterm delivery to reduce respiratory distress syndrome in newborn babies were available already in the 1970s, but it took almost 20 years before this intervention became a common practice (Roberts and Dalziel 2006).

The possible effect of the delay in the adoption of this practice was that a significant number of premature babies probably suffered and possibly died and needed more expensive treatment than was necessary (Rennick 2006).

The movement for the systematic collection of scientific results for dissemination outside the restricted circles of researchers and academics became known worldwide at the beginning of the 1990s (Sackett et al. 1996) and was boosted by the foundation of the Cochrane Collaboration, an international organization aimed at helping “healthcare providers, policy-makers, patients, their advocates and carers, make well-informed decisions about health care, by preparing, updating, and promoting the accessibility of Cochrane Reviews” (Chalmers and Glasziou 2004).

In 1998 an editorial group specifically devoted to drugs and alcohol was founded with its base in Rome (Davoli and Ferri 2000), and since then around 70 reviews on the various interventions (including prevention) for drug and alcohol problems were published and updated.

The availability of good quality research on effectiveness of treatment for drug problems has dramatically increased over the last years, even though important gaps still remain to be bridged with evidence (Turner and McLellan 2009). The availability of studies and of systematic reviews nurtured the production of clinical guidelines as a major tool for the dissemination and application of evidence in practice.

For example, a recent survey for the identification of treatment guidelines in Europe identified more than 140 sets of guidelines for the treatment of drug addiction (EMCDDA 2011). Nevertheless the practical effects of such a massive effort to produce clinical guidelines were not clear. When measured, the impact on quality of treatment seemed not impressive. Some surveys performed in the medical

field, not specifically in the drug addiction one, showed that clinical guidelines are applied to 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). Moreover, in a recent debate promoted by the British Medical Journal about the effectiveness of guidelines (Grol and Wensing 2004), it was pointed out that to ensure clinical guidelines have an impact on actual care and practice, activities beyond the mere production and dissemination should be instigated (Ferri and Bo 2012).

This type of considerations along with the need to reduce cost and improve quality and outcomes must be at the base of the evolution towards the *knowledge translation into practice* approach (Brownson et al. 2012). In fact, moving from the concept of evidence to that of knowledge expands an idea already present in the definition of evidence-based medicine. The practice of evidence-based medicine integrates clinical expertise with the best available evidence from systematic research, explained David Sackett (1996). “Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient” reinforced then. Probably “knowledge” is a better term to put together evidence with expertise. *Knowledge translation* has been defined as a “dynamic and iterative process that includes the synthesis, dissemination, exchange and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the health care system” (Canadian Institutes of Health Research 2012). Knowledge translation is not the only term that has been used to name this tendency towards practical use of knowledge to improve practice. According to Straus and colleagues (2009), more than 90 terms were identified in the literature. According to them, in Europe, preferences are for “implementation science” or “research utilization,” whereas the terms “dissemination and diffusion,” “research use,” and “knowledge transfer and uptake” are more frequently preferred in the United States. The Canadian “knowledge translation” has been adapted by others, including the United States National Center for Dissemination of Disability Research and the World Health Organization (WHO).

The lowest common denominator among the above described different terms is a move beyond dissemination of knowledge into actual use of it to transform practice. “Knowledge creation (i.e., primary research), knowledge distillation (i.e., the creation of systematic reviews and guidelines) and knowledge dissemination (i.e., appearances in journals and presentations) are not enough on their own to ensure the use of knowledge in decision-making” (Straus et al. 2009).

A definition of the “best-practice” concept was recently developed by a group of European experts convened by the EMCDDA. In brief, best practice is the best application of the available evidence to current activities in the drugs field. A number of factors were identified as contributing to making an intervention qualify as “best practice.” In summary, a best-practice intervention is based on the most robust scientific evidence available regarding what is known to be effective in producing successful outcomes, and it is tailored to the needs of those it addresses. Methods used will be transparent, reliable, and transferable and can be

updated as the knowledge base develops. With regard to implementation, local contextual factors will be taken into account, and the intervention will be harmonized with other actions as a part of a comprehensive approach to drug problems. Best practice is closely linked to the concept of “evidence-based practice,” and it requires the careful integration of both scientific knowledge and implementation expertise in order to appropriately adapt the intervention to the single individual and/or to a specific context. A best-practice intervention should provide better outcomes than other interventions and therefore also allow a rational allocation of resources (Ferri and Bo 2012).

There remain challenges associated with the promotion of best practice through guidelines, standards, and other similar tools. The first is to make sure that they are based on reliable scientific evidence and that they are regularly updated when new systematic reviews are published. The second is to make best use of the currently existing guidelines. Finally, it is important to ensure that guidelines and standards are appropriately implemented.

85.2.2 Quality of Interventions: The Main Tools and Their Life Cycle

Clinical guidelines are the main instrument to disseminate evidence-based interventions via recommendations for practice that are based on a clear methodology for the appraisal, synthesis, and grading of the available evidence (Connis et al. 2000). 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. The level of evidence is determined by a synthesis of relevant studies’ design (systematic reviews), number of participants studied, and the number of studies sharing the same results along with the overall measure of effect found by pooling the results of the studies. Each recommendation should have an indication of its strength, which clarifies how and when this is applicable to the patients. 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 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.” In some milestone manuals for guidelines development, these are indicated as *good practice points* (SIGN 2011).

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 general, evidence-based guidelines are published by independent organizations 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 (EMCDDA 2011).

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. This system has been adopted by several international organizations among which the EMCDDA (the Best Practice Portal); the World Health Organization; Agency for Healthcare Research and Quality (AHRQ), United States; and the National Institute for Clinical Excellence in the United Kingdom.

The evidence-based clinical guidelines are meant to facilitate the application of updated evidence to practice, and therefore, they are supposed to be timely revised. An indication of a specific date for revision should be stated clearly, and the choice of this date should be based on an assessment of the time in which new evidence is likely to be available.

This anticipation of a date for the availability of new evidence is in general possible because evidence-based clinical guidelines are based on systematic reviews of studies. These are identified through structured “search strategies” developed on the basis of a list of “clinical questions” that the guidelines should address. On the basis of those questions – which should be relevant to the patients and detailed enough to allow the appropriate search for the available evidence (Schardt et al. 2007) – the methodologists search, identify, and select a number of systematic reviews of evidence. The latter are based on published and unpublished studies and should also identify – in ad hoc created registries (WHO 2013) – the ongoing studies. Those registries collect information from the very beginning of the clinical studies and follow up each step until the publication. The entity (or the individual researcher) registering a clinical trial is requested to include a date of completion. Although these dates can be changed during the study period, they provide an idea when new results can be available.

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 rigor 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.

Several are nowadays the international inventories of guidelines from all over the world which can be consulted freely to find relevant documents. Among those, the more important are the inventory maintained by the Guidelines International Network (<http://www.g-i-n.net/library>) containing over 6,000 sets of guidelines for evidence-based healthcare (in multiple languages) and the National Guidelines Clearinghouse (<http://www.guideline.gov/>), an initiative of the Agency for Healthcare Research and Quality (AHRQ) in the United States, which publishes guidelines from any countries provided they are in English. The website of the National Guidelines Clearinghouse offers an automated function to compare different guidelines upon their main characteristics and to obtain synthesis of guidelines. The main aim of the inventories of guidelines is to avoid duplication of efforts making good quality guidelines available for adoption or adaptation in different contexts.

85.2.2.1 Adaptation of Guidelines to Everyday Practice Under Local Circumstances

Clinical guidelines can be elaborated and published at several levels: international, national, or local level. The World Health Organization and the United Nation Office on Drugs and Crime, for example, published guidelines and principles on the treatment of drug addiction (WHO 2009) (Table 85.1).

Being a very resource-intensive activity, guidelines are in general commissioned to specialized national agencies which have the capacity for convening a number of stakeholders from all the involved parts and reduce the risks of conflicts of interest. Examples of agencies to develop clinical guidelines are the National Institute for Clinical Excellence in the United Kingdom; the Scottish Intercollegiate Guidelines Network; the Finnish STAKES, National Research and Development Centre for Welfare and Health; the French National Health Authority (HAS); the New Zealand Guideline Group (went in voluntary liquidation in 2012); the Canadian Task Force on Preventive Health Care; and many others. An indicative list of organizations which develop and publish guidelines is available in the website of the Guidelines International Network (GIN 2012).

Guidelines which are published at general level may require some further elaboration before they can be effectively applied to the everyday practice. The translation of evidence-based recommendations into practice is the so called “implementation” process.

The implementation activities can follow two general approaches mainly depending from the “distance” between the context where the guidelines were issued and that where they have to be implemented. In some cases it is sufficient to *adopt* the guidelines through the development protocols at service level in which the guidelines’ recommendations are broken down into actions and responsibilities, agreed by the healthcare personnel. This type of protocols (which can be also called *clinical pathways*) supplement clinical recommendations with hospital (or service)-specific details and, in some cases, can amend those recommendations which are considered not fitting with the local context (Groot et al. 2008). These

Table 85.1 Recently published quality standards in the treatment of drug addiction

Title and year of publication	Supporting organization	Target groups	Structure of the standards	Web address
European Minimum Quality Standards (EQUS) 2012	European commission	Professionals performing interventions, service directors and managers responsible for the functioning of their institutions and staff, and health authorities, planners, and policy makers who are mainly concerned with the drug demand reduction activities at the system and network level	Structural standards of services Process standards at the service level Process standards of interventions Outcome standards at the system level	www.isgf.ch
Proposed continental minimum quality standards for treatment of drug dependence 2012	African Union	Unspecified	14 principles of effective drug dependence treatment 15 standards for treatment of drug dependence and 3 standards for evaluation and assessment	http://www.au.int/en/
Principles of drug dependence treatment 2008	UNODC WHO	Unspecified	9 principles: Description and justification Components Actions to promote each principle	http://www.who.int/substance_abuse/publications/principles_drug_dependence_treatment.pdf

National standards	
Service delivery for people with coexisting mental health and addiction 2010	<p>New Zealand Ministry of Health</p> <p>This guidance document is aimed at all those who have an interest and responsibility for planning, funding and providing mental health and addiction services including District Health Boards, Non-governmental organisations and the Ministry of Health. The content will be of interest to staff working in services, consumers and service users, carers and others who have contact with these services.</p> <p>Unspecified</p> <p>General principles Tips for mental health and addiction planners and funders Tips for mental health and addiction service managers and clinical leaders Suggested actions for local planning</p> <p>http://www.health.govt.nz/publication/service-delivery-people-co-existing-mental-health-and-addiction-problems-integrated-solutions-2010</p>
Principles of drug addiction treatment 2012	<p>NIDA USA</p> <p>Unspecified</p> <p>13 principles of effective treatment 22 frequently asked questions</p> <p>http://www.drugabuse.gov/publications/term/33/Guidelines%20and%20Manuals</p>
Alcohol dependence and harmful alcohol use quality standard 2011	<p>National Institute for Clinical Excellence (UK)</p> <p>The public, health and social care professionals, commissioners, and service providers</p> <p>13 statements and 13 quality measures for: Structure Process Outcome</p> <p>http://publications.nice.org.uk/alcohol-dependence-and-harmful-alcohol-use-quality-standard-qs11/list-of-statements</p>
Quality standard for drug use disorders 2012	<p>National Institute for Clinical Excellence (UK)</p> <p>The public, health and social care professionals, commissioners, and service providers</p> <p>10 statements and quality measures for: Structure Process Outcome</p> <p>http://publications.nice.org.uk/quality-standard-for-drug-use-disorders-qs23</p>
<i>(continued)</i>	

Table 85.1 (continued)

Title and year of publication	Supporting organization	Target groups	Structure of the standards	Web address
Quality framework for mental health services in Ireland 2005	Mental Health Commission Ireland	Service users as well as the different nature and scale of organizations involved in service delivery	8 themes 24 standards 163 criteria	http://www.mhcirl.ie/Standards_Quality_Assurance/Quality_Framework.pdf
Standards for integrated care pathways for mental health December 2007	NHS quality improvement Scotland	Local management, health staff at service level	9 process standards 21 care assessment, planning, delivery and outcome standards 16 condition-specific standards (only one relevant to drug addiction) 2 service improvement standards	http://www.healthcareimprovementscotland.org/programmes/mental_health/icps_for_mental_health/standards_for_integrated_care.aspx

protocols can be disseminated in the realm of some peer-led educational activities; and they can include reminders and other initiatives aimed at reinforcing the application of recommendations in practice (Burgers et al. 2003).

In other cases an *adaptation* process is put in place, where the source guidelines are further analyzed by a group of local experts who draft new contextual-wise recommendations. Customizing clinical practice guidelines to a particular context and involving local stakeholders and the end users of the guideline in this process has been identified as a way to improve acceptance and adherence (Harrison et al. 2010). In general, but not necessarily, the *adaptation* occurs when (inter) national guidelines are to be applied at local level. In this case the adaptation process can be kept into consideration more than one set of guidelines and imply a process similar to the one needed for drafting a new guideline. The major difference lies on the search for source documents that in the case of an *adaptation* focus on guidelines rather than on systematic reviews of evidence (and or primary studies) as in the case of a development of a new guideline.

ADAPTE (www.Adapte.org) is an international organization of methodologists researchers, guideline developers, and guideline implementers who aim to promote the development and use of clinical practice guidelines through the adaptation of existing guidelines. The organization created a resource toolkit that can be freely downloaded in the Guidelines International Network website (www.g-i-n.net).

Quality standards are becoming an increasingly popular tool for ensuring quality of interventions in healthcare. In general terms standards are principles and sets of rules about what to do and what to have (Brunsson and Jacobsson 2000) presented as voluntary to a number of potential adopters. According to one of the most known organization for standards development, a standard is a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context (ISO 2004; ISO 2004). Typically the standards proposed in the health field refer to content issues, to processes, or to structural (formal) aspects of quality assurance, such as environment and staffing composition.

Quality standards can be developed by private sector organizations as it is the case for the International Standards Organization (ISO 2013); national private, nonprofit organizations like the American National Standards Institute (ANSI); the Association Française de Normalisations (AFNOR); and the British Standards Institute (BSI). The great majority of these organizations have been founded at the beginning of the twentieth century and some after the Second World War. Standards can also be developed by international governmental organizations like the United Nations, the Organization for Economic Co-operation and Development, and the European Union. In fact standards are a good way to propose harmonization especially by those organizations whose members are sovereign states that cannot be obliged to follow some rules (Brunsson and Jacobsson 2000). Nevertheless there are also several national organizations especially in the health field which develop quality standards. In the case of these organizations, quality standards are intended as sets of rules based on evidence used to implement the interventions

recommended in clinical guidelines. The standards which are developed by the National Institute of Clinical Evidence in the United Kingdom, for example, are typically composed of a general statement and a measure which can be used to assess the quality of care or service provision specified in the statement. “The quality statements are clear, measurable and concise and describe high-priority areas for quality improvement. They are aspirational (they describe high-quality care or service provision) but achievable” (NICE 2012).

Several international organizations are undertaking standards development for health interventions in the drug demand reduction.

The European Commission financed a study on the Development of an European Union Framework for minimum quality standards and benchmarks in drug demand reduction (EQUS), proposing a set of 22 quality standards for treatment (the study included also 33 standards for prevention and 16 for harm reduction).

According to the background paper of this project, in the medical sciences, quality standards are determined by different stakeholders: health authorities, insurance companies, service providers, professionals, and patients. Each of these professional categories brings different goals, interests, and priorities which need to be reflected in the standards in the light of the underlying scientific evidence. The project, whose lead investigator was Ambros Uchtenaghen (Uchtenaghen and Schaub 2011), divided the quality standards into four dimensions:

1. *Structural quality*, e.g., standards relating to the physical environment, staff, training, etc;
2. *Process quality* standards relating to the process of an intervention, e.g., diagnostic assessment;
3. *Outcome quality and economic quality*, e.g., standards to measure the cost-benefit ratio.

The *structural standards for services* cover areas like the physical accessibility of treatment services (which need to be located in places easily reached by public transport) or the environment where the treatment take place which should be adequate (to allow privacy during consultations) and safe. Another important aspect is the need for a documented diagnosis as a basis for treatment choice. Staff education and composition is also mentioned in terms of ensuring the presence of medical and nursing staff along with psychologists or social workers and multidisciplinary with at least three professions represented.

The *process standards at the service level* included the assessment of substance use history, diagnosis, and treatment history along with the somatic and the social status for each patient including an assessment of the psychiatric conditions.

Each patient should be provided information on the treatment options available and should be provided a treatment plan tailored on his/her individual needs.

Treatment plans, assessments, changes, unexpected events, and any relevant information should be recorded and kept confidential. Each treatment service should promote cooperation with other agencies and services to ensure an appropriate response to the needs of their patients (whenever a service is not equipped to deal with all needs of a given patient, an appropriate other service is at hand for referral) and should ensure continuous education for the staff members.

The *outcome standards proposed at the system level* included the goals of health and social stabilization of patients and the reduction of illegal or non-prescribed psychotropic substances. Monitoring included the level of utilization (each service should provide information on the number of slots or bed utilized) and the ratio of discharges occurred as planned or for different reasons.

Internal and external evaluation of services was also proposed as a standard.

Beyond the list of proposed standards, the project-added value lies on the process adopted to consult the stakeholders and to identify several levels of standards. Namely, the stakeholders were interviewed by rounds of Internet-based consultations about the level of implementation status and acceptability of the proposed standards in their respective countries. Through this strategy it was possible to identify a long list of standards and grade them by priority of implementation. In fact, the EQUUS study also included a review, involving experts from 24 European countries, of existing quality standards already implemented at the national level. With regard to drug treatment processes, the standards most frequently reported as already implemented were in the areas of client data confidentiality and assessment of clients' drug use history, whereas the standards concerned with routine cooperation with other services, and those focusing on continuous staff training, were less often implemented. In the area of treatment outcomes, the two types of standard most frequently reported as implemented were those with goals linked to health improvement and reduced substance use. Among the standards less likely to be applied were those focusing on external evaluation and monitoring client discharge; problems related to the implementation of these standards were reported.

This approach may allow the participating countries to set their own goals and to pace the achievement of them on the basis of their own capacity and priority. This process would also be greatly facilitated by the existence of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), a decentralized agency whose aim is to provide sound and comparable information on drugs in Europe. Thanks to its impartiality and comprehensiveness of information, EMCDDA can support the countries volunteering for the adoption of the quality standards in setting their goals and measuring their successes.

The European standards have not been formally adopted yet, but the EQUUS study represents the beginning of an ongoing process to reach consensus over a minimum set of quality standards in drug demand reduction.

Another initiative at supranational level was undertaken by the African Union which has recently proposed a list of Continental Minimum Standards for treatment of drug dependence as a guide to member states (African Union 2012). In the introduction of these standards, there is a synthesis of the current situation of drug consumption in Africa stating that "the levels of drug consumption continue to grow in Africa while there is a tendency toward stabilisation in North America and Europe"; therefore, "an in-depth revision of current drug policies has become necessary (in Africa) in view of the increasing human and social costs and threats to democratic institutions."

Table 85.2 Processes for guidelines adaptation at local level

Document	Process	Professionals involvement	Output	Definition
Guidelines (national or international)	Adoption	Service personnel	Service protocol/ clinical pathway	A comprehensive set of rigid criteria outlining the management steps for a single clinical condition or aspects of organisation (http://www.openclinical.org/guidelines.html#gandp)
Guidelines	Adaptation	Stakeholders	Locally adapted guidelines	The local adaptation of national guidelines has been proposed as a way of increasing the benefit of local ownership, while maintaining scientific validity (Khunti and Lakhani 1998)

The text supports that “provisions should be made towards treatment of drug users which was instrumental in stabilising drug consumption in the West,” while “The criminalisation and marginalisation of drug users has increased drug-related health problems and contravened universal fundamental human rights.” In summary those standards are presented as an application of the lessons learned in a different context to change a particular situation. This intention captures the exact spirit of sharing of good practice. A general description of recent initiatives of standards for the treatment of drug addiction is reported in Table 85.2, and some of them will be deeply explored.

In general terms it can be observed that the existing standards (at their different level of implementation) seem to be triggered by several reasons: the harmonization of the existing services, the translation in practice of the evidence-based guidelines, the consistency between policy decisions and service provision, and the need to measure the results of interventions. These reasons are diversely reflected in the mentioned initiatives mainly in relation with the level where the standards are proposed. The life cycle of quality standards depends on the supporting evidence, but not completely. In fact when it comes to human rights or general safety measures, the relevant principles are imperishable.

Clinical pathways are structured, multidisciplinary plans of care designed to support the implementation of clinical guidelines and protocols. In a recent past it was considered that this definition was variedly interpreted by different stakeholders until a recent systematic review (Kinsman et al. 2010) clarified the concept.

The clinical pathways are essential to the translation of evidence-based guidelines at service level. They are in fact meant to “detail essential steps in care of patients with a specific clinical problem” and sequence “the actions of a multidisciplinary team” (De Bleser et al. 2006). In clarifying which actions should be undertaken to practice evidence-based recommendations, clinical pathways “facilitate translation of national guidelines into local protocols” (Campbell et al. 1998) and allow continuous improvement by monitoring and evaluating variances.

Clinical pathways are commonly adopted in the United States where in 2003 it was reported that almost 80 % of the hospitals used this tool (Kinsman et al. 2010). Evidence supports the adoption of clinical pathways at hospital level for the reduction of in-hospital complications (such as infections, bleeding, and pneumonia), improved documentation, and possibly a reduction in the length of stay (Rotter et al. 2010). An experience of integrated clinical pathways in mental health has been reported in Scotland where the National Health Service (NHS) Scotland is taking a national approach to improving the quality and safety of mental health services. The program started with the publication of national standards by NHS Quality Improvement Scotland (NHS QIS), setting out the framework for development at local level.

The emphasis of development and implementation of the ICPs lies with local NHS boards to ensure they are developed with local ownership and to meet the needs of the local population. However, to ensure accreditation by NHS QIS, the local ICPs must incorporate the national standards and evidence improvement to the quality of care provided (El-Ghorr 2010). In Belgium there is the European Association for the development of clinical pathways (<http://www.e-p-a.org/about-epa/index.html>). Among the objectives of this organization, there is the setup of an international network for pooling know-how on clinical pathways and the promotion and fostering of international cooperation between healthcare researchers, managers, and healthcare providers from European countries and the wider international community. The association has a journal which publishes research results on the development of clinical pathways.

85.2.3 Participation: A Key for Successful Implementation

There are two main elements underlying all the instruments for quality improvement mentioned in the previous paragraphs (evidence-based clinical guidelines, quality standards, and clinical pathways). These two elements are the evidence base and the stakeholders consensus. The last three decades have been devoted to define and share a valid methodology for the identification assessment and synthesis of the available evidence. This activity successfully brought to a general understanding about the terminology and the sources of correct information. Nowadays the role of evidence to base decisions is widely recognized, and the access to good quality sources of evidence is increasingly available.

The new challenge seems to lie on the promotion of an authentic participatory implementation of evidence-based interventions.

The same pioneers of the evidence-based medicine are now exploring strategies to communicating and involving two crucial stakeholders: the decisions makers and the patients (this latter category includes also family members, civil society organizations, community representatives (Deber et al. 2005)). Projects like SUPPORT financed by the European Commission's 6th Framework Programme (Lavis 2009) and the most recent DECIDE (Treweek et al. 2013) co-funded by the European Commission under the Seventh Framework Programme are both aimed at supporting decision makers in the use of evidence.

SUPPORT targets policy makers as a diverse group that includes cabinet members (e.g., Ministers of Health or Finance), elected officials (e.g., chairs of legislative committees), senior civil servants (e.g., directors of primary healthcare programs), and high-level political appointees (e.g., heads of government agencies). In spite of being aware of the differences that can exist among the countries due to the different political systems, the leading project managers of SUPPORT state that what all the decision makers have in common is the authority to take or influence decisions directly. The project encompasses several tools for boosting evidence-based decision making in various settings including low- and middle-income countries and high-income countries. As the other mentioned project, DECIDE, also SUPPORT, sought strategies for the involvement of public in evidence-based decision making (Oxman et al. 2009). In particular DECIDE, whose target is Europe, is composed of eight work packages, three of which devoted to identify best strategies to communicate with specific target groups such as health professionals, policy makers and managers, and patients and public.

The two projects have similar objectives though following different approaches: DECIDE focuses on guidelines and recommendations, while SUPPORT aimed to support policy-relevant reviews and trials. DECIDE on the other hand is developing tools that will help policy makers to make a decision about, say, whether to pay for a particular healthcare innovation in their region. Additionally, it is developing tools to make understanding the research information that forms the basis for guideline recommendations easier for a wide audience, including policy makers and the public. To some extent, DECIDE builds on the work of SUPPORT.

Even though these projects are important, quite often the exercise of knowledge translation brings to the appreciation of huge gaps in knowledge, gaps that are difficult to fill with methods for gathering consensus and taking decisions in the lack of evidence. The only possible way forward to fill those gaps is to propose new studies to find answers. These new studies should rely on mixed methods to get sound evidence from several sources and, of course, to be based on the priorities of the end users of the answers they should provide, such as the patients (Liberati 2011). In the United Kingdom, Sir Iain Chalmers, one of the founders of the Cochrane Collaboration, has undertaken a new initiative for the proactive involvement of patients in the setting of research priorities through the James Lind Alliance initiative (Petit-Zeman S FAU – Cowan and Cowan). The James Lind Alliance brings together patients, carers, and clinicians to identify and prioritize the uncertainties, or “unanswered questions,” about the effects of treatments that they agree are most important and makes the list of research questions public and available for researchers and research funders. Not always the area of addiction is represented in these initiatives. The main linkages are granted by the Cochrane Group on Drugs and Alcohol and by the European Monitoring Centre for Drugs and Drug Addiction which are working in partnership to bring the typical problems of this field in the broader perspective of knowledge translation.

Some of the characteristics of the drug addiction field can be shared by other medical conditions. For example, the behavioral component calls for research that cannot be only based on experimental studies. Important aspect of knowledge can

be in fact found on long-term observational studies, and in some cases they require qualitative analysis which is more difficult to be systematically retrieved with the typical search strategies adopted in systematic reviews and even more difficult to be assessed for quality and included in meta-analysis (Gough 2012). Nevertheless there are some added values in the drug addiction field which compensate for those extra efforts. The impact of interventions on public health and security makes drug addiction an important point on every political agenda and need to be based on the best available evidence.

85.2.4 Examples of Frameworks for Quality Standards

Several evidence-based guidelines are currently available for the treatment of drug addiction, in particular for the combined pharmacological and psychological approaches for opioid dependence, and these guidelines are issued at international and national level. Differently, the publication of quality standards for drug addiction treatment is less common, as the majority of the existing standards in drug addiction refer to prevention (UNODC 2013; EMCDDA 2012). Following we will describe two examples of standards for drug addiction treatment at national level, in European countries, namely, in the Czech Republic and in the United Kingdom.

In Czech Republic the implementation of quality standards for treatment of drug addiction dates back to 1995 for initiative of the Interdepartmental National Drug Commission (now Government Council for Drug Policy Coordination). Called minimal standards, these were adopted by the Association of Non-Governmental Organizations (ANO) for Addiction Prevention and Treatment for evaluating the quality of member organizations and newly established facilities. After further elaboration occurred in the subsequent 4 years, those standards became the basis for a certification process, which recognizes that a specific service provider is in line with predefined quality standards. Since 2004 the adherence to quality standards is assessed by specifically trained external evaluators. The current process for the certification of treatment providers was kicked off in 2005, and it included a transition period to allow the treatment provider services to start the certification process. After that period, certification became a prerequisite for applying for state grant programs. The overall aim of the certification process was the improvement of the quality of the network of services including a cost-effective administration of public funds. The certification process brought to the integration of the drug addiction services into the medical and social national system.

The underlying principles are as follows: voluntariness, certification is not required to provide drug services but only to apply for public funds; transparency, the evaluation process is carried out according to published criteria; and objectivity, the actual evaluation of quality is performed by an independent agency who appoints trained evaluators and the facility providers can point out any possible conflict of interest.

The standards are at the base of certification and accreditation process. The core activity of the certification process includes that a group of trained assessors visits the service providers to collect relevant information. Active participants in this

process are the facilities requesting the certificate of quality (those wishing to apply for public funds); the Certification Agency (an independent institution that arranges on-site examinations, communication between the parties of the certification process, and training of certifiers); the certification team carrying out on-site examinations (composed by at least three trained certifiers); the Certification Board of the Government Council for Drug Policy Coordination (deciding about certification request results and validity of certification ranging from 1 to 4 years); and the Executive Board of the Government Council for Drug Policy Coordination – to which the facilities can address their complaints about, for example, the composition of the certification team. In fact, before the certification can start, the agency and the requesting facility have to agree on the date and the composition of the team of assessors. Subsequently a number of previously identified employees and clients are interviewed with semi-structured questionnaires. The on-site examination in general lasts one day at the end of which the team of assessors drafts a report with a proposal for certification or suggestions for improvement. The report is shared with the interested facility which is given the opportunity to comment in writing.

The report is therefore completed and forwarded by the Certification Agency to the Certification Board of the Government Council for Drug Policy for the final decision.

Overall the process takes around 2 months, and the facilities requesting certification have 15 days to contest the results.

In the United Kingdom the National Institute for Clinical Excellence (NICE) publishes evidence-based clinical guidelines for many different medical disciplines including drug addiction. Sets of quality standards are derived from the best available evidence such as NICE guidance and other evidence sources accredited. They are developed in collaboration with NHS and social care professionals, their partners, and service users. The standards consider issues like evidence of effectiveness and cost-effectiveness, people's experience, safety, equality, and cost impact. The quality standards are considered central to supporting the government's vision for an NHS and social care system focused on delivering the best possible outcomes for people who use services (Health and Social Care Act 2012). This act clarifies that the Secretary of State "must have regard to the quality standards prepared by NICE." The care system should consider those standards in planning and delivering services to secure continuous improvement in quality. NICE quality standards do not provide service specifications but rather define priority areas for quality improvement. Nevertheless those standards are the basis to ensure that the providers of health and adult social care in England meet the standards of quality and safety required to by the Care Quality Commission.

The standards developed by NICE are typically composed of a general statement complemented by a measure. These quality measures are drafted only after the quality statement wording has been agreed and addresses the structure of care or services, process of care or service provision, and, if appropriate, outcome of care or service provision. The majority of measures refer to process and are expressed as a numerator and denominator to define a proportion in which the numerator is

a subset of the denominator population. For example, for the standard “People who inject drugs have access to needle and syringe programmes in accordance with NICE guidance,” there is a measure at the structure level, which is “Evidence of local arrangements to ensure people who inject drugs have access to needle and syringe programmes in accordance with NICE guidance,” complemented by a measure of outcome: (a) proportion of people who inject drugs who access needle and syringe programs, wherein the numerator is the number of people who access needle and syringe programs and the denominator is the estimated prevalence of injecting drug users, and (b) incidence of blood-borne viruses among people who inject drugs.

To clarify the implications of the standard, a breakdown of meanings of the standard for each stakeholder is included: service providers ensure systems are in place for people who inject drugs to have access to needle and syringe programs in accordance with NICE guidance; needle and syringe program staff ensure people who inject drugs have access to needle and syringe programs in accordance with NICE guidance; commissioners ensure they commission services for people who inject drugs to have access to needle and syringe programs in accordance with NICE guidance; and people who inject drugs have access to needle and syringe programs that are nearby, have suitable opening hours, and provide injecting equipment and advice on reducing the risk of harm. The standards include also that the sources of data should be considered in the measurement. Furthermore, at NICE there is an implementation team to support key audiences and organizations to maximize the uptake of guidance and quality standards. The team assesses the aids and barriers to implementation and provides practical support tools for commissioning, service improvement and audit, education, and learning. The team prepares reports on the uptake of guidance that are used to inform the development of the quality standard. The implementation team collaborates with national bodies and local organizations, through local implementation consultants, to support the use of quality standards and to facilitate shared learning. Overall the process to produce standards at the National Institute for Clinical Excellence lasts indicatively for 42 weeks.

These two examples suggest the possibility of different approaches to the use of quality standards. In the Czech experience in fact, the development of the standards represents an initial effort, whereas the actual focus seems to lie on the certification and accreditation process including several levels of training and a “learning by experience” process. Furthermore, the entire experience initiated around 20 years ago has been conceived and developed specifically in the treatment of drug addiction.

On the other hand the National Institute for Clinical Evidence has created along with the Department of Health and other key partners a core library of topics for quality standard development in health-related topics, among which alcohol dependence and drug use were included. In this case the focus seems to be on the development itself of the standards which *translate the evidence-based guidelines* into general statements and measures of outcomes at the system level including the indication of the sources of data to be used for the assessment of the implementation. Furthermore, NICE offers the support of an implementation team to enhance local adoption initiatives.

85.3 Conclusion

Quality of intervention is entrenched to evidence base, and in the last 20 years, important progress has been made in the availability of good quality systematic reviews of effectiveness in the field of drug addiction treatment. Nevertheless important gaps in knowledge still exist and need to be addressed by further investment in research. To ensure that research answers concrete problems arising from the daily experience of those affected by the drug problems at several level, it is crucial that the end users of research results – such as practitioners, patients, and decision makers – are involved in the selection of priority for investigation.

Currently the attention seems to be focused on how to better communicate evidence to policy makers, patients, and the general public. It is clear that the achievement and maintenance of quality in the treatment of drug addiction need the participation of all the stakeholders. The agencies which provide the data needed to assess the current situation and set the future goals, the organizations producing evidence-based documents, the decision makers at service provider level, and those managing the local, regional, and national level have to collaborate with the practitioners, to offer the best possible treatment to the drug users. The drugs users, the families, and the public have to proactively be involved in any decision and should be able to speak out their needs and problems.

The tools to translate evidence into quality of treatment have to be understandable by all the relevant stakeholders to empower them in a reiterative process of testing and lessons learned.

Quality is a continuous process where each new achievement has to be seen as a step towards new goals.

Glossary of Terms

Accreditation is the process by which an institution delivering a service is independently assessed for quality against some predefined 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 or to implement some guidelines at individual service level.

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, to processes, or to structural (formal) aspects of quality assurance, such as environment and staffing composition. In some cases, standards are legally binding.

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