EXPERT CONSENSUS DOCUMENT ON TOBACCO ADDICTION TREATMENT IN SPAIN

Tobacco Prevention Observatory

National Committee for Smoking Prevention

Ministry of Health and Consumer Affairs

EXPERT CONSENSUS DOCUMENT ON **TOBACCO ADDICTION** TREATMENT IN SPAIN

TOBACCO PREVENTION OBSERVATORY

CNPT

GOBIERNO DE ESPAÑA

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Smoking: magnitude of the problem

Tobacco use, as a determinant of different pathologies and as the leading cause of preventable mortality and morbidity is the main public health problem in developed countries. The World Health Organization (WHO) and the World Bank, in its 2000 report, pointed out several measures of proven effectiveness as basic tobacco control tools: increasing taxes on cigarettes, ensuring that public spaces and workplaces are smoke-free, banning advertising and promotion of tobacco products; spreading the risks from tobacco use through counter-advertising campaigns and health warnings on tobacco packaging, providing access to effective treatment of smoking, and control of smuggling (1).

On May 21st, 2003, 171 WHO member countries signed the Framework Convention for Tobacco Control promoted by WHO (FCTC), an international treaty containing a minimum of necessary measures to protect the right to health of the population through the development of policies that, at least, include: the increase of taxes, information to consumers on the risks of tobacco use, the banning of advertising, the promotion of smoke-free public spaces, and funding for tobacco prevention and cessation programs (2).

In 2004 the European Commission reviewed the status of the EU countries regarding the development of their policies on smoking (3) and in this evaluation the six interventions considered to be most cost-effective for tobacco control were considered: increasing the price of cigarettes and other tobacco products, banning the advertising and promotion of all tobacco products, logos and trademarks, prohibitions and restrictions on smoking in public and work places, consumer and general information, including general public information campaigns, media and advertising use, health warnings about the effects of smoking on cigarette packages and treatment to help people who have developed a dependency to quit smoking, including access to medications.

As it has been shown, there is now an absolute consensus in pointing out that only by combining all the above measures, will it be possible to achieve a significant decrease in smoking prevalence. WHO further notes –in a recent report– that in order to achieve significant reductions in morbidity and mortality in the next 30 to 50 years

caused by the use of tobacco, preventive and control measures must be accompanied by effective cessation policies (4).

In Spain, the adoption of the Law 28/2005 constituted an important step in the direction set out by international agencies, and the different developments in this field occurring in all Autonomous Communities constitute a guarantee that the progress in the field of smoking cessation is gaining momentum. For this reason and by the requirements of the law, both the different governments and scientific societies, believe that our country is in the best position to review the progress achieved so far and to set out the basis of technical nature that, according to the available evidence and resources, would be helpful so as to orientate the actions regarding the treatment of smokers within the framework of the National Health System.

Aims and objectives of the consensus document

The purpose of this document, of a purely technical and scientific character, is to agree a basic quality proposal for the provision of smoking cessation services that serves as guidance in the context of our country.

The practical application of these guidelines may be carried out through multiple models in the provision of services, all valid, that will depend on the organisational structure of the different administrations involved in its implementation.

The objectives of this process are:

- To analyze why is it necessary a strategy for smoking cessation.
- To review the effectiveness of the existing smoking cessation options.
- To synthesize the available evidence on the impact of the smoking cessation policies in reducing the percentage of smokers.
- To achieve a consensus on minimum criteria that allow to orientate the provision of quality smoking cessation services in Spain.

Why is it necessary a smoking treatment strategy?

The main justifications for launching quality responses for smokers willing to quit are:

- **Smoking is an addictive disorder and is considered a chronic disease**

The publication in the U.S. of the report “U.S. Surgeon General” entitled "Nicotine Addiction", sets the stage for considering tobacco as a product that causes dependence due to its content in nicotine that produces a series of physiological changes and psychological dependence comparable to other legal (alcohol) and illegal drugs (heroin and cocaine) (5). Nicotine meets all the criteria of the definitions of addiction or dependence: compulsive use despite the desire and repeated attempts to quit smoking, psychoactive effects due to the direct action of the substance on the brain and behavioural alterations caused by the reinforcing effects of nicotine as a psychoactive substance. The tobacco dependence is recognized as a mental and behavioural disorder in the WHO International Classification of Diseases of the (ICD-10) (6) and the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) of the American Psychiatric Association (7).

The recognition of smoking as a chronic disease caused by an addictive disorder is essential for the design of smoking prevention and control policies, as it indicates to the need to develop an effective treatment strategy addressed to people who smoke that does not discriminate them in comparison to other people who suffer addiction to other drugs for which there is an adequate treatment in Spain.

- **Smoking increases social inequalities in health**

Several studies currently show that the rates of smoking cessation are higher in more advantaged socioeconomic groups. Adolescent smoking uptake has also a marked social gradient, both in males and females, as the highest smoking prevalence is seen in individuals with lower educational attainment and lowest in those with university degrees (8), (9) (10) (11) (12). Available data indicate, in this sense, that if the probability smoking cessation without help is low in the general population, quitting is more difficult for those living in adverse conditions and / or face stressful life events. In these populations, higher levels of nicotine dependence have also been observed. One hypothesis to explain why individuals of low socioeconomic status are currently less likely to quit smoking is based on the idea that they are less informed and concerned

about the adverse health effects and, therefore, that leads them to try quitting fewer times. However, in our country some studies show that 61% of smokers of middle and lower classes had tried to quit, while for the upper class, the figure was 56% (13). That is, motivation would be greater in individuals of lower class, and thus, the lower proportion of ex-smokers observed in the lower socioeconomic strata may not be attributed to their having less motivation to give up.

The relevance of this lies not only on the fact that smoking is more prevalent within socio-economic groups of population, but also its in contributing to increasing inequalities in health as smoking significantly increases the risk of multiple diseases. This increases in inequalities due to the incidence of smoking related diseases and premature mortality for the same cause, is something that has occurred in males and available evidence shows that in a short period of time these inequalities will also affect women.

- **Smoking increases gender inequalities in health**

Smoking has specific characteristics of gender that need to be addressed in all matters regarding assistance to quit. Like other groups suffering inequalities, women may require a specific approach that takes account their different needs and expectations.

- **We have effective treatments to help smokers quit**

Most smokers want to quit and 60% of them have ever tried (14). However, in a single year, only between 3% and 5% of those who smoke and make cessation attempts succeed (15) (16). This low success rate can be explained partly by the fact that most quitting attempts are carried out without help, which is popularly known as the spontaneous exercise of the "strength of will." Until recently, most people who managed to quit smoking did it without any assistance (17). Tobacco dependence is a chronic medical condition, difficult to overcome, if support and appropriate treatment is not available (18) and (19).

Since the late 50s, intensive research has been carried out in order to measure the effectiveness of different interventions for smoking cessation. Table 1 presents the results of the most widely used interventions in which there is scientific evidence of effectiveness (20).

Table 1 **Effectiveness of various interventions in the treatment of smoking versus no intervention or placebo**

TYPE OF INTERVENTION	EFFECTIVENESS OR (CI 95%)*
Self help Manuals	
- Tailored materials	1,24 (1,07-1,45)
- Untailored materials	1,80 (1,46-2,23)
Brief interventions	
- Medical advice	1,69 (1,45-1,98)
- Nursing advice	1,50 (1,29-1,73)
- Phone advice by trained personnel	1,56 (1.38-1.77)
Intensive psychological interventions	
- Individual	1,62 (1,35-1,94)**
- Group therapy	2,19 (1,42-3,37)
- Aversive therapy	1,98 (1,36-2,90)
Pharmacological Interventions	
- Nicotine Gum	1,66 (1,52-1,81)
- Nicotine Patches	1,74 (1,57-1,93)
- Nicotine nasal Spray	2,27 (1,61-3,20)
- Nicotine Inhaler ***	2,08 (1,43-3,04)
- Nicotine sublingual tablets	1,73 (1,07-2,80)
- Bupropion	2,75 (1,98-3,81)
- Nortriptiline	2,80 (1,81-4,32)
- Clonidine	1,89 (1,30-2,74)

* All findings were statistically significant.
** Individual advice will have greater effectiveness depending on the contact time (OR = 3.2 for 91-300 minutes, OR = 2.8 for over 300 minutes) and the number of sessions held (OR = 1.9 for 4-8 sessions; OR = 2.3 for over 8 sessions).
*** Presentation not marketed in Spain.

Source: Spanish Agency for Health Technology Assessment, 2003.

- **Helping people quit is cost-effective**

Due to its characteristics and current extension, smoking is the health problem that causes the highest mortality and morbidity rates in Spain. Therefore, it is the health problem that causes the highest health and social costs faced by the Spanish society (21), (22), (23) (24) (25) (26). In its Report on the draft Law of the recently passed Law 28/2005, the Spanish Council of State echoed that –according to a financial summary report that accompanied the text of the draft law submitted to the Council by the

government– State expenditure to cover the health and social costs caused by smoking, exceed the excise duty levied on tobacco products (27).

In the last decade many studies have been published o cost-effectiveness and economic impact of the treatment of smoking, most of them have been done in the United Kingdom and the U.S. These studies demonstrate that certain support and cessation interventions show a very favourable cost-effectiveness ratio. Both the low-intensity interventions (health advice and supply of drug treatment) to large population groups who want to quit, and more intensive interventions, including pharmacological and psychological treatment aimed at special needs groups have shown up to be cost-effective. According to cost-effectiveness studies available it can be concluded that compared with other preventive or treatment interventions, detection and treatment of tobacco dependence within the health service is considered a cost-effective intervention in terms of cost per year of life gained. Treating tobacco dependence has been considered several times more efficient than other preventive and treatment interventions widely introduced, such as: detection and clinical management of hypercholesterolemia and hypertension or breast cancer screening (20).

- **Cessation interventions complement other smoking prevention and control measures**

Many smokers want to quit, and the more prevention and control measures are developed, the more increases the proportion of people who want to achieve abstinence. But most do not get it, because due to their dependence, they need appropriate help to achieve their goal. Smoking cessation policies have a relatively small effect on the prevalence of smoking, achieving reductions of about 1-2 percentage points, and although this effect may be increased, their development is particularly important to help those who face more difficulties to quit. In this context, WHO points out that people who want to quit should have access to suitable treatments according to their individual needs and characteristics (2), (20), (4).

The development of effective smoking cessation policies is an essential element in addressing the control of tobacco use in order to reduce its effects on public health. Table 2 presents some basic recommendations on elements to be considered in quality smoking cessation policies. The potential increase in quit rates means direct benefits in the short, medium and long term for people who receive the intervention. Funding for

smoking cessation services can: increase quit rates, increase the number of quit attempts and the use of treatment, as well as improve rates of self-reported abstinence, where it is compared to partial or no funding (28). In addition the availability of care services contributes to raise the awareness that smoking is a major health problem. Moreover, promoting or funding for these services can help change the health culture and contribute to many health professionals becoming interested in providing these services to their patients, although more studies are needed on the impact of financing systems on the behaviour of health professionals (28), (4).

Table 2 **Recommendations to health systems regarding the provision of smoking cessation services**

- Each health centre should implement a system to identify and register patients who smoke, when they come for consultation
- Every health system should provide training, resources and answers to promote interventions to help quit smoking.
- Health centres should dedicate staff to assist smokers quit smoking, and ensure that treatment is provided when the activities undertaken are evaluated.
- Hospitals should promote policies that support and provide services to help smokers quit.
- Health systems should include treatments for tobacco addiction (behavioural and pharmacological), as part of their service to their users.
- Health systems should reward clinicians for providing effective treatments for smoking cessation, and include these interventions among the obligations of health care professionals.

Source: Fiore et al., 2000.

Types of smoking cessation interventions

There are different types smoking cessation interventions: brief intervention, intensive intervention, specialised intervention, community level interventions, interventions developed through communication technologies (telephone, internet, etc.), and interventions based on self-help materials.

- **Counselling and brief intervention** [1]

Counselling to quit tobacco, carried out during routine consultations, is one of the most cost-effective clinical interventions to promote smoking cessation (20).

The effect of brief advice versus no intervention increases the likelihood of achieving abstinence, and it has also been shown that the more intensive the intervention the greater the efficiency gained. Thus, if apart from brief advice, patients are offered scheduled follow up, i.e., the patient is offered one or more follow-up and reinforcement visits, abstinence rates can be significantly increased (29), (30).

All health professionals should know and be able to implement brief opportunistic advice, regardless of the level of care in which they work. The scientific evidence indicates that there are benefits derived from the health advice provided by nursing and medical professionals to patients to quit smoking (31), (32).

Brief Intervention is an opportunistic intervention strategy aimed at smokers that is based partly on scientific evidence and partly on opinion of experts in the treatment of smoking. It differs from intensive clinical intervention on the time dedicated to providing help to stop smoking and the number of follow-up sessions, and should be carried out by health professionals who care for many different patients and that work under time constraints. The main purpose of brief interventions is to ensure that every smoker is identified when coming to the clinic for any consultation and has an offer of treatment, and at the same time it is expected that he or she progresses in the process of quitting and makes attempts to achieve it. Finally, many smokers are reluctant to attend intensive programs to stop smoking and at least, they should receive brief interventions during routine medical visits.

[1] This concept encompasses other definitions in the literature on treatment of tobacco (eg structured advice, low-intensity intervention, minimal intervention, basic intervention, etc).

Brief intervention consists of asking the patient whether he or she smoke, giving advice to quit, assessing the readiness to make a quit attempt, helping each person in the quitting attempt and, finally, setting up follow up visits (33) , (18), (34).

- **Intensive Intervention**

As outlined in the previous paragraph, a strong dose-response relationship between intensity of intervention and results has been shown. There is evidence that higher intensity interventions result in higher rates of success. Intensity is achieved by longer interventions and a greater number of sessions (4 or more sessions).

Intensive interventions should include behavioural and cognitive strategies (developing skills and coping strategies and problem solving techniques, among others) and pharmacotherapy (nicotine replacement therapy, bupropión and varenicline) and ensure an appropriate social support within and outside the therapy sessions.

Intensive intervention can be provided individually or in groups. There is reasonable evidence that the group therapy is better than self-help and other less intensive interventions intended to help people quit smoking. There is insufficient evidence to determine how effective these therapies are compared with intensive individual counselling (19), (35), (36), (37).

Intensive interventions are more cost effective than other less intensive interventions, and are suitable for anyone motivated to quit.

The effectiveness of intensive support is based on adequate training of professionals and the availability of resources (especially time and infrastructure) and is not dependent on the type of professional or the setting where they are applied. The organization of these intensive interventions can take into account planning criteria (resources, availability of professionals, etc.), as the setting where they are going to take place will not condition the effectiveness of treatment (38).

- **Specialized Treatment**

The specialized smoking treatment combines pharmacological and psychological therapies and is not directed to the entire smoking population, but high-risk groups and individuals who have previously failed to brief and intensive interventions, and that

their health status makes a priority for them to stop smoking in the short term.. Efficiency reasons recommended not offering specialized treatment to all persons who want to quit. The main groups that may require specialized care interventions are being dissonant smokers highly dependent and with previous failure in the consolidation of abstinence, patients who have serious health problems associated with the use of tobacco, pregnant or breastfeeding women, and patients with psychiatric pathology (39).

Specialized tobacco treatment meets the specific needs of these groups to whom it provides scheduled support resources in the context of more structured interventions. Specialised clinics in this type of treatment, through scheduled sessions and therapeutic monitoring, offer efficient multicomponent clinical interventions (a combination of psychotherapy with drug therapy or psychological treatment only when drugs are contraindicated or the patient refuses to use them).

This approach offers a high efficacy (30-50% abstinence at one year of follow-up). The revisions have not found significant differences between this type of treatment either individually or in groups (40).

- **Community interventions**

It has been shown that comprehensive programs have a positive effect on decision making related to health, including the use of tobacco, having thus resulted in positive changes in the health of populations in Europe and North America (41).

Population or community programs are based on the recognition of the importance of social components of dependence and motivation (42). They include multiple intervention strategies, mainly increasing media messages supporting smoking cessation (TV, radio, newspapers) and the participation of community and health leaders and politicians, along with the provision of resources, usually self-help materials, in order to promote and achieve abstinence (brochures, programs in businesses, offering health advice, awards, etc.).

Good examples of this kind of interventions are MRFIT, COMMIT and ASSIST programmes developed in the U.S. In our country several initiatives have been developed, as for example: quitting support through mail (16) "Quit & Win", a popular programme in some European countries and introduced in some of the Spanish Autonomous Communities. Although there is no experimental evaluation, evaluation

results indicate that in general, these programmes have little effect on heavy and/or highly dependent smokers, and moderate effect on light smokers with low levels of dependence. However, as they are programs capable to reach all population, they can achieve a significant rate of abstinence at a low cost (43).

- **Approaches to smoking cessation through the use of communication technologies**

– Quit lines

Treatment of smoking can be adapted to the possibilities that allow a telephone follow-up of the individual patient. There are two therapeutic approaches:

Proactive, that offers a fully managed intervention through the telephone support unit and includes a series of contacts with the person who is in the process of quitting smoking, as well as scheduled interventions throughout a given time.

Reactive, in which the therapist intervenes only at the request of the patient

Proactive approaches increase quit rates in comparison with reactive interventions (OR 1.56, 1.38 to 1.77) (44), and at 6 months of follow-up, is as effective as face to face treatment (45).

– New technologies based smoking cessation programmes

These programmes are offered via the Internet (e-health) or through portable electronic devices that provide information and support to those wishing to quit. According to those involved and the channels used, the currently available interventions are:

Virtual Communities. They are social networks formed or enhanced by electronic means that may take the form of mailing lists, discussion forum, chat, and website and blogs.

Professionalised programmes. These encompass psycho-educational or structured therapeutic programmes that often include direct contact with a

trained health professional. Its theoretical value is related to its accessibility as they could complement or replace face contact, reach more people and may be a cheaper and more flexible intervention. Currently there is little research so as to confirm or rule out its effectiveness, although there are some international evaluated experiences that still do not allow generalizations. (46).

Services provided through portable electronic devices. They provide information and support to smokers (PDAs, mobile phones, etc). They are categorised as computer-generated interactive behavioural interventions and can be customized to the individual. The lack of uniformity in the evaluation studies makes it impossible to evaluate their effectiveness (47).

- **Self-help materials**

The distribution of self-help materials contributes to promote smoking cessation at higher rates than those achieved with no intervention, although this effect is small. Up to now there is no evidence that they provide an additional benefit to other interventions such as brief intervention and nicotine replacement therapy. There is evidence that materials tailored to each individual profile, are effective and more effective than general, although its effect is low (19).

Available smoking cessation treatments

Regarding the types of treatment that can be used in evidence based cessation interventions, current treatments available are: pharmacological treatments, psychological treatments, or both offered in combination.

- **Pharmacological treatments** [2]

  – First line medications

First e treatments for smoking cessation are those drugs that have proven to be safe and effective as clinically appropriate and specific medication for treating tobacco dependence. These drugs have demonstrated their effectiveness through clinical trials in which they have been prescribed in addition to brief advice or through specialized services for smoking cessation. The drugs so considered as first line are: **nicotine replacement therapy (NRT), bupropion** and **varenicline**. Other drugs are currently under investigation (33) (20) (4).

The appropriate use of **NRT** in people who want to quit has shown to be an effective approach that doubles abstinence rates at 6 and 12 months, compared to the placebo intervention. Their results improve when used taking into account the characteristics of each patient (presentation and dosage) and when their administration is accompanied by a support intervention (brief advice and / or psychological support). However, it has been shown effective, though to a lesser extent, in the absence of such support. In any case, even though they are sold as OTC in pharmacies, its administration should follow the directions established by the health professional. NRT can be administered via transdermal (patch), oral (chewing gum, lozenges for sucking and sublingual), intranasal (nasal spray) and by inhalation. Currently, in our country only gum, patches, and lozenges are available. The effectiveness of NRT has been evaluated

[2] **Note:** *Since the Spanish version of this document was published (april 2008), new scientific evidence makes it necessary to amend this section (see Fiore, M et al. Treating Tobacco Use and Dependence: 2008 Update. U.S. Department of Health and Human Services. Public Health Service. May 2008). A section called "New pharmacological treatments: varenicline" in the Spanish version, has dissapeared, and its content is dealt with in the section "First line medications". This change has been approved by the Redaction Team.*

through controlled trials conducted at different levels of clinical activity (primary care, specialty medical consultation and specialized smoking cessation clinics). Mean abstinence rate at 6 months and one year of treatment reach between 25% and 35% (48).

Bupropion hydrochloride extended release (bupropion LP) is the first non-nicotine medication that has proven effective in the treatment of smoking dependence. It is an antidepressant that selectively inhibits the neuronal reuptake of norepinephrine and dopamine, increasing the levels of these substances in neuronal synapses, without inhibiting the action of monoamine oxidase. Thus, bupropion acts as an atypical antidepressant with effects both dopaminergic and noradrenergic. This can simulate the same effects of nicotine and thus reduce the typical symptoms of withdrawal. Furthermore, the effectiveness of bupropion hydrochloride in the treatment of smoking does not seem to derive from its antidepressant effects because this drug has the same effect on smoking cessation, both in patients without a diagnosis of depression and in patients with a history of depression. Bupropion is an effective treatment for smoking cessation, a coadjuvant of brief advice, as well as psychological treatment. The use of bupropion doubles abstinence rates at 6 and 12 months of intervention, when compared with placebo. The efficacy of bupropion hydrochloride is between 18% and 36% at 12 months after finishing treatment. These results were verified through double-blind randomized clinical trials with large samples (49), (50) and (51).

Varenicline is a drug approved by FDA in May 2006 and authorized for sale in the EU in September 2006. Varenicline is a non-nicotine medication specifically designed for smoking cessation. It act as an *α4β2* nicotinic acetylcholine receptor partial agonist, producing an effect sufficient to relieve the urge to smoke and nicotine withdrawal symptoms (agonist activity), while simultaneously producing a reduction in the rewarding and reinforcing effects of smoking by preventing nicotine binding to α4β2 receptors (antagonist activity).

Varenicline triples the chance of long-term smoking cessation compared with quitting attempts with no pharmacological treatment. In the early clinical trials conducted to date in healthy smokers, varenicline is more effective than bupropion.

The effectiveness of varenicline as an aid to relapse prevention has not been clearly established. The development of more independent controlled clinical trials is needed to verify these initial results. There is also a need for studies comparing the

efficacy of varenicline to other treatments (NRT and bupropion) in order to establish the relative efficacy of these treatments. (52) (53) (54) (55).

– Second-line medications

There is another group of medications (second line) consisting on drugs that have proven effective in smoking cessation, but have a more limited role compared to those mentioned above (first line drugs), especially because there is greater consensus regarding side effects, when compared with first line drugs. Furthermore, these drugs have not been approved by the General Directorate of Pharmacy of the Spanish Ministry of Health and Consumer Affairs as specific medications for treating tobacco dependence.

The main second-line drugs are:

- **Clonidine.** It is an α2-noradrenergic agonist that suppresses sympathetic activity. It has been shown effective in treating nicotine addiction, doubling the results with respect to placebo treatment. It has proved more effective in women than in men in most clinical trials. Clonidine should be prescribed under medical supervision in patients who can not use first line drugs due to contraindications or for having failed using first line medications. Its main disadvantage, w compared to first-line drugs, consists in that results in higher dropout rates due to side effects
- **Nortriptyline**. It is a tricyclic antidepressant, useful for treating smoking dependence, with properties primarily noradrenergic and to a lesser extent, dopaminergic. It also doubles the rate of abstinence compared to placebo. It seems that its activity in the treatment tobacco addiction is not associated with the presence of depressive symptoms. Nortriptyline should be prescribed under medical supervision in patients who can not use first line medications due to contraindications, or for having failed when using first line drugs.

- **Psychological Treatments**

The early psychological treatments for smoking cessation took place at the same time as the techniques of behaviour modification raised in the early 60s of last.20th

century. Since its emergence, different cognitive and behavioural techniques have been used and evaluated (56), (5), (57), (58) (59) (60) (61) (16), and those most studied include aversive therapy (rapid smoking, satiation, aversive smoking, keep the smoke, covert sensitization, electric shock), the self-monitoring, relaxation, stimulus control, gradual reduction of tar and nicotine intake, smoking control, contingency management; systematic desensitization; restricted environmental stimulation therapy, contingency contracting, self-management and self-control methods; multicomponent programs, and relapse prevention programs.

Cognitive-behavioural treatments, by providing resources and training in coping strategies, are aimed at helping patients to RECOGNIZE their dependence characteristics and identifying situations where it is more likely to feel the urge to smoke; AVOID conflict situations whenever possible, and effectively ADDRESS the risks arising from dependence that lead to relapse through skills and alternative behaviours training. The theoretical framework that underpins these techniques raises the fact that the learning processes play a key role in the establishment and consolidation of drug dependence. Therefore, the same learning processes can be used to help overcome tobacco dependence.

Three types of behavioural therapies have shown particularly effective (37):

a) provision of practical advice (problem solving techniques, skills and competences training);

b) provision of social support as part of treatment (intra-treatment social support);

c) help to ensure social support outside of treatment (extra-treatment social support)

The American Psychiatric Association recorded ten years ago the existence of approximately 100 prospective controlled studies that demonstrate the efficacy of behaviour therapy (63). Effective behavioural techniques achieve high rates of abstinence, getting at a one follow up –in the most successful programmes– up to a 40-50% abstinence (62), (56) (63) (64) (65).

- **Other types of treatment**

Available studies reviews so far on the effectiveness of other techniques to stop smoking (acupuncture, digitopuncture, auriculopuncture, hypnosis, various forms of electrostimulation, laser, etc..) indicate that the application of these techniques fail to outperform those achieved by any placebo (66) (67).

Areas of intervention within the different levels of care for an efficient organisation of smoking cessation services in Spain

According to available evidence, it is recommended that the involvement of the different health professionals in providing interventions to help quit smoking is based on criteria such as: accessibility, professionals' training, experience and interests of professionals rather than on professional specialization. The available scientific evidence does not openly favour any form of professional specialty over another, but it is obvious that every one must act within its own scope (35).

The common ground for the organization of smoking cessation services in Spain is described in Royal Decree 1030/2006 of September 15, laying down the portfolio of common services of the National Health and the procedure for updating.

However, the development of a quality care response goes beyond the simple reorganization of health services for treating tobacco dependence. It encompasses extensive actions whose cost-effectiveness has been widely tested. As seen above, these actions can range from comprehensive community programmes (community campaigns or contests, virtual programs via Internet, telephone services, distribution of self-help materials, etc.) to the offer of intensive specialized treatment for high-risk groups.

- **Role of Primary Health Care Teams in helping people quit**

Ii is estimated that 75% of the population visits their family doctor at least once a year, and that smokers do so more often than non smokers. This provides an important opportunity to promote quitting attempts and provide effective help to those who have decided to do it. It has been estimated that if every family doctor were to advice in a protocolized and systematic way during routine visits, this could lead 5% of smokers to quit smoking in a single year. This means that about 500,000 people would quit smoking each year in Spain. Therefore, to achieve a significant health impact on population it is recommended that the overall strategy on smoking cessation services is strongly focused on the first-level of the health care system (Primary Care) (36) (20) (65) (34). The main arguments behind the role of Primary Care in its involvement in smoking cessation are: its accessibility, its role as gateway to the health system, and the continuity of care for people who smoke.

- Accessibility. Virtually the entire Spanish population has got its family doctor, paediatrician and nurse. Over 75% of the population visits the primary care centre at least once a year, and the average number of times they visit the centre each year is between 5 and 6 (68). This means a unique opportunity, specific to primary care, to intervene in large populations on many occasions, in key intervention moments to promote preventive measures in persons that have still not started any disease.
- Point of *entry* into the *health system*. Primary Care, through the joint work of doctors and nurses, may have great impact on the treatment of smokers, can exercise a guiding role in smokers who want to quit and is the optimal level of care to select those who need to be referred to more intensive interventions. Probably with less iatrogenics, lower costs and better identification of risk groups.
- Continuity of care. Smokers who attend the surgery and are more permeable and receptive to quit due to health reasons. Furthermore over 60% of people who smoke want to quit and most have made some quit attempt. Finally, patients expect healthcare staff to worry about their habits and lifestyle. The Primary Care professionals know their patients and their social environment and there is a chance of long-term monitoring.

The first step in the normalization of smoking cessation aid is diagnosis, so the systematic recording of the smoking status in the medical history of each patient and the health opportunistic advice to stop smoking should be a routine widespread practice of primary health care, this being one of the most efficient approaches. This intervention protocol should be included in the portfolio of services in Primary Health Care (20), as it is reflected in the Royal Decree 1030/2006 of September 15, as seen above. Primary Care should also provide brief interventions and intensive interventions to those who want to quit smoking and to encourage the adoption of healthier lifestyles to those who have not yet decided to quit. The need for specific smoking cessation clinics in primary care is currently under discussion and there are various proposals regarding how smoking cessation should be provided in Primary Care clinics (69). In any case, smokers reported high levels of satisfaction with their tobacco-related care provided in Primary Health Care (70).

- **The Role of Specialized Care**

Specialized health care services and other specialised networks (mental health care, health care services for drug users, social health services ...) play a key role in dealing with smoking, taking advantage of face to face contact with their patients, either by providing brief advice or intensive intervention, depending on their abilities and should have criteria for referral to the appropriate resource in each case.

- **Specialist smoking cessation clinics (SSCC)**

It has been shown a dose-response relationship between intensity of health intervention and the rate of abstinence obtained. However, efficiency reasons make it unreasonable to offer intensive support and specialized treatment to all who wish to quit smoking (20).

It is desirable that the SSCC are integrated by a multidisciplinary team, whose professionals have received specific training in smoking. In addition to specialized care, these teams can carry on other tasks as teaching, research and health promotion and coordination of the various levels smoking cessation care (71). These criteria do not necessarily have to be met in full or be exclusive.

Specialist smoking cessation clinics (SSCC), through relatively few intensive therapy sessions and follow up, offer efficient multicomponent clinical interventions that usually combine psychological and pharmacological treatment.

Table 3 shows the main groups of patients who may require specialized care intervention.

Specialized cessation treatment allows adapting scheduled and intensive support to the needs of these groups at risk or with special social and health vulnerability (sick people, pregnant women, youths, people with low income and cultural minorities). Therefore it is appropriate that this aspect be considered in the planning of smoking cessation care in our country, as it has been done in surrounding countries (72).º

Table 3	Main groups of patients that could be treated in a smoking unit
1.	Those who, after three or more serious quit attempts, adequately assisted by a health professional, have failed to quit.
2.	People with psychiatric disorders, whose illness is under control, who wish to give up smoking.
3.	Patients who have serious health problems associated with the use of tobacco (decompensated CHD or that has less than 3 months of evolution, COPD, decompensated hypertension, severe uncontrolled cardiac arrhythmias, uncontrolled vascular disease, etc.)..
4.	People who have suffered from other addictive disorders.
5.	Pregnant smokers who want to quit and cannot do it without specialised help.
6.	High social and health risk populations

Sources: Adapted from Jimenez-Ruiz. 2001, Jiménez-Ruiz 2003

- **Quit smoking lines**

Quit lines are telephone services offering information and support to quit smoking. In practice they are often part of larger intervention programmes, which include face to face contacts, distribution of self-help materials, drugs, and offer options for telephone contact (proactive or reactive, as described above). Its theoretical usefulness is explained in Table 4.

Table 4	Potential usefulness of quit lines
	They could supplement or replace face to face contact.
	Might reach large numbers of people.
	Treatment is cheaper and flexible than face to face contact.
	People who do not accept rigid schedules or inconvenience of travel.
	People with reduced mobility.
	Potential role of information and awareness.
	They could attract underprivileged minorities and ethnic groups if advertised specifically.
	Lines for drug users.

It is necessary a public debate on the implementation of quit lines including aspects regarding accessibility, use of existing ones, promotion and outreach organization and management, quality and results and, finally, funding and costs.

- **Role of pharmacists in promoting abstinence**

Community pharmacists can make regular interactions with large numbers of healthy and sick persons. This provides an excellent opportunity to pharmacists to contribute to health promotion and disease prevention activities, in collaboration with health care providers in the context of pharmaceutical care. Access to NRT without prescription in our country makes its role in helping those who want to quit smoking and seek support. Its role should go beyond advising on the use of pharmacological products, in order to provide appropriate guidance and support to contribute to help achieve abstinence or, where appropriate, to refer the patient to an adequate resource. The studies conducted to date indicate the interventions made by trained community pharmacy professionals, providing advice and a support programme to its customers can achieve a positive effect on quit rates (73).

- **Workplace interventions for smoking cessation**

Most of the adult population spends approximately one third of the day in their workplace. Therefore, the work environment provides an excellent framework to reach large groups of people through health promotion and smoking treatment programmes. Quit smoking methods, such as group therapy, individual counselling and NRT are equally effective when applied in the workplace. The evidence is less clear with regard to self-help methods.

In our country, some experiences that have been evaluated show that the work environment is another opportunity for accessing to healthy people, which can quit with the help of a programme within the company. (74) (75).

Additionally, the current legal regulation regarding tobacco use in the workplace can help reduce smoking in this environment (76). In Spain, the entry into force of Law 28/2005 can reinforce the development of these programmes at present.

- **Dental services and support to quit smoking**

Besides the well known effects of smoking in the respiratory and the cardiovascular systems, tobacco use has significant adverse effects on oral health. Smoking is associated with an increased risk of mouth diseases, which includes cancer of the mouth, periodontal disease, delayed healing and poorer performance of dental implants.

The dental and oral health care professionals have in their practices a unique opportunity to increase tobacco abstinence rates in the general population. Current studies show that guidance for quitting provided by these professionals is beneficial (8).

- **Therapeutic aspects to be considered for populations who are in special situations**

– Role-model professionals

Due to its importance regarding their contact with large general population groups, health professionals and education professionals are two professional groups whose lifestyles regarding smoking, play an important key role to promoting healthy lifestyles among the general population and, in the case of teachers, among the students.

Therefore, the promotion of smoking cessation between these groups is a priority in our country, where tobacco use among some of these professional groups is still very high.

– Hospital patients

Smoking is implicated in many of the health problems that cause hospitalization, particularly vascular disease, respiratory disease and certain cancers. The hospital admission provides an opportunity to help people quit smoking. People admitted to hospital may be more willing to receive help in a time where they feel vulnerable and may find it easier to quit in an environment where smoking is prohibited. The delivery of services to quit smoking during hospitalization may increase the number of people who try and maintain the desire to abandon the use of tobacco.

Pharmacological treatment combined with high-intensity behavioural interventions that include at least one month of follow-up are effective in promoting quitting among in- hospital patients (77), besides being highly cost-effective as it leads to a decrease in the length of hospital stays and the number of future hospitalizations (36).

– Patients facing a surgical operation

Smoking is a risk factor both before and after surgery. Quitting smoking prior to an intervention reduces the risk of complications, therefore it is desirable that if the patient can not stop smoking permanently, he or she should quit at least during the 6 weeks prior to intervention. NRT as a risk reducing therapy can be used in patients who do not want to stop smoking completely (78).

In this context it is worth noting the potential impact of the intervention of the health professionals (anaesthesiologists and surgeons), during the preanesthetic consultation, offering the most appropriate therapeutic option in each case, to promote cessation before surgery.

– Pregnant women and infants

Tobacco use in one of the few preventable risks regarding low birth weight, very preterm birth and perinatal death.

Despite the damage caused by tobacco on women and the unborn child, two thirds of pregnant women continue to smoke during pregnancy. Intensive programmes to help quit smoking for pregnant women are effective (79) (12).

Interventions to help pregnant women quit smoking should be systematic, designed specifically for them, carried out by trained personnel, with specific support materials and with objective validation of abstinence. It is advisable to also consider the involvement of the couple, whether a smoker or not.

In this context, it seems appropriate to emphasize the need for training and involvement of professionals of services and programmes dealing with pregnancy, delivery and the postpartum period by highlighting the role of midwives as well as those services and programmes related to paediatric care and specific areas in preventive and

therapeutic activities in relation to passive smoking in children and tobacco consumption in early life.

Since the safety and efficacy of NRT during pregnancy has not been sufficiently studied, it has not been approved by the Spanish Agency of Medicines and Sanitary Products (Agencia Española de Medicamentos y Productos Sanitarios, AEMPS), and presents contradictory results (80) (81) (82), psychological treatment (behavioural and cognitive) has to be the first choice of care for pregnant women and infants. However, in those cases where, despite having correctly received this treatment approach, smoking persist, pregnant women should be referred to an accessible intensive intervention or specialist smoking cessation clinic, where she will receive the most appropriate psychological and pharmacological treatment for her.

– Teens

Over 80% of smokers start smoking during adolescence. Currently, there are some preventive programmes available, developed in the school environment, that have shown to be effective. These programs are based on skills learning or on how to cope with social pressure, but are not always those that are implemented (83) (84). If school programmes are not complemented by family prevention programmes, and clear social rules regarding no smoking, its effects diminish over time. Hence the importance of legislation that restricts access to minors to tobacco, limits its use in public places and prohibits advertising and sponsorship.

It is scarce the number of teens who want to quit smoking and fewer those who attend formal cessation treatment. For teens, only psychological treatments have shown to be effective, although with lower effectiveness than in adults (85), (86) (87). Drug therapy to date has not shown to be effective in adolescents (88).

In any case it seems necessary to carry out further research on the effectiveness of the different options, given the importance of avoiding smoking being consolidated at teen age and hence the development of future pathologies (12).

– Patients with psychiatric disorders

There are now an increasing number of smokers willing to quit and suffer from any psychiatric disorder. This could be due to psychopathology associated with tobacco use in those who seek treatment and some psychopathology that emerges in some of those who stop smoking, mainly depression (89), or to the number of people who come to treatment and have the same time a problem of alcoholism or schizophrenia (90).

The relationships between smoking and psychopathology have as a result greater difficulty in quitting in those who have comorbidity, as well as greater vulnerability at smoking onset and relapse. These patients require intensive specialized treatment in Specialist Smoking Cessation Clinics (36) (65) or in mental health services whose professionals have been trained in smoking cessation and have appropriate protocols for such care.

– Patients with problems of addiction to other drugs

Besides alcohol consumption, smoking can occur associated to dependence to other drugs such as cannabis, cocaine, synthetic drugs or heroin. These patients do not usually have good prognosis regarding quitting, until there has been a consolidation in abstinence from other drugs, but in any case, they should be treated in specialized care facilities (91), (92).

Aspects to be considered in order to promote efficiency, equity and sustainability in the supply of smoking cessation services

Besides relying on the institutional advances already made and described above in this document, it would be convenient that the development and maintenance of a supply of smoking cessation services be based on efficiency, equity and sustainability criteria. Attention to these criteria suggests the need to consider some additional matters:

- To point out the importance of exploring the establishment of stable funding. The main reasons for considering this aspect are:
  a) An ethical obligation to maximize smoking cessation programmes in parallel with a progressive increase of taxes on a drug like tobacco;
  b) An extension of the principle of equity, so that the rising price of tobacco, at the same time that penalizes the least privileged social sectors, facilitates the access to free treatment to these groups and
  c) It is a well socially accepted action.
- It seems appropriate to point out the need for the institutions to ensure the training of smoking in the curricula of all undergraduate and graduate studies related to the Health Sciences as well as ensuring the development of continuing education programmes aimed at practicing health professionals.
- It is desirable that smoking cessation services be included as a priority theme in the standard research plans.

Agreed minimum criteria for the provision of smoking cessation services in Spain

Smoking remains a serious public health problem in Spain. A coordinated strategy integrating prevention, control and care measures is essential to achieve significant reductions in morbidity and mortality associated with tobacco use in our country. Most smokers want to quit, and there are interventions at different levels of intensity that have proved to be effective. Both the Ministry of Health and Consumer Affairs and the Health Ministers of the Autonomous Communities (Regions) are beginning to adopt, amongst others, relevant care interventions to address the problem. For this reason it is appropriate to review where we have come in this area, both from the standpoint of scientific knowledge, and institutional development, and agree the minimum common criteria from where to advance from now on, as stated by the Act 28 / 2005.

A response capable of promoting a significant decline in smoking in the population should include measures proven effective that facilitate that most people who smoke can quit smoking by themselves, and at the same time must provide specific help to those who have greater addiction.

Smoking quit rates achieved through the development of prevention and control legislative measures can be increased when there is a widespread support offer in health facilities, there is easy access to telephone quit lines and other intensive interventions of proven effectiveness are promoted.

Currently, a wide range of procedures that have clearly proven effective in the treatment of smokers are available. Out of these treatments, brief advice, psychological behavioural treatment, and specifically the multicomponent behavioural programmes are highly effective and efficient. It has been shown that, among pharmacological treatments, nicotine replacement products, besides Bupropion and Varenicline, are effective when compared to placebo.

Support for interventions aimed at promoting smoking cessation, both in general population and in high risk groups, is one of the priority lines of action in a comprehensive tobacco control strategy capable of reducing the impact of this problem on the health of the population. Under the system envisaged in Law 28/2005 and Royal

Decree 1030/2006, the National Health Service must undertake measures to control smoking, and to do it as efficiently as possible, it seems appropriate to clarify criteria for the adequacy and equity in service delivery, human resource allocation, the allocation of economic resources, the use of appropriate tools and treatments, as well as foresee measures to ensure availability of adequate training (both pre and post graduate, of specialization and continuing education).

According to the current situation, it seems appropriate to note that the definition of a strategy in the treatment of smoking should take into account a number of criteria of adequacy and equity, which can be summarized as:

a. Health risk criteria: It is recommended that the therapeutic offer prioritize the care of high health risk population, that according to herein established, should include the following population groups:

- Patients who have serious health problems as a consequence of tobacco use, mainly patients with diagnosis of ischemic heart disease, cerebrovascular disease, post-infarction patients, lung cancer, angina pectoris, chronic obstructive pulmonary disease (COPD), asthma exacerbation, and other diseases for which there is a causal link in relation to tobacco consumption.
- Patients with mental and behavioural disorders.
- Pregnant women and adolescents.

b. Accessibility criteria: It is recommended that the therapeutic offer satisfies criteria of balance regarding geographical distribution. The Primary Care network of should routinely offer medical advice to quit, along with brief or intensive interventions, depending on patient needs. Some people, as required by their special circumstances, should be referred to specialised smoking treatment units or other referral services, capable to provide specialised and intensive treatment (e.g., mental health centres, drug centres, hospital units, NGOs, etc.). These services should be established on the basis of number of people to be attended, as well as geographic accessibility of that population.

c. Equity criteria: As mentioned above, the most disadvantaged social classes, are the ones who die earlier and have more frequently unhealthy lifestyles. In this context, smoking in Spain is beginning to focus on the most vulnerable groups in terms of social and health problems. Therefore, smoking is a contributing factor to health inequalities. The potential relationship between smoking and social inequalities must

be addressed through policies that help to reduce these inequalities, and in this context, the availability of treatment programmes that take into account equity criteria, can help increase quit rates among the less advantaged socio-economic groups as well as address gender needs.

Taking these criteria into account, it seems reasonable to point out that the final definition of a common minimum care strategy in our country should:

1. Be based on criteria of cost-effectiveness.
2. Include cessation within the portfolio of both primary and specialized care services (hospital, mental health services, services for drug addicts, etc.)..
3. Have a basic intervention protocol, agreed between governments and scientific societies, for each of the different levels of intervention: community, primary care, specialised care, specialised smoking cessation units, telephone services, treatment programmes over the Internet and new information technologies etc..
4. Include clear criteria for referral from primary care to other specialized services.
5. Take into account criteria of health risk, equity, attention to gender inequalities and population coverage for the planning of resources aimed at providing intensive cessation treatment, capable of ensuring the coverage of these resources in large areas currently not cared for and avoiding duplication of services focused on specific areas.
6. Promote public awareness of the treatment resources including regular outreach campaigns, especially targeting the least privileged social sectors and groups at high health risk, as well as health and education professionals (role models).
7. Take into account criteria of efficiency and resources synergy for the use of existing cessation programmes over the phone, as well as define referral routes between programmes.
8. Consider the strengthening and territorial expansion of extensive community outreach programmes, such as "Quit and Win", the celebration of “World No tobacco Day ", the "Smokefree week" promoted by the Spanish Society of

Family and Community Medicine (SEMFyC), etc. These initiatives contribute to the spread of quitting smoking through the media at national, regional and local levels.

9. Develop and operate comparable, effective and sustainable registration and service evaluation systems, through the framework provided by the Observatory for Tobacco Prevention (Coordinating body created by the Tobacco prevention and control Law 28/2005), in order to facilitate assessment of smoking cessation policy and to help making informed decisions aimed at improving the efficiency of resources deployed.
10. Advance in the development of stable and sustainable financing mechanisms of smoking cessation therapies (psychological and / or pharmacological) that have proven their efficacy and safety.
11. Promote and encourage training in the treatment of smoking through a comprehensive programme of further education for professionals in the National Health System, this would ensure the spread of advice to quit, as well as expand and improve specialised resources.

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