# Part B: Selected issues

## 11. History, methods and implementation of national treatment guidelines

### 11.1. Introduction

#### 11.1.1. Rationale and objectives

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

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

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

In France, the High Authority for Health (HAS), former ANAES[102], defines clinical practice guidelines as “proposals developed according an explicit method in order to help healthcare professionals and patients to seek for the most suitable care related to specific clinical situations”. Guidelines are based on systematic literature reviews and expert opinion. They can be requested by diverse public or private bodies (Health ministry, scientific societies, associations, etc.). In the field of drug addiction, demands are generally referred to the HAS which can also launch a reflection at its own initiative.

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

In the light of these elements, both the definition and implementation processes of the targeted guidelines are considered in this study of the French situation. According to the EMCDDA's query, an historical narration of the emergence of the guidelines developed in

[102] Agency for Accreditation and Evaluation of Scientific Evidence.

France precedes the description of these two phases. From then on, the evocation of the implementation of guidelines designates not only their application by the targeted professionals but also the whole accompanying measures deployed in this aim (since the final utilisation of guidelines has not been evaluated in general). The focus is on the treatment of illicit drug uses, excluding the issue of the addiction to licit drugs (alcohol, tobacco, etc.). The main objective is to figure out possible ways, in the national context, to enhance a better integration of knowledge of evidence-based good practices in respect to drug addiction treatment. A comparison with the guidelines edited by the WHO is to be found in Annex IV.

### 11.1.2. Method

The study covers five out of the six identified treatment guidelines related to illicit drug use. The inclusion of the guidelines dealing with detoxification (1998) has not appeared relevant given the French context characterised by the predominance of opioid maintenance treatment and the regular decrease of both demand and supply of opioid detoxification programmes. The final list of the studied guidelines is:

- Access to methadone in France (Auge-Caumon et al. 2002)
- Therapeutic strategies for opiates addicts: place of substitution treatments (ANAES 2004)
- Reducing the misuse of opiate substitution medication (2004) (ANAES 2004)
- Abuse, addiction and polyuse: strategies of care (HAS 2007)
- Strategies of care for cocaine users (HAS 2010)

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

The development and the implementation of addiction treatment guidelines being poorly documented, an original data collection was required. Therefore, 15 field experts, field actors and stakeholders (*i.e.* 80% of the interviewees originally selected for their deep knowledge of the question) expressed their perception of the events and the existing logics and stakes, through semi-structured face-to-face interviews. The aim was to gather the institutional, professional, researchers and users' standpoints all together.

Finally a benchmarking model has enabled to highlight the strengths and gaps of the successive guidelines and to some extent to visualize the technical evolutions of their development.

## 11.2. History and overall framework of the substitution

The law of 31 December 1970[103] sets the legal framework of the drug policy in France. It stipulates that drug use is an offence but drug users can avoid prosecution by complying with a drug treatment, ever since anonymous and free of charge. The objectives of this law are also to repress trafficking and to control the use of drugs (Derks et al. 1999) (Angel et al. 2005). From then on drug addiction has become a matter of national solidarity directly within the competence of the State. In 1982 a cross-departmental body was established to coordinate the public action in the fields of prevention, health and social care, law enforcement and international cooperation. This body became the interministerial Mission for the fight against drug and drug addiction (MILDT). It operated under Ministry of Health before coming under Prime Minister in 2009.

[103] Loi n°70-1320 du 31 décembre 1970 relatif aux mesures sanitaires de lutte contre la toxicomanie et de l'usage illicite des substances vénéneuses

This so-called law of 1970 has not been fundamentally modified since then but many ministerial directives (decrees and circulars) were issued to supplement the patterns of health and social care towards drugs addicts.

Historically, drug treatment responses developed in France have largely been influenced by a psychoanalytical approach. In the 60s, drug addicts were addressed to psychiatric hospitals for detoxification, like alcoholic people. At that time, treatment basically focused on abstinence. In a way, from the adoption of the anti-drug law, the State entrusted the specialists, mainly psychiatrists and psychologists, with the care to drug addicts: the psychological and behavioral disorders implicated in addiction appealed to individual clinical responses. These professionals developed a psychoanalytical approach, based on a relation of trust between the drug-addicted patient and the practitioner and still aimed at abstinence. This practice became more and more professionalized over the 70s. The overrepresentation of psychiatrists in the edification of drug treatment knowledge must also be related to the relative reluctance from the traditional health system to undertake drug users, seen as a problematic population. Furthermore, the predominance of specialists in the field might have contributed to arise the feeling among general practitioners (GP) that this issue was not their affair especially since they were poorly trained on the subject. Until the early 1990s, the more curative vision of drug addiction related care tended to delay a more global apprehension of the problem and finally the acceptance of the pragmatic approach of risk reduction (Boekhout van Solinge 1996). The main professional actors thought that prescribing opiates to a drug addict could not but comfort the ascendency of the product over the patient. For the political authorities, the extension of substitution would have left the door opened for the liberalization of drug use.

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

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

In 1995, specialised centres were authorized to provide methadone[104]. One year later, High Dosage Buprenorphine (HDB) was chosen as main substitution substance, despite its higher cost compared to methadone. France opted for this molecule since it could be prescribed in primary health care, which was considered as frontline system to respond to the important

[104] Circulaire DGS n° 4 du 11 janvier 1995

wave of demands (Escots, S. et al. 2004b; Escots, S., Fahet, G. 2004). This was quite naturally accepted among the general practitioners who started to prescribe HDB. The conversion was less simple among specialists, who were gradually organising methadone programmes (Coppel, A. 2004). In a way, HDB was left to general practitioners. This rapid and important shift in the French policy caused an animated polemics. They particularly issued from professionals who considered opiate substitution seen like a setback for the therapeutic ambition. Questions subsisted about the GPs' ability to take the change of direction towards substitution on. They rooted in the perception of their lack of training and of insufficient psychosocial care facilities to address drug addicted patients to (Bergeron 1999). At the time, the only directive from authorities concerned the maximum duration of any prescription of HDB fixed at 28 days (*versus* 14 days for methadone)[105]. As the risk of overdose was not perceived yet and in the absence of any other specification, physicians were free to determine the dosage to prescribe. In the opposite, strict controls were imposed for methadone in order to prevent such accidents. But some of the first prescribers could work in a network, compare their practices and then fine-tune the pharmacological indications. The collaboration between GPs and the hospital sector could also rely on the specific so-called "ville-hôpital" network. The principles of the clinical practice, empirically conceived and tested, diffused via addictology networks (Coppel, A. 2004).

Few years later, the improved access to harm reduction and substitution cares resulted in a sharp fall in the number of fatal overdoses (184 in 1998 *vs.* 451 cases in 1994) and a decrease of the prevalence of HIV infections among drug injectors (10 % in 2007 *vs.* 30% in the early 90s). A major change had taken place in France and had demonstrated the efficacy of opioid substitution treatment. Faced with these incontestable outcomes, many drug specialised centres reconsidered their position and adopted the principle of substitution.

Thus, the large diffusion of substitution treatment brought to the surface other issues like misuse and related health damages but also the apparition of a black market, in particular based on HDB. But those issues were not immediately handled, the priority being at first the consolidation of the still recent substitution policy (Coppel, A. 1998).

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

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

The year 2004 was also marked by the adoption of several measures aimed at curbing the misuse of substitution substances. The Law of 13 August 2004 relative to National Health Insurance (CNAMTS)[106] imposes on any patient "to indicate to his attending physician, for each prescription, the name of the pharmacist who will be responsible for the delivery (of the medicine)" and imposes on any physician "to mention this name on the prescrption that must be issued by the concerned pharmacist for acceptance of financial liability" (Article L.162-4-

[105] Circulaire DGS n° 29 du 31 mars 1995 (DGS/SP3/951°29)

[106] Loi n°2004-810 du 13 août 2004 relative à l'assurance maladie. NOR: SANX0400122L

2). In addition, the National Health Insurance launched during the same year a National Action Plan on the Control of substitution treatments *"to fight against fraud and abuse while preserving the right of patients to benefit with quality care"*. Together with the Ministry of Health and the French Agency for Safety of Health Products (AFSSAPS), it also proposed clinical practice guidelines (CPG) focusing on the prescription of opioid substitution medication so as to reduce their potential misuse. These ones were published by the ANAES and the AFSSAPS in 2004 (ANAES 2004).

Later on, the HAS published two other guidelines to improve quality of addiction treatment. The raising concern about polyuse among drug users lead to the elaboration of the guidelines on the subject, in 2007 on the request of the French Federation of Addictology (HAS 2007). Faced with the sharp rise of the prevalence of cocaine use reported in France and the increase of treament demands related to this product, the HAS studied the question. On the basis of the available international scientific works dealing with cocaine use treatment, it supervised the development of specific guidelines, published in June 2010 (HAS 2010). At last, more recent guidelines taking over the involvement of drug users referred to medico-social addictology establishments were issued in April 2010 by the ANESM[107]. But their ins and outs could not be analysed within the scope of this study.

## 11.3. Characteristics of the definition and implementation patterns of the existing guidelines

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

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

### 11.3.1. Definition process

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

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

**Contributors**

In France, representative bodies of specialised professionals (federations, national associations) and public health authorities (ministry of Health, National Insurance, etc.) are the *sine qua non* protagonists of the elaboration process of guidelines related to drug addiction treatments. Guidelines can be produced at the instigation of any of these bodies. Any of them can be at the instigation of guidelines. For this purpose, they seize the public health agency that will supervize works (HAS, former ANAES, which is the first producer of medical guidelines or AFSSAPS that specifically publishes recommendations on

[107] National Agency for the Evaluation and the quality of the social and medico-social establishments and services.

medications). In general rule, other categories of contributors are consulted: field actors, researchers, epidemiological data providers or even representatives of drug users. Their diversity and representativeness of profiles varied from one to another experience but in general the consultation mainly focuses on physicians. Pharmacists or nurses are more scarcely associated and sociologists, economists or jurists are even more rarely so. The authors' notoriety contributes to legitimizing these guidelines and to promoting them towards professionals (Davis et al. 1997). In other words, the commitment of influential professionals (constituting a kind of leadership) allows the introduction of innovative clinical practices among peers.

**Definition methods**

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

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

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

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

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

**Quality control methods**

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

Usually The HAS uses the AGREE criteria to evaluate the guidelines written under its responsibility, developed according to the method of clinical practice guidelines (CPG). Nevertheless it could not apply these evaluation criteria to the two guidelines dealing with the misuse of substitution medication (2004) and cocaine use (2010), both developed according to this CPG method.

The Appraisal of Guidelines Research and Evaluation (AGREE) questionnaire and its criteria were developed by scientists and health policymakers at the beginning of 2000s so as to assess the quality of clinical practice guidelines (CPG) developed by local, regional, national or international groups. This generic tool can be applied to any type of CPG regarding any health problem, medical intervention or type of care (AGREE Collaborative Group 2000)

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

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

### 11.3.2. Implementation process

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

The implementation measures organised in France are examined here against four criteria:

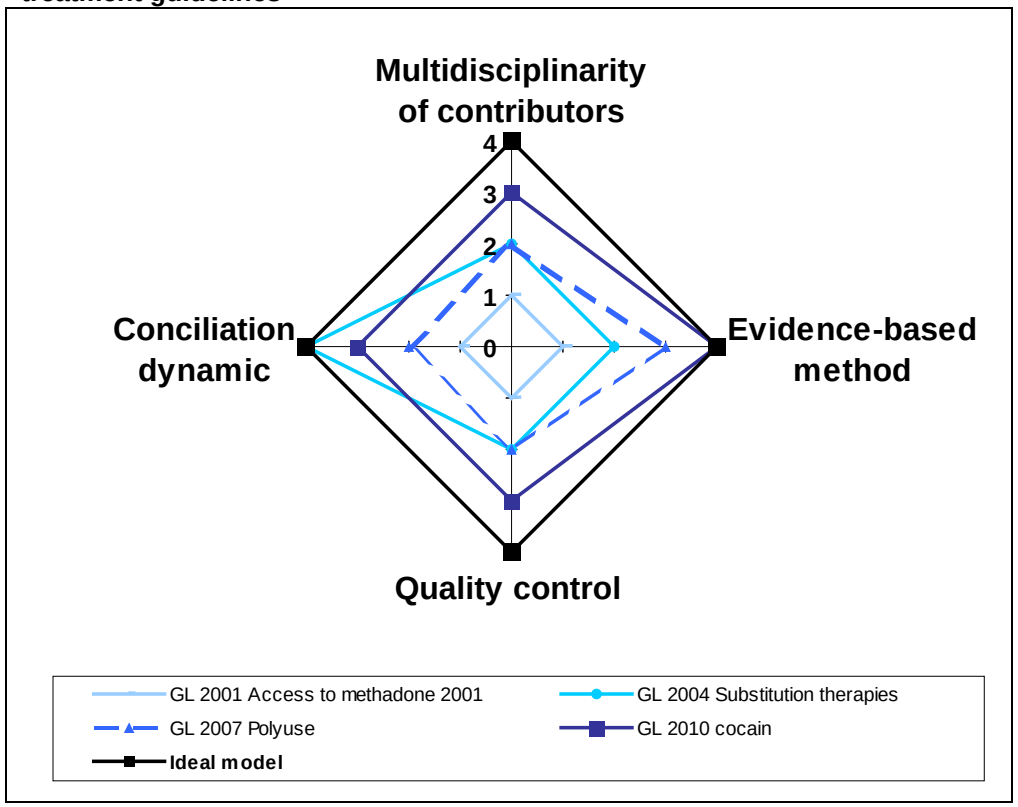
- the multidisciplinarity of promoters, as an indicator of their representativeness and legitimacy while sustaining the adoption of guidelines;
- the accessibility of publications, in other words the operational and pragmatic nature, characterising a primary level of dissemination;
- the existence of accompaniment measures, in particular for active information strategy (i.e. a second level of dissemination);
- the used resources and means to support the application of guidelines.

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

**Accessibility of publications**
In all cases, the guidelines were published in medical reviews and on the websites of the involved institutions or associations. Most often, a short version was also produced in order

to facilitate the distribution of recommendations and an easier access for practitioners. On one occasion, the HAS announced the publication of new guidelines through newsletters to physicians. But it stopped these mailings given the difficulty of updating the addresses database. Other publication forms were produced, as brochures or letters to general practitioners, summing-up the recommendations that directly concerned them. After the 2004 consensus conference, reminder systems like doctor letters were diffused, but punctually.

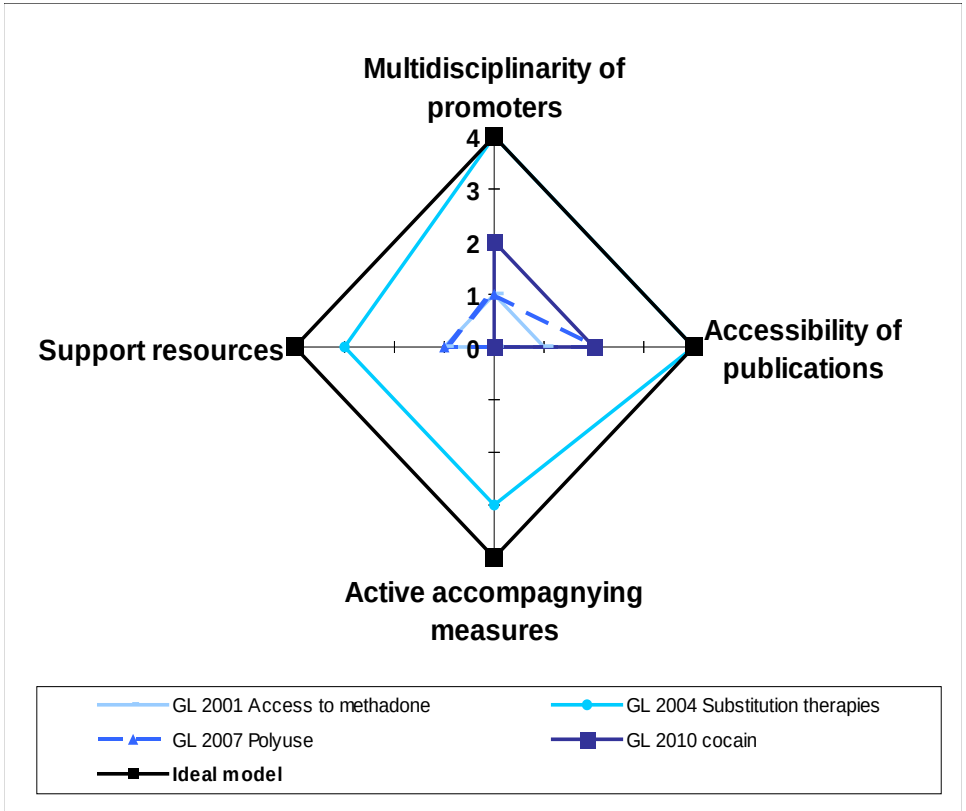
**Chart 11-1: Benchmarking of definition processes of the French drug treatment guidelines**




**Categories of the benchmarking – Definition process**

| Bench-mark | Multi-disciplinarity of contributors | Evidence-based method | Conciliation dynamic | Quality control |
|---|---|---|---|---|
| 1<br>Very low level | Policy makers, concerned professionals[108]<br>, | Professional empirical expertise | Epidemiological identification of needs | Internal |
| 2<br>Low level | Level 1<br>+ final target population | Partial literature references | Level 1<br>+ consulting the diverse existing stakeholders | Independent |
| 3<br>Moderate level | Level 2<br>+ researchers | Systematic review | Level 1<br>+ active contribution of the diverse existing stakeholders | Cross independent |
| 4<br>High level | Level 3<br>+ other relevant professionals | Level 3<br>+ standardized grading of evidence | Level 3<br>+ consensus | Level 3<br>+ process evaluation |

**Chart 11-2: Benchmarking of implementation processes of the French drug treatment guidelines**




**Categories of Benchmarking – Implementation process**

| Bench-mark | Multi-disciplinarity of promoters | Written Information tools | Active Information tools[109] | Support resources |
|---|---|---|---|---|
| 1<br><br>Very low level | Policy-makers | Written material, Internet (Online version) | Academic continuous education | Legislative texts |
| 2<br><br>Low level | Level 1<br>+ Strategic change actors[110] | Level 1<br>+ short version of GL | Opinion leader and audit feedback | Level 1<br>+ specific funding |
| 3<br><br>Moderate level | Level 2<br>+ Economic actors | Level 2<br>+ targeted short version | Interactive workshops/ seminars/ trainings | Level 2<br>+ prescription control system OR implementation unit |
| 4<br><br>High level | Level 3<br>+Final target population | Level 3<br>+Newsletter, prescription reminder system | Durable combination of the aforesaid components | Level 2<br>+ prescription control system AND Implementation unit |

[109] Adapted from the SIGN work (SIGN: Scottish Intercollegiate Guidelines Network)

[110] Corporations, experts, personalities

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

**Table 11-1: Effectiveness of communication patterns for effective implementation of a policy**

| Not effective | Low effective (Mixed effects) | Moderate effective | High effective |
|---|---|---|---|
| - Continuous medical education | - Opinion leader | - Audit-feedback | - Interactive training |
| | - Conferences | - Mass media campaign | |

In France, no accompaniment measures (such as training, workshop, seminars) were organised at national level to support the publication of drug treatment guidelines. They were often discussed but did not ever materialize on a national level. Whatever they were, they remained punctual.

In 2004 meetings and trainings for practitioners were locally organised by the pharmaceutical company distributing HDB. This laboratory also sponsored brochures for practitioners and drug users.

Some years after the publication of the 2004 consensus conference, academic modules of addictology were integrated in the initial medical curricula. Now, short modules of continuous training and diploma in addictology also exist. But overall, the integration of clinical recommendations in these curricula is not assessed.

**Resources and support system**
In France neither law nor any control body compels practitioners to apply the issued recommendations. The only control in force has been established by the National Health Insurance (CNAMTS) and concerns abusive or suspicious prescriptions (mean daily dose of HDB > 32mg). It aims at reducing the misuse of the substitution medication.

On the other hand, professional orders (physicians or pharmacists' ones) can provide for clinical or technical advice. But there is neither local nor national administration overseeing the substitution treatment delivered. Except for the creation of the *département* committees for the follow-up of opioid substitution treatments (which finally disappeared), adequate resources were not developed so as to support the application of guidelines. No permanent resources unit (ex.: mediators, dedicated staff) liable to help practitioners to understand or to implement recommendations, could be set up neither locally nor nationally, neither by heath authorities, nor by professional organisations.

Through the reported experiences, gaps identified in respect to the implementation systems of guidelines seem to be largely imputable to the recurrent lack of funding, major obstacle to a structured, proactive and viable implementation strategy.

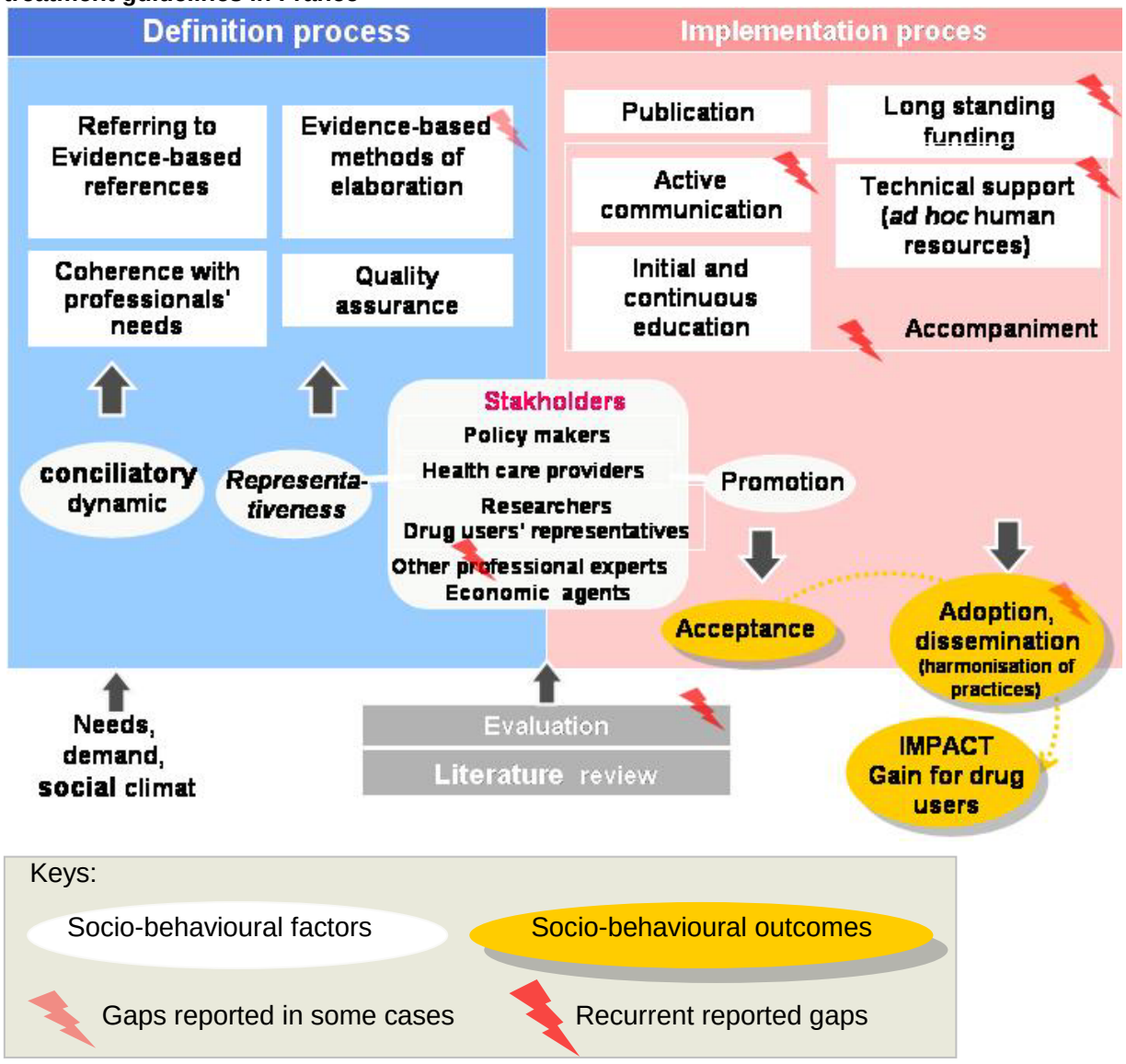
**Available evaluation details**
None of the reported experiences was evaluated. Nonetheless, with the passing of time, professionals have perceived that the diverse guidelines have had a limited impact, apart from the benefits attributed to the 2004 consensus conference regarding the social climate among professionals. The main criticisms refer to recurring weaknesses in the accompaniment of the guidelines.

A recent study carried out by the ANITeA (forthcoming publication) shows a great heterogeneity of substitution practices and knowledge on good practices among specialised treatment centres (CSAPA). These findings tend to confirm the perception expressed by the experts interviewed for the present study.

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

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

**Chart 11-3: Determining factors of the definition and implementation of drug addiction treatment guidelines in France**




## 11.4. Possible paths of improvement

Some paths of improvement can be drawn from this analysis. However their budgetary weight has not been estimated in the scope of this study.

Involving from the beginning to the end of the process the different concerned publics, in particular opinion leaders, is essential in order to manage correctly all stakeholders' expectations and to find realistic methods to sustain changes. The opinion leaders' commitment and accountability prove to be important to achieve effective development and diffusion of guidelines just like appointed human resources and support conditions are necessary to sustain their viability.

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

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

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

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

## 11.5. Conclusion

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

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

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

Though the method of definition of guidelines and of quality control did not always follow the most recognized international standards, this absolutely does not allow any depreciation of the quality of recommendations. The most obvious gaps concern above all the diffusion of the guidelines which rarely went beyond a primary level consisting in their publication.

Communication and assistance to professionals also lacked. Nowadays, the intervention of opinion leaders is a major asset in the production of guidelines, particularly when they defend innovative practices. It appears as a key ingredient not only so that guidelines contents gain in consistency but also to favour their acceptance by professionals and finally the adoption of new practices.

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

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

**Appendix a: Synopsis of guidelines related to addiction treatment**

| Guidelines (year) | Objectives | Targeted interventions | Targeted professionals | Actors | Method and quality control | Implementation resources |
|---|---|---|---|---|---|---|
| **Access to methadone in France (2002)**<br>*Reviewed and renewed by following consensus conference in 2004* | To formalize, clarify and organise public health policy regarding substitution treatment<br>▪ To develop and to sustain what works, to assess and correct what does not work<br>▪ To improve the quality of care with substitution treatment in prisons<br>▪ To improve ease of use of methadone and to enhance adherence to therapy among drug addicts | Substitution treatment | Field health care providers[111] | **Initiator and promoter:** Delegated Minister of Health<br>**Contributors:**<br>Health professionals<br>(Psychiatrist, Internist Pharmacist, GP) | ▪ Report<br>▪ Professional empirical expertise<br>▪ Internal quality control | ▪ Publication (92 pages)<br>▪ Online version<br>Sub regional committees to support opioid substitution treatment |

http://lesrapports.ladocumentationfrancaise.fr/BRP/024000177/0000.pdf

[111] Drug addiction specialists, Psychiatrists, GPs

| Guidelines (year) | Objectives | Targeted interventions | Targeted professionals | Actors | Method and quality control | Implementation resources |
|---|---|---|---|---|---|---|
| **Therapeutic strategies for opiates addicts: place of substitution treatments (2004)** | To determine goals and expected results for substitution treatment<br>To identify the necessary modalities of support for implementation and follow-up of treatment<br>▪ To find ways for the adoptions of treatments in primary health care<br>To promote good practices in the management of patients receiving treatment | Substitution treatment provided with methadone and high dosage of buprenorphine (HDB)<br>*More details: see section 4* | Field health care providers | **Initiator:** FFA<br>**Contributors:**<br>Health professionals[112], ANAES, Representatives of drug users<br>**Promoters:** ANAES, FFA, Pharmaceutical laboratories, Health professionals, Representatives of drug users | ▪ Consensus conference<br>▪ Partial literature references<br>▪ Independent quality control<br>▪ Prescription control system | ▪ Publication of a short and long versions of guidelines (15/40 pages)<br>▪ Online version<br>▪ Extra short version addressed to GPs<br>▪ Brochures<br>▪ Trainings/Worksh ops |

http://www.has-sante.fr/portail/upload/docs/application/pdf/TSO_court.pdf (short version)
http://www.has-sante.fr/portail/upload/docs/application/pdf/TSO_%20long.pdf (long version)

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

| Guidelines (year) | Objectives | Targeted interventions | Targeted professionals | Actors | Method and quality control | Implementation resources |
|---|---|---|---|---|---|---|
| **Reducing the misuse of opiate substitution medication (2004)** | ▪ To identify available substitution medication, their misuse and the determinant factors<br>▪ To improve the prescription by monitoring and reassessing patient's treatment and follow-up<br>▪ To improve the organization of care | ▪ Diagnostic according to DSM-IV or CIM-10<br>▪ Prescription of medication | Field health care providers | **Initiator:** Ministry of Health, CNAMTS, AFSSAPS<br>**Contributors:**<br>Health professionals[113], ANAES, Representatives of drug users<br>**Promoters:** ANAES, AFSSAPS | ▪ Clinical practice guidelines<br>▪ Partial literature references<br>▪ Cross independent quality controls | ▪ Publication (15 pages)<br>▪ Online version<br>▪ Fact sheets for prescribing physicians as reminders for good practices<br>▪ Centres for Evaluation and Information on Pharmacodepen-dence (CEIP)<br>▪ Prescription control system |
| http://www.has-sante.fr/portail/upload/docs/application/pdf/opiaces_recos.pdf | | | | | | |
| **Abuse, addiction and polyuse: strategies of care**<br><br>**(2007)** | ▪ To educate all professionals involved in the management of various addictions<br>▪ To provide these professionals with operational recommendations<br>▪ To propose studies, programmes and trainings | ▪ Application of the Addiction Severity Index (ASI)<br>▪ Therapeutic care | ▪ Field health care providers, especially the ones in contact with the youth, pregnant women, elderly, inmates, precarious population, sportsmen<br>▪ Researchers | **Initiator:** Ministry of Health<br>**Contributors:**<br>Health professionals, HAS Representatives of drug users<br>**Promoter:** HAS | ▪ Public Hearing<br>▪ Systematic review<br>▪ Independent quality control | ▪ Publication (36 pages)<br>▪ Online version |
| http://www.has-sante.fr/portail/upload/docs/application/pdf/reco_polyconsommations_-_version_finale_2007_12_21__21_47_28_78.pdf | | | | | | |

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

| Guidelines (year) | Objectives | Targeted interventions | Targeted professionals | Actors | Method and quality control | Implementation resources |
|---|---|---|---|---|---|---|
| **Strategies of care for cocaine users (2010)** | ▪ To improve health care of cocaine users<br>▪ To facilitate their identification and the cessation | ▪ Counselling<br>▪ Psychological follow-up<br>▪ Detoxification<br>▪ Psychotherapy | ⇨Field health care providers, especially the ones in contact with pregnant women and young people[114] | **Initiator:** Ministry of Health<br><br>**Contributors:**<br>Health professionals, HAS Representatives of drug users, Researchers<br><br>**Promoter:** HAS | ▪ Clinical practice guidelines<br>▪ Systematic review and standardized grading of evidence<br>▪ Cross independent quality controls | ▪ Publication of a short and long versions of guidelines (28/ 148 pages)<br>▪ Online version |

http://www.has-sante.fr/portail/upload/docs/application/pdf/2010-05/consommation_de_cocaine_-_recommandations.pdf (short version)

http://www.has-sante.fr/portail/upload/docs/application/pdf/2010-05/consommation_de_cocaine_-_argumentaire.pdf (long version)

[114] In primary health care, hospitals or specialised centres.

## Appendix b: List of participants by alphabetic order

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

**Appendix c: List of abbreviations**

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

**Appendix d: Comparison with the WHO guidelines**

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

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

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

**1. Choice of treatment**

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

**2. Opioid agonist maintenance treatment**

2.1 Two opioid agonist maintenance treatments exist: methadone and high dosage buprenorphine (HDB). None of those two treatments is more recommended than the other. However, the guidelines mention that methadone is more adequate for injecting drug users. On the other side, methadone can be only prescribed in a restricted way (specialised centres) whereas HDB can be given to the patient by every physician and in the primary health care.

2.2 The initial dose for methadone is between 10-40 mg per day and can be increased by 5-10 mg from 1 to 3 days per week without exceeding 50% of the initial dose.

The daily initial dose for buprenorphine is 4 mg to 8 mg and can be increased by 1 to 2 mg from 1 to 3 days until the optimal dose.

2.3 The majority of patients treated with methadone are stabilized by a dose of about 60-100 mg per day but some people need higher doses. No maximum dose has been indicated for methadone.

2.4 For HDB, the majority of people are stabilized between 8 and 16 mg per day. However, some require higher doses of 16 mg per day (24 mg exceptionally). Maximum dosage authorized by the marketing authorization is 16 mg per day. So if higher dosages are expected it is recommended that the prescriber requires a specialist opinion (CSAPA, ES, addictologist, psychiatrist, etc.).

2.5 The initial treatment is prescribed for 1 or 2 days, with daily delivery, which requires the collaboration of the pharmacist. He must be contacted by the prescriber by telephone and must agree on the conditions. His details will be listed on the prescription secure. The contacts between prescriber and pharmacist must be regular.

In the initial phase, it is recommended that consultations are done several times a week to adjust the dosage if necessary, to reassess the effect sought by the person, to estimate adherence, to investigate the association with other psychoactive substances and to deepen the therapeutic alliance. Therefore, the first weeks a therapeutic relationship has to be established, assessing the patient's situation and adapting treatment.

For methadone, the regulation requires a urine test before starting treatment and a supervision.

2.6 No take-away dose has been specified in the present guidelines

2.7 Offering routinely psychosocial support in association with pharmacological treatment for opioid dependence is not mentioned in the present guidelines. However, cooperation between health care and social workers are highly recommended in the guidelines. Marketing authorization stresses on this global approach (medical, psychological and social).

**3. Management of opioid withdrawal**

Three different management methods of opioid withdrawal are recommended: prompt and progressive withdrawal and change of molecule in order to stop substitution treatment.

None of those methods is more recommended than another.

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

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

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

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

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

**4. Pregnancy**

The prescription of opioid agonist maintenance treatment is recommended, at best before a wanted pregnancy or in the first or the second quarter. However, the initialization of opioid agonist maintenance treatment in late pregnancy is controversial.

The perinatal effects of methadone and HDB are identical. Therefore, there is no preference given to one specific maintenance treatment.

**5. Closed settings**

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

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

Since the 30th of January 2002, any doctor practising in a health establishment is authorised to suggest a methadone-based substitution treatment to any opioid-dependent adult. Until then, this possibility was reserved for doctors working in specialised drug addiction treatment services (associations or hospitals), and operating in open or penal environments. The growth in the initial prescription of methadone in both hospitals and prisons has been included in the governmental plan to combat illegal drugs, tobacco and alcohol (2004-2008).

It is also recommended to develop a best practice guide (promoted by the General Department of Health, Prison Service and health and social actors) which would facilitate the establishment of opioid maintenance treatments and allow a surveillance of prisoners in better conditions.